

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

**AMENDMENT NO. 15
TO
FORM S-1
REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933**

ALOPEXX, INC.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

2836
(Primary Standard Industrial
Classification Code Number)

86-3959763
(I.R.S. Employer
Identification Number)

Alopexx, Inc.
186 Alewife Brook Pkwy #1068
Cambridge, Massachusetts 02138
(617) 780-1598

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Daniel R. Vlock
President and Chief Executive Officer
Alopexx Inc.
186 Alewife Brook Pkwy #1068
Cambridge, Massachusetts 02138
(617) 780-1598

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Gregory Sichenzia
Marcelle S. Balcombe
Sichenzia Ross Ference Carmel LLP
1185 Avenue of the Americas, 31st Floor
New York, NY 10036
(212) 930-9700

W. David Mannheim
Michael K. Bradshaw, Jr.
Nelson Mullins Riley & Scarborough LLP
301 Hillsborough Street, Suite 1400
Raleigh, North Carolina 27603
(919) 329-3800

Approximate date of commencement of proposed sale to the public: **As soon as practicable after this Registration Statement is declared effective.**

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☒

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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

Large accelerated filer ☐
Non-accelerated filer ☒

Accelerated filer ☐
Smaller reporting company ☒
Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

EXPLANATORY NOTE

This registration statement contains two prospectuses, as set forth below.

- Public Offering Prospectus. A prospectus to be used for the public offering of 2,400,000 Shares of Common Stock of the Registrant (the “Public Offering Prospectus”) through the underwriter named on the cover page of the Public Offering Prospectus.
- Resale Prospectus. A prospectus to be used for the resale by the Selling Stockholder of up to 300,000 Selling Stockholder Shares of the Registrant (the “Resale Prospectus”).

The Resale Prospectus is substantively identical to the Public Offering Prospectus, except for the following principal points:

- they contain different outside and inside front covers and back covers;
- they contain different Offering sections in the Prospectus Summary;
- they contain different Use of Proceeds sections;
- the Capitalization and Dilution sections are deleted from the Resale Prospectus;
- a Selling Stockholder section is included in the Resale Prospectus; and
- the “Underwriting” section in the Public Offering Prospectus is deleted from the Resale Prospectus and a “Selling Stockholder Plan of Distribution” is inserted in its place in the Resale Prospectus.

The Registrant has included in this Registration Statement a set of alternate pages after the back-cover page of the Public Offering Prospectus (the “Alternate Pages”) to reflect the foregoing differences in the Resale Prospectus as compared to the Public Offering Prospectus. The Public Offering Prospectus will exclude the Alternate Pages and will be used for the public offering by the Registrant. The Resale Prospectus will be substantively identical to the Public Offering Prospectus except for the addition or substitution of the Alternate Pages and will be used for the resale offering by the Selling Stockholder.

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state or other jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS

SUBJECT TO COMPLETION

DATED JANUARY 8, 2025

**2,400,000 Shares
Common Stock**

ALOPEXX, Inc.

Alopexx, Inc.

This is a firm commitment initial public offering of shares of common stock of Alopexx, Inc. Prior to this offering, there has been no public market for our common stock. We anticipate that the initial public offering price of our shares will be \$5.00 per share. The underwriters have informed us that the gross proceeds of this offering will not be less than \$12,000,000.

We have applied to have our common stock listed on the New York Stock Exchange American LLC (the “NYSE American”) under the symbol “ALPX”. Our initial public offering is conditioned upon the approval of our listing by the NYSE American, which approval may not be granted. If our listing is not approved by the NYSE American, we will not be able to complete this initial public offering.

We are an “emerging growth company” as defined under the federal securities laws and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and may elect to do so in future filings.

Upon completion of this offering, Daniel Vlock, our President and Chief Executive Officer, will hold a majority of the voting power of our capital stock through his ownership of 58.5% of our outstanding common stock. As a result, we will be a “controlled company” under the listing requirements of the NYSE American, or the NYSE American Marketplace Rules. We do not intend to rely on any exemptions from the corporate governance requirements of the NYSE American Marketplace Rules. See the section titled “Management – Controlled Company Status.”

In addition, we are registering 300,000 shares of common stock for resale by a selling stockholder by means of the Resale Prospectus. The selling stockholder in the resale offering may not commence the resale of its shares pursuant to the Resale Prospectus until after our primary offering closes.

Investing in our common stock involves a high degree of risk. Before buying any shares, you should carefully read the discussion of the material risks of investing in our common stock under the heading “Risk Factors” beginning on page 14 of this prospectus.

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

	Per Share	Total
Initial Public Offering Price	\$	\$
Underwriters Discounts and Commissions (7.0%) ⁽¹⁾	\$	\$
Proceeds before expenses, to us	\$	\$

(1) Underwriting discounts and commissions do not include a non-accountable expense allowance equal to 1% of the initial public offering price payable to the underwriters. We refer you to “Underwriting” beginning on page 162 for additional information regarding underwriters’ compensation.

We have granted a 45-day option to the underwriters to purchase up to 360,000 additional shares of common stock solely to cover over-allotments, if any.

The underwriters expect to deliver the shares to purchasers on or about , 2025.

ThinkEquity

The date of this prospectus is , 2025

TABLE OF CONTENTS

<u>PROSPECTUS SUMMARY</u>	1
<u>RISK FACTORS</u>	11
<u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	53
<u>USE OF PROCEEDS</u>	54
<u>DIVIDEND POLICY</u>	55
<u>CAPITALIZATION</u>	55
<u>DILUTION</u>	56
<u>MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	57
<u>BUSINESS</u>	68
<u>MANAGEMENT</u>	102
<u>EXECUTIVE COMPENSATION</u>	108
<u>CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS</u>	115
<u>PRINCIPAL STOCKHOLDERS</u>	116
<u>DESCRIPTION OF CAPITAL STOCK</u>	118
<u>SHARES ELIGIBLE FOR FUTURE SALE</u>	120
<u>MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK</u>	122
<u>UNDERWRITING</u>	124
<u>LEGAL MATTERS</u>	129
<u>EXPERTS</u>	129
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	129
<u>INDEX TO FINANCIAL STATEMENTS</u>	F-1

Neither we nor the underwriters have authorized anyone to provide you with information other than that contained in this prospectus, or any free writing prospectus prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are offering to sell, and seeking offers to buy, common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus, or any free writing prospectus is accurate only as of its date, regardless of its time of delivery or of any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside of the United States: We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

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. Our fiscal year ends on December 31 of each year. Unless the context otherwise requires, all references in this prospectus to “we,” “us,” “our,” “our company” and “Alopecx” refer to Alopecx, Inc.

Overview

We are a clinical stage biotechnology company developing novel immune therapeutics for the prevention, treatment and mitigation of bacterial, fungal, and parasitic infections that express the antigenic target poly N-acetyl glucosamine (PNAG). That target has been found on an expanding number of pathogens. While the ultimate decision on the safety and efficacy of our therapeutics will be determined by the FDA and other health authorities, it is our management’s assessment that the broad-spectrum potential of our therapeutics will allow them to be used for the prevention, treatment, and mitigation of a wide range of infections. In a first-in-man trial, our vaccine candidate, AV0328, has been shown to be well tolerated with no serious adverse events observed. It was noted to induce protective antibodies against all PNAG-expressing pathogens tested. We believe our vaccine’s broad-spectrum potential will allow it to be used for the long-term prevention of a wide range of infections including pneumococcal pneumonia, methicillin-resistant *Staphylococcus aureus* (MRSA), meningitis, and sexually transmitted diseases. Similarly, our fully human monoclonal antibody, F598, that also targets PNAG, has been shown to be well tolerated and no serious adverse events were noted in phase 1 and pilot phase 2 trials. We believe it can provide immediate protection lasting 2-3 months. We seek to establish F598 as the standard of care for preventing and ameliorating gram-negative and gram-positive bacterial infections along with fungal infections by organisms that express PNAG in patients admitted to intensive care units (ICU). Utilization of these therapeutics also has potential applicability beyond infectious diseases, including treatment of neurological conditions and cognitive decline due to inflammation.

Our Lead Programs

To date over 75 separate pathogens have been found to express PNAG, including antimicrobial resistant (AMR) microbes. PNAG is a critical factor in pathogen survival and virulence (its ability to produce disease) and is used by bacteria to adhere to tissue and prostheses and to protect microbes from host immune defenses. Targeting PNAG offers the potential of creating the first broad-spectrum, anti-infective immune therapeutics. Our lead products are:

- **Vaccine AV0328** - a synthetic PNAG vaccine. A phase 1, first-in-man trial has been completed and the vaccine was found to be well tolerated, and no serious adverse events were observed. It induced antibodies that were capable of killing a wide range of PNAG-expressing pathogens. *In vitro* efficacy in killing was noted against every pathogen tested which included over 10 different microbial species. Based on those results, Alopecx proposed to the FDA that AV0328 be developed as a complement to currently approved *Streptococcus pneumoniae* vaccines (Prevnar, Pneumovax and Vaxneuvance). Those vaccines, including the recently approved versions, cover at best 23 of the 100 known *Streptococcus pneumoniae* serotypes. AV0328 could provide protection against many of the remaining 80+ serotypes. Feedback from the FDA supported pursuing accelerated approval of AV0328 based on safety in vaccinated humans and utilization of a validated surrogate assay – opsonic killing mediated by the antibodies induced by the vaccine. The FDA’s Accelerated Approval Program allows for earlier approval of drugs that treat serious conditions based on a surrogate endpoint. A surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Management believes that this points to a development path comparable to those that have led to FDA approval of other vaccines for *Streptococcus pneumoniae* infections. However, our vaccine has not been approved by the FDA and there is no guarantee that the FDA will ultimately approve the vaccine.

- **Monoclonal antibody F598** - Phase 1 and pilot phase 2 trials of F598 have been completed. The antibody was found to be well tolerated, and no serious adverse events were observed. A single infusion was noted to provide sustained serum levels for 2-3 months. Unlike vaccines which may take several weeks or longer to induce protective immunity, administration of a monoclonal antibody provides immediate protection. Therefore, the antibody will be utilized in settings where an individual is at an immediate or near-term risk of developing an infection. Hospital-associated infections are one of the major settings where this occurs. Monoclonal antibody F598 will not replace antibiotics but will instead complement and augment their efficacy and by doing so reduce the development of antibiotic resistant organisms. Use of monoclonal antibody F598 in that setting offers the potential for it to become the first broad-spectrum therapeutic antibody. We will study this in a setting where the prevalence of acquired infections is very high – intensive care units. Demonstrating that monoclonal antibody F598 can reduce the morbidity/mortality related to microbial infections in ICU patients would constitute a major health advancement. We believe it would establish administration of F598 as part of the standard of care in that setting.

The immune-mediated anti-infective therapeutics being developed by Alopexx are unique. In the view of our management, no other immune therapeutics offer such broad-spectrum potential. The initial target indications being pursued will permit development of anti-PNAG therapeutics in a focused fashion and, if successful, will establish Alopexx's therapeutic platform to prevent and treat a wide range of disorders.

Our Pipeline

Alopexx Pipeline

Compound	Indication	Discovery	Pre-Clinical	Phase I	Phase II	Phase III
F598	ICU Infections					
F598	Prevention of infection after Emergency Abdominal Surgery/Abdominal Trauma					
AV0328	<i>S. pneumoniae</i> infections					
AV0328	Meningococcal infections					

As illustrated in the table above, we believe that both monoclonal antibody F598 and vaccine AV0328 can be developed for multiple indications. Beyond the initial indications detailed in this prospectus, clinical and pre-clinical data would support pursuing additional indications.

The completed phase 1 and pilot phase 2 trials of F598 justify the planned study to reduce the morbidity/mortality related to microbial infections in ICU patients. In addition, those studies can also be used to justify pursuing another indication where microbial infections are a significant concern - following emergency abdominal surgery.

A similar approach is envisioned for vaccine AV0328. While the initial focus will be as a complement to currently approved *Streptococcus pneumoniae* vaccines, serologic results in the phase 1 trial would also support developing the vaccine for meningococcal infections as well. In addition, as detailed below, ongoing pre-clinical research has noted the role of bacteria in the pathogenesis of Alzheimer's Disease and Type 1 Diabetes mellitus. Vaccination against PNAG in murine models has resulted in reduction in the development of diabetes and in other studies prevents behavioral and cognitive decline in preclinical mouse models of Alzheimer's disease. Those results support the possible utility of our vaccine in those settings as well.

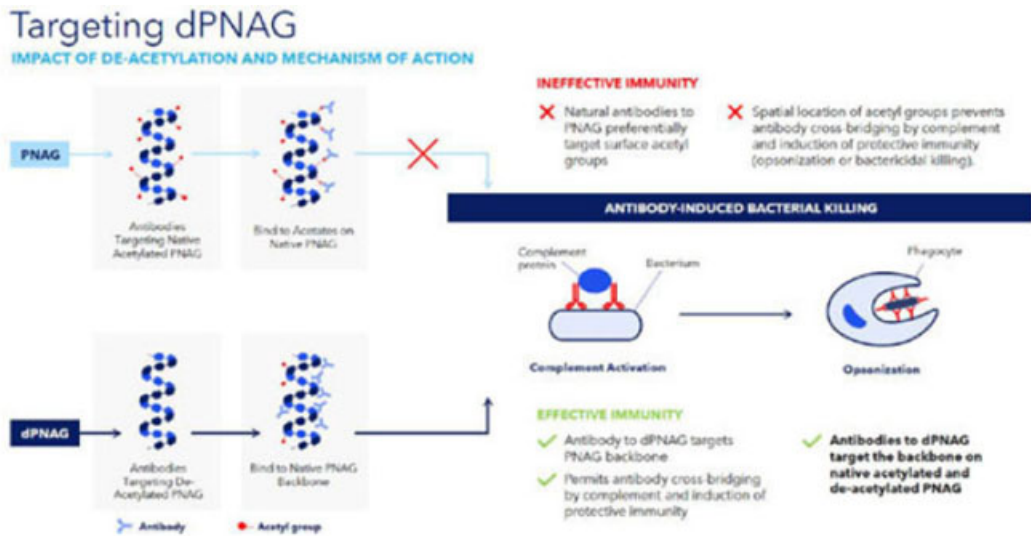
Beyond the broader indications mentioned above, use of the antibody may be effective in patients with an underlying immunodeficiency – specifically B cell deficiencies. B-cells are the immune cells that are involved with the humoral or antibody response. There are a number of conditions where patients are unable to produce a sufficient or any antibody in response to a pathogen. These disorders can be inherited (common variable Immunodeficiency, X-linked agammaglobulinemia, severe combined immunodeficiency) or associated with immunosuppressed population (cancer, transplant, treatment for autoimmune or inflammatory diseases, AIDS/HIV). In those cases, providing a fully functional antibody that could target a wide range of pathogens could treat or prevent the development of infections.

Our Science

For microbial pathogens, surface capsules, often composed of highly varied carbohydrate polymers, have been used successfully to vaccinate humans against *Streptococcus pneumoniae*, *Hemophilus influenzae type b*, *Neisseria meningitidis* and *Salmonella enterica serovar typhi*. However, efficacy is limited to the capsule types included in the vaccines. The PNAG polysaccharide is different. It has been found to be a component of the microbial surfaces of a large and expanding number of bacterial, fungal and parasitic pathogens. Beyond its wide distribution, another key component of PNAG, as a target antigen, is its critical role in virulence--the ability to cause an infection. Bacterial strains such as *S. aureus* that are genetically manipulated so they cannot produce PNAG have been found to have a significantly reduced ability to cause infections in mice. Laboratory studies have shown that loss of PNAG production decreases a given microbe's virulence. The synthesis of PNAG by all of these types of pathogens suggests an important role for this molecule in microbial biology. This indicates that PNAG could serve as a therapeutic target against many different microbes.

Natural antibodies to PNAG are common in humans and many animal species but these antibodies do not routinely have robust opsonic killing or immune protection against PNAG-producing microbes. This is due to inadequate engagement of the serum complement co-factor system that is needed for the induction of protective immunity. Thus, broad-based immunity to this antigen rarely develops naturally in human or animal populations. Naturally occurring microbial colonization or infection does not usually induce effective antibody responses to PNAG.

Alopexx's major proprietary advance was the recognition that this ineffective natural immunity was due to the high degree of acetylation of the native PNAG molecule. As illustrated in the figure below, natural PNAG has many acetyl groups on its surface. Those surface acetyl groups are responsible for inducing a natural but ineffective immune response. The acetyl groups can be removed by chemically altering PNAG. This results in a strong protective immunogen that now targets the backbone of PNAG and avoids participation from the acetyl groups. As illustrated in the figure below, targeting the backbone of PNAG leads to the induction of antibody-mediated bacterial killing. Alopexx's vaccine and antibody target the backbone on native PNAG and provide an effective immune response.



Our Market

We have performed independent commercial assessments for the initial indications that we intend to pursue use of the vaccine as a complement to currently approved *Streptococcus pneumoniae* vaccines and reducing the morbidity/mortality related to microbial infections in ICU patients for the antibody.

For the vaccine, the assumption was that AV0328 would be added as a complement to current *Streptococcus pneumoniae* vaccines. The relevant population would be the same adult and pediatric patients who currently receive approved *Streptococcus pneumoniae* vaccines, Prevnar and Pneumovax. Our initial target market segment included adults who had received existing pneumococcal vaccines and *de novo* pneumococcal vaccines and pediatric patients who receive such vaccines. The expected global revenue for the *Streptococcus pneumoniae* indication alone is expected to be over \$2 billion per year.

For the antibody the initial indication would be for the prevention and/or mitigation of hospital-associated infections in ICU patients. In the United States there are approximately 5 million ICU admissions per year (including pediatric patients). Our goal is that F598 would be added to the existing standard of care. In the market analysis we performed we considered adults discharged from the ICU with MRSA (methicillin resistant *Staphylococcus aureus*) colonization using a base case of 15%. We applied the same to the EU5 and Canada. Based on those assumptions peak sales were estimated to be \$2.3 billion per year.

If our monoclonal antibody is approved for the prevention and/or mitigation of hospital-associated infections in ICU patients, we believe it would be difficult for hospitals not to use it as part of the standard of care. Such approval would be based on the Alopexx monoclonal antibody demonstrating increased anti-infective efficacy in the ICU setting where antibiotics and anti-fungal drugs are routinely administered. Utilization of mAb F598 is unlikely to encounter the same adoption issues as the introduction and use of newer antibiotics, as it will augment prevention and treatment of infections in a clinically- and cost-effective manner. Newer antibiotics, such as those targeting AMR infections, retain their effectiveness only if they are used sparingly to avoid, as long as possible, microbial resistance to those newer agents. Because Alopexx's long-lasting, anti-infective immune therapeutics are not associated with the development of resistance and can be added to improve on the current standards of care, we believe objections to employing them will be low.

Our Strategy

The broad distribution of PNAG allows for an expansive range of microbial targets and disease indications to be targeted by Alopexx's immunotherapeutics. The products we have developed permit us to explore and develop the vaccine and monoclonal antibody to prevent or treat a wide range of disorders caused by PNAG-expressing organisms. These can be divided into two broad categories – specific microbial infections such as a Staph infection and diseases where PNAG-containing factors derived from the microbiota (microbes normally found in and on our body surfaces) have been implicated in driving disease progression. Our goal is to develop a broad-spectrum, non-antibiotic therapeutic platform for the prevention and treatment of microbial infections.

These anti-infective immune therapeutics represent a potential paradigm shift in the prevention, treatment, and amelioration of many microbial infections. In the view of our management, no other therapeutics offer such broad-spectrum potential that could target bacteria, fungi, and higher order microbial causes of infection. Anti-bacterial antibiotics and anti-fungal drugs must be administered frequently and over periods of days to months, whereas antibodies induced by the vaccine or administered as a monoclonal antibody are injected once or twice months apart and remain at high levels for 2-12 months. The Alopexx immunotherapeutics would be used in the same settings that antibiotics are used such as the intensive care unit, individuals undergoing surgery, people with suppressed immune systems and persons at high risk for microbial infections. This paradigm shift would be driven by the increased efficacy in reducing infections and costs due to effective immunity to PNAG. The Alopexx vaccine and monoclonal antibody could dramatically alter the way many infections are prevented and treated and significantly reduce reliance on antibiotics and the development of anti-microbial resistance.

The key elements of our strategic approach are the following:

- Develop vaccine AV0328 as a complement to currently approved *Streptococcus pneumoniae* vaccines (Prevnar, Pneumovax and Vaxneuvance). Feedback from the FDA has supported pursuing accelerated approval of AV0328 based on safety in vaccinated humans and utilization of a validated surrogate assay – opsonic killing mediated by the antibodies induced by the vaccine. The FDA's Accelerated Approval Program allows for earlier approval of drugs that treat serious conditions based on a surrogate endpoint. A surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Management believes that this points to a development path comparable to those that have led to FDA approval of other vaccines for *Streptococcus pneumoniae* infections. However, our vaccine has not been approved by the FDA and there is no guarantee that the FDA will ultimately approve the vaccine.
- Establish monoclonal antibody F598 as the standard of care for preventing and ameliorating gram-negative and gram-positive bacterial infections along with fungal infections by organisms that express PNAG in patients admitted to ICUs.
 - We have developed a collaboration with Europe's largest health care system which has agreed to perform a 1600 patient phase 2 ICU study. The Assistance Publique-Hôpitaux de Paris (AP-HP) is the largest hospital system in Europe and one of the largest in the world. It provides health care, teaching, research and emergency medical services in 44 hospitals and sees more than 5.8 million patient visits annually.
- Collaborate with additional organizations in the hospital consortium arena and other pharmaceutical companies to advance our candidates
- Pursue the development of AV0328 and F598 for other bacterial infectious indications

- Enhance our intellectual property portfolio
- Establish scalable production of AV0328 and F598

These anti-infective immune therapeutics represent a potential paradigm shift in the prevention, treatment, and amelioration of many causes of microbial infections. This paradigm shift would be driven by the increased efficacy in reducing infections, costs due to effective immunity to PNAG, and a shift away from antibiotics. Our vaccine and monoclonal antibody could dramatically alter the reliance on antibiotics and the development of anti-microbial resistance would be dramatically reduced.

Intellectual Property

Our patent portfolio contains 4 patent families with coverage through 2040-2042. This includes both composition of matter and use patents. We have also exclusively licensed four issued U.S. and PCT patents from Brigham and Women's Hospital. Those patents cover the vaccine and methods of use, the F598 monoclonal antibody and variants and the methods of use of the vaccine and/or the anti-PNAG antibody. We continue to seek to maximize the scope of our patent protection for all our programs. In addition to patents, synthesis of the PNAG oligosaccharide is covered by a trade secret agreement. The F598 monoclonal antibody is produced using a proprietary master cell bank.

Our Leadership Team

We have assembled an experienced management team with deep research, development, and commercialization experience in the areas of infectious diseases, immunotherapy as well as other medical areas - oncology, endocrinology, neurology, and rare diseases. They have held academic appointments at Harvard Medical School, Yale University School of Medicine, University of Pittsburgh and others. Members of our team bring experiences from multiple biotech and pharmaceutical companies including Pfizer, Boehringer Ingelheim, Pharmacia and Eli Lilly, among others.

Our Corporate Information

Our company was re-organized in June 2021 and is located at 186 Alewife Brook Pkwy #1068, Cambridge, MA 02138. The founders have been associated with the development of our technologies since they were originally licensed from Harvard in 2006 for the monoclonal antibody and 2011 for the vaccine. Our telephone number is (617) 780-1598. Our website address is <https://www.alopexx.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. These risks are discussed more fully in the "Risk Factors" section of this prospectus immediately following this prospectus summary. Some of these risks include the following:

- We are in the early stages of clinical development and have a very limited operating history and no products approved for commercial sale, 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.
- Our history of recurring losses and anticipated expenditures raises substantial doubts about our ability to continue as a going concern. Our ability to continue as a going concern requires that we obtain sufficient funding to finance our operations.
- 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 of our development programs or other operations.
- Our approach to the development of our vaccine and antibody candidates is based on novel technologies that are unproven, which may expose us to unforeseen risks and makes it difficult to predict the time and cost of vaccine candidate development and time to obtain regulatory approval.
- Approvals by the FDA and EMA for existing pneumococcal vaccines, such as Prevnar 13 and Pneumovax 23, may not be indicative of what these regulators may require for approval of our vaccine. For example, we expect to use opsonophagocytic killing (OPK) titers as the primary immunogenicity surrogate endpoint for the AV0328 program in adults because Prevnar 13 was approved based on the establishment of non-inferiority of serotype-specific OPK responses relative to Pneumovax 23; however, there can be no assurance that this streamlined non-inferiority approach will be sufficient for regulatory approval or that regulators will not require field efficacy trials.

- Our business is highly dependent on the success of AV0328 and F598, both of which are in the early stages of clinical development. If we are unable to obtain approval for AV0328 or F598 and effectively commercialize them, our business would be significantly harmed.
- Our primary competitors have significantly greater resources and experience than we do, which may make it difficult for us to successfully develop our vaccine, or may result in others discovering, developing or commercializing products before or more successfully than us.
- 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.
- We currently rely on third-party manufacturing and supply partners, including Lonza and Glycosyn to supply raw materials and components for, and manufacture, our vaccine and antibody candidates. Our inability to have sufficient quantities of our candidates 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.
- The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our vaccine.
- If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets. See “Legal Proceedings” below for a description of current litigation that involves our intellectual property.
- We have identified a material weakness in our internal control over financial reporting, and the failure to remediate this material weakness may adversely affect our business, investor confidence in our company, our financial results and the market value of our common stock.

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;
- 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 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. However, as described in Note 2 to our financial statements included elsewhere in this prospectus, we early adopted certain accounting standards, as the JOBS Act does not preclude an emerging growth company from adopting a new or revised accounting standard earlier than the time that such standard applies to private companies to the extent early adoption is permitted. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

The Offering

Issuer	Alopetx, Inc.
Common stock offered by us	2,400,000 shares
Over-allotment option	360,000 shares
Common stock to be outstanding immediately after this Offering	7,596,769 shares (7,956,769 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 \$9.9 million or approximately \$11.6 million if the underwriters exercise their over-allotment option in full), based on the assumed initial public offering price of \$5.00 per share, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. 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 currently intend to use the net proceeds we receive from this offering to fund completion of proof-of-concept clinical trials of vaccine AV0328 and monoclonal antibody F598, including manufacturing scale-up activities, and for general corporate purposes, including working capital, operating expenses and capital expenditures. See the section entitled “Use of Proceeds” for additional information.
Risk factors	See the section entitled “Risk Factors” for additional information.
Controlled company	Following the completion of this offering we will be a “controlled company” within the meaning of the corporate governance rules of NYSE American. See the section titled “Management – Controlled Company Status.”
Proposed trading symbol on the NYSE American	“ALPX”

The number of shares of our common stock that will be outstanding after this offering is based on 4,899,218 shares of our common stock outstanding as of September 30, 2024, and includes the conversion of the convertible notes currently outstanding into 297,551 shares of our common stock upon the closing of this offering.

The number of shares of our common stock that will be outstanding after this offering excludes:

- 1,419,388 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock with an exercise price of \$4.04; and
- 1,312,612 shares of our common stock to be reserved for future issuance under our 2023 Equity Incentive Plan.

Unless otherwise indicated, the information in this prospectus assumes:

- an initial public offering price of \$5.00 per share;
- no exercise of the outstanding options described above;
- no exercise of the underwriters' option to purchase up to an additional 360,000 shares of our common stock;
- assumes no exercise of the representative's warrants to be issued to the representative of the underwriters in this offering;
- the filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, each of which will occur prior to the closing of this offering; and
- the conversion of the convertible notes currently outstanding into 297,551 shares of our common stock upon the closing of this offering.

Summary Financial Data

The following tables set forth our summary statements of operations data for the years ended December 31, 2023 and 2022 and the nine months ended September 30, 2024 and 2023 and our summary balance sheet data as of September 30, 2024. The balance sheet and statements of operations data for the years ended December 31, 2023 and 2022 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.

	Year Ended,		Nine Months Ended,	
	December 31, 2023	December 31, 2022	September 30, 2024	September 30, 2023
Statements of Operations Data:				
Operating expenses:				
Research and development	\$ 357,234	\$ 471,326	\$ 177,605	\$ 290,000
General and administrative	3,223,999	1,760,501	1,806,561	2,557,685
Total operating expenses	<u>3,581,233</u>	<u>2,231,827</u>	<u>1,984,166</u>	<u>2,847,685</u>
Loss from operations	(3,581,233)	(2,231,827)	(1,984,166)	(2,847,685)
Other expense, net	<u>(198,956)</u>	<u>(86,237)</u>	<u>(180,403)</u>	<u>(147,653)</u>
Net loss	<u>\$ (3,780,189)</u>	<u>\$ (2,318,064)</u>	<u>\$ (2,164,569)</u>	<u>\$ (2,995,338)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.81)</u>	<u>\$ (0.50)</u>	<u>\$ (0.44)</u>	<u>\$ (0.64)</u>
Weighted-average common shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	<u>4,689,460</u>	<u>4,640,000</u>	<u>4,865,557</u>	<u>4,659,812</u>
Pro forma as adjusted net loss per share, basic and diluted (1)	<u>\$ (0.51)</u>	<u>\$ (0.32)</u>	<u>\$ (0.29)</u>	<u>\$ (0.41)</u>
Weighted average shares outstanding used in computing pro forma as adjusted net loss per share, basic and diluted (1)	<u>7,387,011</u>	<u>7,337,551</u>	<u>7,563,108</u>	<u>7,357,363</u>

- 1) The pro forma as adjusted net loss per share and pro forma as adjusted weighted average shares give effect to the issuance of 297,551 shares of our common stock as a result of the automatic conversion of all outstanding convertible notes into shares of common stock in addition to the sale of 2,400,000 shares of our common stock in this offering.

	September 30, 2024		
	Actual	Pro Forma (1)	Pro Forma As Adjusted (2)
Balance Sheet Data:			
Cash	\$ 638,522	638,522	11,466,022
Deferred offering costs	883,417	883,417	—
Total assets	<u>1,521,939</u>	<u>1,521,939</u>	<u>11,466,022</u>
Convertible notes payable	950,000	—	—
Notes payable	1,450,000	1,450,000	1,450,000
Accrued interest	<u>468,706</u>	<u>302,886</u>	<u>302,886</u>
Preferred stock	—	—	—
Common Stock	490	520	760
Additional Paid in Capital	8,606,289	9,722,078	19,665,922
Accumulated Deficit	<u>(13,208,504)</u>	<u>(13,208,504)</u>	<u>(13,208,504)</u>
Total Stockholders' (deficit) equity	<u>\$ (4,601,725)</u>	<u>(3,485,906)</u>	<u>6,458,178</u>

- 1) The pro forma balance sheet data gives effect to the issuance of 297,551 shares of our common stock as a result of the automatic conversion of all outstanding convertible notes into shares of common stock and the filing of the Amended and Restated Certificate of Incorporation.
- 2) The pro forma as adjusted column gives effect to: (i) the pro forma adjustments set forth in footnote (1) above and (ii) the sale of 2,400,000 shares of our common stock in this offering at the assumed initial public offering price of \$5.00 per share, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Recent Developments

Collaboration and License Agreement

On September 5, 2024, the Company and Biotech Consortia, Inc (“BCI”), an affiliate of Bharat Biotech International Limited (“BBIL”), entered into a Collaboration and License Agreement (the “License Agreement”), which was subsequently amended effective December 27, 2024.

Pursuant to the License Agreement, the Company agreed to grant an exclusive royalty-bearing license to BCI to certain intellectual property rights controlled by the Company related to its proprietary broad-spectrum anti-microbial vaccine, AV0328, for the prevention of infections caused by *Streptococcus pneumoniae*; and two additional target indications in India and other countries classified as “low income” and “lower middle income” countries by the World Bank, subject to certain retained rights by Alopecx. In addition, the License Agreement provides for the grant to the Company of a limited non-exclusive, non-royalty bearing, non-sublicensable license to certain patent and technology rights of BCI, as set forth in the License Agreement, to conduct certain development activities as part of the collaboration contemplated by the License Agreement.

Under the terms of the License Agreement, BCI will co-develop and commercialize AV0328, a synthetic vaccine targeting poly N-acetyl glucosamine (PNAG) (the “Licensed Product”), in India and other licensed territories. In addition, Alopecx will be entitled to upfront, development and milestone payments, including royalties on sales of AV0328 in the licensed territories.

Pursuant to the terms of the License Agreement, the Company has received an initial upfront payment of \$666,666 and will receive additional upfront payments in the aggregate amount of approximately \$1.3 million upon the occurrence of certain events. In addition, pursuant to the terms of the License Agreement, the Company may receive an aggregate of up to \$3 million in consideration of the Company’s preclinical work and upon achievement of certain milestones. In addition, the Company may receive royalty payments in the single digits percent on net sales of each product (as defined in the License Agreement) in the public market and in the low teens on net sales in the private market. Public market includes sales of the vaccine to individuals or groups with limited financial resources as would be encountered in “low income” and “lower middle income” countries (as classified by the World Bank). The private market includes sales to individuals and groups better able to afford the full cost of the vaccine. The royalty obligations under the License Agreement will commence upon the first commercial sale of such product through the expiration or termination of the License Agreement.

Unless earlier terminated, the License Agreement continues from the date of the License Agreement through the commercial life of the last Licensed Product under the License Agreement. Either party may terminate the License Agreement by providing notice in writing to the other party (i) if the other party is in material breach of the License Agreement, and in the case of a breach that is curable within 60 days, that is not cured in such time period upon notice from the other party, (ii) in the event the other party challenges or assist in a third party in challenging any technology controlled by such party, or (iii) the other party makes a general assignment for the benefit of creditors, files a voluntary petition in bankruptcy, an involuntary petition in bankruptcy is undismissed for a period of more than 60 days. In addition, the Company may terminate the License Agreement in the event BCI ceases development of the Licensed Product (subject to certain exceptions for normal pauses or gaps between clinical studies).

Upon termination of the License Agreement, BCI shall have the right to sell, use or dispose of any unsold or unused product for a period of 18 months after termination, provided it remains in compliance with all other provisions of the License Agreement.

If the License Agreement is terminated by the Company upon the expiration of a 60 days’ notice of default, the licenses granted to BCI under the License Agreement will terminate and be of no further effect and BCI shall assign to the Company all regulatory filings, as such term is defined in the License Agreement. Further, within 45 days after termination, BCI will provide a summary of the status and results of its development, manufacturing and commercialization activities for the product prior to the effective date of the termination. In addition, BCI shall use commercially reasonable efforts to transition to the Company all development, manufacturing and commercialization activities and responsibilities for the product as in existence as of the date of termination and upon the request of the Company grant to the Company a fully paid-up, non-royalty bearing, perpetual license under BCI’s right in the joint program technology and joint program patent rights.

If the License Agreement is terminated by BCI upon the expiration of a 60 days’ notice of default then the licenses granted to BCI shall continue to be valid in accordance with the License Agreement, provided that BCI continues to pay amounts due to the Company for the balance of the term.

The last patent subject to the License Agreement is set to expire in 2040.

The foregoing description of the License Agreement does not purport to be complete and is qualified in its entirety by the provisions of the License Agreement, which is attached hereto as Exhibit 10.8.

Stock Purchase Agreement

On December 26, 2024, the Company entered into a Stock Purchase Agreement with BCI (the “Purchase Agreement”) for the sale by the Company of 300,000 shares of its common stock at a purchase price of \$5 per share for gross proceeds of \$1,500,000. Pursuant to the terms of the Purchase Agreement, the Company granted BCI “piggy-back” registration rights. In addition, BCI will enter into a lock-up agreement with the underwriters for approximately 180 days after the date of this prospectus, which will impose certain restrictions on the resale of the shares purchased under the Purchase Agreement. The transactions contemplated by the Purchase Agreement have not yet closed. However, the parties intend to close the transactions prior to the effective date of this Registration Statement of which this prospectus forms a part.

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 vaccine development and have a very limited operating history and no products approved for commercial sale, 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 successfully complete clinical development, obtain regulatory approvals, or 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 two clinical programs. 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 candidates. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a 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.

Our stock is a highly speculative investment. We are a clinical stage biotechnology company that was incorporated in June 2021. Investment in clinical stage companies and vaccine development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential vaccine candidate will not gain regulatory approval or become commercially viable. The same challenges apply to our monoclonal antibody. We do not have any products approved for sale and 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 \$3,780,189 and \$2,318,064 for the years ended December 31, 2023 and 2022, respectively. Our net losses were \$2,164,569 and \$2,995,338 for the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, we had an accumulated deficit of \$13,208,504.

We expect to continue to spend significant resources to fund research and development of, and seek regulatory approvals for, our vaccine and antibody candidates. We expect to incur substantial and increasing operating losses over the next several years as our research, development, manufacturing, preclinical testing and clinical trial activities increase. 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. However, we do not expect to generate any revenue from commercial product sales unless and until we successfully complete development and obtain regulatory approval of our vaccine, which we expect will take a number of years. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders’ equity and working capital. Even if we eventually generate revenue, 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.

Our history of recurring losses and anticipated expenditures raises substantial doubts about our ability to continue as a going concern. Our ability to continue as a going concern requires that we obtain sufficient funding to finance our operations.

We have incurred operating losses to date and it is possible we may never generate sufficient cash flow from operations to operate as a going concern. We have concluded, and the report from our independent registered public accounting firm for the year ended December 31, 2023 includes an explanatory paragraph stating, that our significant working capital deficiency, recurring losses and negative cash flows from operations and required additional funding to finance our operations raise substantial doubt about our ability to continue as a going concern. If we are unable to obtain sufficient funding, we could be forced to delay, reduce or eliminate all of our research and development programs, product portfolio expansion or commercialization efforts, and our financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. After the completion of this offering, future reports from our independent registered public accounting firm may also contain statements expressing substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all.

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 September 30, 2024 we had cash and cash equivalents of approximately \$639 thousand. We believe that the net proceeds from this offering will be approximately \$9.9 million, based on an assumed public offering price of \$5.00 per share, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We believe that such proceeds, together with our existing cash and cash equivalents 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 will need to raise additional capital before we can progress any of our vaccine into a pivotal clinical trial. 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. 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 FDA, and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform field efficacy studies for our pneumococcal conjugate vaccine, or PCV, candidates, require more studies than those that we currently expect or change their requirements regarding the data required to support a marketing application;
- the cost of building a sales force in anticipation of any product commercialization;
- the costs of future commercialization activities, including product manufacturing, marketing, sales, royalties and distribution, for our vaccine for which we receive marketing approval;
- 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 revenue, if any, received from commercial sales, or sales to foreign governments, of our vaccine for which we may receive marketing approval;
- 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 or commercialization of our vaccine 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 vaccine 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 vaccine in markets where we otherwise would seek to pursue development or commercialization ourselves.

Due to the significant resources required for the development of our vaccine, and depending on our ability to access capital, we may need to prioritize development of the vaccine over the antibody. Moreover, we may expend our limited resources on a program that does not yield a successful result.

Due to the significant resources required for the development of our vaccine and antibody, we may decide to pursue one program over the other. Our decisions concerning the allocation of research, development, management and financial resources toward a particular program may not lead to the development of any viable commercial product and may divert resources away from better opportunities. If we make incorrect determinations regarding the viability or market potential of our programs or misread trends in the biopharmaceutical industry our business could be seriously harmed.

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.

Risks Related to Our Business and Industry

Our approach to the development of our vaccine candidate is based on novel technologies that are unproven, which may expose us to unforeseen risks and makes it difficult to predict the time and cost of candidate development and obtaining regulatory approvals.

The preclinical and clinical trial requirements of the FDA, European Medicines Agency, or EMA, and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a vaccine candidate are determined according to the type, complexity, novelty and intended use and market of the potential products. Approvals by the FDA and EMA for existing pneumococcal vaccines, such as Prevnar 13 and Pneumovax 23, may not be indicative of what these regulators may require for approval of our vaccine. Furthermore, while there have been approvals granted for both pneumococcal conjugate vaccines and meningococcal conjugate vaccines based on surrogate immune endpoints rather than field efficacy studies, we will not be able to confirm this approach's applicability for our vaccine until we complete our Phase 2 clinical development program. More generally, approvals by any regulatory agency may not be indicative of what any other regulatory agency may require for approval or what such regulatory agencies may require for approval in connection with new vaccine. Moreover, our vaccine may not perform successfully in clinical trials.

We have limited experience in the conduct of clinical trials and have never obtained approval of any product candidates and may be unable to do so successfully.

We have not yet demonstrated our ability to operate successfully including large-scale, pivotal clinical trials, obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Commencing clinical trials is subject to finalizing the trial design based on discussions with the FDA and other regulatory authorities. Any guidance we receive from the FDA or other regulatory authorities is subject to change. These regulatory authorities could change their position, including, on the acceptability of our trial designs or the clinical endpoints selected, which may require us to complete additional clinical trials or impose stricter approval conditions than we currently expect. Successful completion of our clinical trials is a prerequisite to submitting a Biological Licensing Application or BLA, to the FDA and a Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMA, for each product candidate and, consequently, the ultimate approval and commercial marketing of each product candidate. We have completed phase 1 studies with vaccine AV0328 and monoclonal antibody F598, but we do not know whether any of our future clinical trials will begin on time or ever be completed on schedule, if at all.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- be subject to post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

If we are unable to complete development of or commercialize our vaccine or antibody or experience significant delays in doing so, our business would be materially harmed.

Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for and successfully commercializing our vaccine and antibody, either alone or with third parties. We cannot guarantee that we will ever obtain regulatory approval for our vaccine or antibody. Before obtaining regulatory approval for the commercial distribution of our vaccine and antibody, we must conduct extensive clinical trials to demonstrate their safety and efficacy.

We may not have the financial resources to continue development of, or to enter into new collaborations for, a vaccine or antibody candidate if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, our vaccine or antibody, including:

- negative or inconclusive results from our preclinical or clinical trials, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- product-related adverse effects experienced by patients in our clinical trials;
- timely completion of our preclinical studies and clinical trials, including any field efficacy studies that may be required, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- delays in submitting INDs or compatible foreign applications or delays or failures in obtaining necessary approvals from regulators to commence a clinical trial, or suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or similar foreign authorities regarding the scope or design of our clinical trials, including any requirements to perform field efficacy studies;
- delays in enrolling patients in our clinical trials;
- the availability of coverage and adequate reimbursement and pricing from third-party payors, including government authorities,
- pertaining to the vaccine, once approved, and patients' willingness to pay out-of-pocket if third-party payor reimbursement is limited or not available;
- greater than anticipated costs of our clinical trials, including chemistry, manufacturing and controls, or CMC, activities related to our clinical trials;
- harmful side effects or inability of our vaccine or antibody to meet efficacy endpoints;
- unfavorable FDA or other regulatory agency inspection and review of one or more of our clinical trial sites or our contract manufacturers' facilities;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their obligations in a timely manner, or at all;

- the impact on the various regulatory, clinical trial or manufacturing processes as result of the COVID-19 pandemic;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology or vaccine in particular; or
- varying interpretations of our data by the FDA and comparable foreign regulatory authorities.

In particular, while we believe our vaccine could receive regulatory approval based on well-defined surrogate immune endpoints, consistent with how other PCVs have obtained regulatory approval in the past, rather than requiring clinical field efficacy studies, there can be no assurance that the FDA or comparable foreign regulatory authorities will provide approvals on such basis.

Our inability to complete development of or commercialize our vaccine, or significant delays in doing so due to one or more of these factors, could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authorities may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authorities, as the case may be, and may ultimately lead to the denial of marketing approval of our vaccine.

Our business is highly dependent on the success of vaccine AV0328 and antibody F598 which are in clinical development. If we are unable to obtain approval for AV0328 and F598 and effectively commercialize them, our business would be significantly harmed.

Our business and future success depends on our ability to obtain regulatory approval of, and then successfully commercialize our vaccine and antibody. The ultimate decision on the safety and efficacy of our therapeutics will be determined by the FDA and other health authorities. Both the vaccine and antibody are in the early stages of clinical development. Both have been noted to be well tolerated, no serious adverse events have been noted and preliminary laboratory-based efficacy has been noted. However, subsequent studies may not demonstrate the safety and efficacy of our vaccine and/or antibody. Both the vaccine and antibody will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient preclinical, clinical and commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. We cannot provide any assurance that we will be able to successfully advance the antibody and vaccine through the development process.

The clinical and commercial success of our antibody and vaccine will depend on a number of factors, including the following:

- our ability to raise any additional required capital on acceptable terms, or at all;
- timely completion of our clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- whether we are required by the FDA or similar foreign regulatory agencies to conduct additional clinical trials, including field efficacy studies, or other studies beyond those planned to support the approval and commercialization of our vaccine and antibody;
- acceptance of our proposed indications and primary surrogate endpoint assessments for our vaccine by the FDA and similar foreign regulatory authorities;
- our ability to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities the safety, efficacy and acceptable risk to benefit profile of our antibody and vaccine;
- any vaccine-vaccine interference studies that may be required, particularly with the standard of care pediatric vaccine regimen;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our vaccine and antibody, if any;
- the timely receipt of necessary marketing approvals from the FDA or comparable foreign regulatory authorities;

- achieving, maintaining and, where applicable, ensuring that our third-party contractors achieve and maintain compliance with our contractual obligations and with all regulatory requirements applicable to our vaccine or any future vaccine or approved products, if any;
- obtaining and maintaining an Advisory Committee on Immunization Practices, or ACIP, preferred recommendation or comparable foreign regulatory authority's recommendation of our vaccine and the willingness of physicians, operators of clinics and patients to utilize or adopt our vaccine to prevent or treat age-associated diseases;
- the ability of third parties with whom we contract to manufacture adequate clinical study and commercial supplies of our vaccine and antibody to remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or cGMP;
- our ability to successfully develop a commercial strategy and thereafter commercialize our vaccine and antibody in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- the convenience of our treatment or dosing regimen;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our vaccine or antibody if approved, including relative to alternative and competing treatments;
- patient demand for our vaccine, if approved;
- our ability to establish and enforce intellectual property rights in and to our vaccine and antibody; and
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims.

These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize our vaccine and antibody. Even if regulatory approvals are obtained, we may never be able to successfully commercialize our vaccine or antibody. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of our antibody or vaccine to continue our business or achieve profitability.

Our primary competitors have significantly greater resources and experience than we do, which may make it difficult for us to successfully develop our vaccine and antibody, or may result in others discovering, developing or commercializing products before or more successfully than us.

The vaccine market is intensely competitive and is dominated by a small number of multi-national, globally established pharmaceutical corporations with significant resources. For instance, Pfizer, Merck, GlaxoSmithKline and Sanofi together control approximately 75% of the global vaccine market. We may also face competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. For example, Sanofi and SK Chemicals have partnered to develop a PCV, and Affinivax and Astellas have partnered to develop an affinity-bound pneumococcal vaccine.

Our vaccine may be viewed as competition with existing vaccines and new vaccines that may become available in the future. Many of our competitors have substantially greater financial, lobbying, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior vaccines, including the potential that our competitors may develop chemical processes or utilize novel technologies for developing vaccines that may be superior to those we employ. In addition, many of these competitors have significantly greater experience than we have in undertaking preclinical testing and clinical trials of new products and in obtaining regulatory approvals, including for many vaccine franchises. Accordingly, our competitors may succeed in obtaining FDA approval or a preferred recommendation for their products. For example, Prevnar 13 obtained FDA approval for the prevention of invasive pneumococcal disease, or IPD, in infants based on non-inferior IgG antibody responses relative to Prevnar, using the surrogate immune endpoints established by the prior Prevnar field efficacy study. Pfizer is currently implementing a similar approach to development of its 20-valent PCV vaccine candidate and may have a more efficient path to regulatory approval given Pfizer's and the FDA's previous experience with Prevnar 13. For more information, see the section entitled "Business—Competition."

Many of our competitors have established distribution channels for the commercialization of their vaccine products, whereas we have no such established channels or capabilities. In addition, many competitors have greater name recognition, more extensive collaborative relationships or the ability to leverage a broader vaccine portfolio. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize vaccines that are safer, more effective, more convenient, less expensive or with a more favorable label than any vaccine that we may develop.

As a result of these factors, our competitors may obtain regulatory approval of their products before we are able to, which may limit our ability to develop or commercialize our vaccine. Our competitors may also develop vaccines that are safer, more effective, more widely accepted or less expensive than ours, and may also be more successful than we are in manufacturing and marketing their products. These advantages could render our vaccine non-competitive before we can recover the costs of such vaccine development and commercialization.

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 scientific, management and commercial personnel, establishing clinical trial sites and subject enrollment for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

To date, no non-serotype-specific vaccine has received approval from the FDA or been commercialized.

Currently approved *Streptococcus pneumoniae* vaccines are serotype-specific. They have multiple components that specifically target a subset of *Streptococcus pneumoniae*. Prevnar 13 targets 13 of the 100+ known serotypes. A non-serotype specific vaccine such as AV0328 can potentially address all serotypes. While the FDA has not approved a vaccine for use that is non-serotype-specific such as Alopexx's vaccine our communications with the FDA lead us to believe that such an approach is feasible. There is no assurance that the FDA will approve our vaccine and the non-serotype-specific nature of our vaccine could make FDA approval more difficult to achieve.

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

Even if any of our vaccine receives marketing approval, they may fail to receive recommendations for use by regulators or advisory boards that recommend vaccines, or gain market acceptance by physicians, patients, third-party payors and others in the medical community. If they do 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 vaccine, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- receiving CDC and ACIP recommendations for use, as well as recommendations of comparable foreign regulatory and advisory bodies;
- prevalence and severity of the disease targets for which our vaccine is approved;
- physicians, hospitals, third-party payors and patients considering our vaccine as safe and effective;
- the potential and perceived advantages of our vaccine over existing vaccines, including with respect to spectrum coverage or immunogenicity;
- 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 vaccine 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 vaccines and alternative treatments; and
- the effectiveness of our sales and marketing efforts,

In the United States, the CDC and ACIP develop vaccine recommendations for both children and adults, as do similar agencies around the world. To develop its recommendations, ACIP forms working groups that gather, analyze and prepare scientific information. The ACIP also considers many of the factors above, as well as myriad additional factors such as the value of vaccination for the target population regarding the outcomes, health economic data and implementation issues. ACIP recommendations are also made within categories, such as in an age group or a specified risk group. For example, the ACIP may determine that a preferred recommendation in a smaller child population may be more economical than recommending vaccinations for a larger adult population, which could adversely impact our market opportunity. New pediatric vaccines that receive an ACIP preferred recommendation are almost universally adopted, and adult vaccines that receive a preferred recommendation are widely adopted. For example, in 2014, the ACIP voted to recommend Prevnar 13 for routine use to help protect adults aged 65 years and older against pneumococcal disease, which caused Prevnar 13 to become the standard of care along with continued use of Pneumovax 23.

ACIP can also modify its preferred recommendation. For instance, in June 2019, the ACIP voted to revise the pneumococcal vaccination guidelines and recommend Pevnar 13 for adults 65 and older based on the shared clinical decision making of the provider and patient, rather than a preferred use recommendation, which means the decision to vaccinate should be made at the individual level between health care providers and their patients. Pfizer recently noted that this revised recommendation is expected to have a negative effect on Pevnar 13 revenue for future periods.

If our vaccine is approved but fail to receive CDC and ACIP recommendations, or recommendations of other comparable foreign regulatory and advisory bodies, or achieve market acceptance among physicians, healthcare providers, patients, third-party payors or others in the medical community, we will not be able to generate significant revenue. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

We currently rely on third-party manufacturing and supply partners, including Lonza and Glycosyn, to supply raw materials and components for, and manufacture, our vaccine and antibody. Our inability to have sufficient quantities of our vaccine and antibody 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 vaccine supply. However, our assumptions as to our ability and our contract manufacturer's ability to produce vaccines 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.

We rely on third-party contract manufacturers to manufacture preclinical and clinical trial product materials and supplies for our needs. There can be no assurance that our preclinical and clinical development product supplies will not be limited or interrupted or be of satisfactory quality or continue to be available on acceptable terms. The manufacturing facilities in which our preclinical and clinical trial product materials and supplies are made could be adversely affected by pandemics, earthquakes and other natural or man-made disasters, equipment failures, labor shortages, power failures, and numerous other factors. Please see the risk factor titled *"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."*

The manufacturing process for a vaccine or antibody 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 cGMPs. If our contract manufacturers 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 vaccine or antibody. Moreover, we do not control the manufacturing process at our contract manufacturers 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. In some cases, the technical skills, raw materials or technology required to manufacture our vaccine may be unique or proprietary to the original manufacturer or supplier, and we may have difficulty applying such skills or technology or sourcing such raw materials ourselves, or in transferring such skills, technology or raw materials to another third party. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to enable us, or to have another third party, manufacture our vaccine. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines, and we may be required to repeat some of the development program. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop our vaccine in a timely manner or within budget.

We expect to continue to rely on third-party manufacturers and suppliers, including Lonza and Glycosyn, if we receive regulatory approval. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. If we are unable to obtain or maintain third-party manufacturing for our vaccine, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our vaccine successfully. Our or a third party's failure to execute on our manufacturing requirements and comply with cGMPs could adversely affect our business in a number of ways, including:

- an inability to initiate or complete clinical trials of the vaccine under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for our vaccine;
- subjecting third-party manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of our vaccine or antibody; and in the event of approval to market and commercialize our vaccine or antibody, an inability to meet commercial demands for our products.

Additionally, we and our contract manufacturers may experience manufacturing difficulties due to limited manufacturing experience, resource constraints or as a result of labor disputes, unstable political environments, pandemics or other unforeseen activities or developments. If we or our contract manufacturers were to encounter any of these difficulties, our ability to manufacture sufficient vaccine supply for our preclinical studies and clinical trials, or to provide product for patients once approved, would be jeopardized.

We or the third parties upon whom we depend may be adversely affected by natural disasters or acts of war, such as the conflict in Ukraine, 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, including acts of war, such as the conflict in Ukraine, that result in us being unable to undergo clinical trials, fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, 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 candidates 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 contract manufacturers, 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.

The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. 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 contract manufacturers, 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.

Our vaccine and antibody may cause undesirable side effects or have other properties, including interactions with existing vaccine regimens, or antibiotics 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 vaccine or antibody 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 antibody or vaccine. 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. In addition, any vaccine to be approved in pediatric populations may need to undergo extensive vaccine-vaccine interference studies with the standard of care pediatric vaccine regimen. Further, to the extent field efficacy studies are required, prophylactic vaccines typically require clinical testing in thousands to tens of thousands of healthy volunteers to define an approvable benefit-risk profile. 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. Any of these occurrences may harm our business, financial condition and prospects significantly.

Negative developments and negative public opinion of new technologies on which we rely may damage public perception of our vaccine and antibody or adversely affect our ability to conduct our business or obtain regulatory approvals for our vaccine.

Negative developments and negative public opinion of new or existing technologies on which we rely may damage public perception of our vaccine and antibody or adversely affect our ability to conduct our business or obtain regulatory approvals for our vaccine. Public perception may be influenced by claims that the vaccine or antibody are unsafe. Adverse public attitudes may negatively impact our ability to enroll patients in clinical trials. Moreover, our success will depend upon physicians specializing in our targeted diseases prescribing, and their patients being willing to receive, our vaccine or antibody in addition to the current standard of care. Any increase in negative perceptions of the technologies that we rely on may result in fewer physicians prescribing our products or may reduce the willingness of patients to utilize our products or participate in clinical trials.

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, or 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 the COVID-19 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 and recruiting suitable patients to participate in our clinical trials;
- 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;
- delays in having patients complete participation in a study or return for post-injection follow-up;
- patients dropping out of a study;
- occurrence of side effects associated with our vaccine or antibody 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 vaccine or antibody 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 vaccine or antibody and may harm our business and results of operations.

If we encounter difficulties enrolling patients in any clinical trials we may conduct, including any field efficacy trials that may be required, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in any clinical trials we may conduct for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including:

- the 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;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents;
- the referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the risk that patients enrolled in clinical trials will drop out of the trials before the injection of our vaccine or trial completion.

To the extent we are required to conduct any field efficacy studies for the vaccine, enrollment of a sufficient number of patients may require additional time and resources given widespread vaccination rates in the United States, particularly in the pediatric population. As a result, we may be required to conduct any such trials outside the United States, which could cause additional complexity and delay. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of any clinical trials we may conduct, which could prevent completion of these trials and adversely affect our ability to advance the development of our vaccine.

Interim topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim topline or preliminary data from our preclinical or clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data when we publish such data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we may publish. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular vaccine candidate and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant by you or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular vaccine candidate or our business. If the topline data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, vaccine may be harmed, which could significantly harm our business prospects.

We might not receive Fast Track designation for AV0328 and F598, and even if we do, such designation may not actually lead to a faster development or regulatory review or approval process.

If a drug is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, a drug sponsor may qualify for FDA Fast Track designation. We have submitted an application for Fast Track designation for AV0328 and F598. The FDA has broad discretion whether to grant this designation, and we may not receive it. Moreover, even if we receive Fast Track designation, Fast Track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular time frame. We may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

We may seek a Breakthrough Therapy designation for AV0328 or F598, but we might not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process.

We may seek a Breakthrough Therapy designation for AV0328 or F598 if future results support such designation. A Breakthrough Therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for priority review if supported by clinical data at the time the NDA is submitted to the FDA. Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe that AV0328 or F598 meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. Even if we receive Breakthrough Therapy designation, the receipt of such designation may not result in a faster development or regulatory review, or approval process compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if AV0328 or F598 qualifies as a breakthrough therapy, the FDA may later decide that it no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

We may conduct certain of our clinical trials for our product candidates outside of the United States. However, the FDA and other foreign equivalents may not accept data from such trials, in which case its development plans will be delayed, which could materially harm its business.

We may choose to conduct one or more of our clinical trials for our product candidates outside the United States. For example, for our anticipated Phase 2 trial of antibody F598, we are evaluating conducting these trials outside the United States, including potentially in France. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to certain conditions imposed by the FDA. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless (i) those data are applicable to the U.S. population and U.S. medical practice; (ii) the studies were performed by clinical investigators of recognized competence; and (iii) the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. For studies that are conducted only at sites outside of the United States and not subject to an IND, the FDA requires the clinical trial to have been conducted in accordance with GCPs, and the FDA must be able to validate the data from the clinical trial through an on-site inspection if it deems such inspection necessary. For such studies not subject to an IND, the FDA generally does not provide advance comments on the clinical protocols for the studies, and therefore there is an additional potential risk that the FDA could determine that the study design or protocol for a non-U.S. clinical trial was inadequate, which could require us to conduct additional clinical trials. There can be no assurance the FDA will accept data from clinical trials conducted outside of the United States. If the FDA does not accept data from our clinical trials of our product candidates, it would likely result in the need for additional clinical trials, which would be costly and time consuming and delay or permanently halt our development of our product candidates.

Many foreign regulatory bodies have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any similar foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any similar foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of Our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction or permanently halt our development of our product candidates.

Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research; and
- diminished protection of intellectual property in some countries.

We currently have no marketing and sales organization, and as an organization have no experience in marketing products.

If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our vaccine, we may not be able to generate product revenue. We currently have no sales, marketing or distribution capabilities and as an organization have no experience in marketing products. If we develop an in-house marketing organization and sales force, we 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.

If we are unable or decide not to 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 vaccine ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our vaccine.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product that receives regulatory approval in the United States or overseas. If we are unable to develop in-house sales and distribution capabilities or enter into relationships with third-party collaborators on acceptable terms or at all, we may not be able to successfully commercialize our products. If we are not successful in commercializing our products or any future products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

A variety of risks associated with potentially conducting research and clinical trials abroad and marketing our vaccine internationally could materially adversely affect our business.

As we pursue approval and commercialization for our vaccine overseas and conduct CMC and other operations overseas, we will be subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- increased difficulties in managing the logistics and transportation of storing and shipping vaccines abroad;
- import and export requirements and restrictions;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- potential liability under the U.S. Foreign Corrupt Practices Act of 1977, as amended, or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect;
- intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations and our collaborations with Lonza, based in Switzerland and Glycosyn, based in New Zealand, may materially adversely affect our ability to attain or maintain profitable operations.

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, including our Co-Founder, President and Chief Executive Officer, Daniel R. Vlock. The loss of the services of any 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 Boston 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.

We depend on a sole source supplier for a critical vaccine component; the inability to obtain this component as required, with favorable purchase terms, could harm our business.

We currently source a key component of our vaccine from one supplier. Supply shortages for this particular component can delay vaccine production. This could cause us to experience a delay in clinical trials, reduction in sales, increased inventory levels and costs, and could adversely affect relationships with existing and prospective customers. In the past, we have secured sufficient allocations of the component. If we are unable to procure this necessary component under favorable purchase terms from this supplier, including at favorable prices and with the order lead-times needed, our results of operations could suffer.

Obtaining and maintaining regulatory approval of our vaccine in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our vaccine in other jurisdictions.

Obtaining and maintaining regulatory approval of our vaccine in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a vaccine candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the vaccine candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a vaccine or antibody must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our vaccine or antibody will be harmed.

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 vaccine and any future vaccine 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 vaccine 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 vaccine as having the requisite potential to demonstrate safety and efficacy. Any delays in entering into new strategic partnership agreements related to our vaccine could delay the development and commercialization of our vaccine 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.

Revenue from any “catch up” opportunity may decline over time as more of the patient population is vaccinated

Even if we obtain approval to serve as a “catch up” or booster to those adults who have previously received Pneumovax 23 or a lower valent PCV, previous vaccines with a “catch up” opportunity have seen sales decline over time after a high initial capture rate as the number of individuals who remain unvaccinated with the new vaccine, and eligible for “catch up” opportunities, declines. Such decline could adversely affect our revenue over time.

Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and the systems of our CROs, contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. Additionally, the increased usage of computers operated on home networks due to remote work arrangements may make our systems more susceptible to security breaches. While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our vaccine could be delayed.

We may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure.

We rely on information technology systems that we or our third-party providers operate to process, transmit and store electronic information in our day-to-day operations. In connection with our product discovery efforts, we may collect and use a variety of personal data, such as name, mailing address, email addresses, phone number and clinical trial information. A successful cyberattack could result in the theft or destruction of intellectual property, data or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial-of-service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. Although we devote resources to protect our information systems, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition. Any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under state (e.g., state breach notification laws), federal (e.g., HIPAA, as amended by HITECH), and international law (e.g., the European Union, or EU, General Data Protection Regulation, or GDPR) and may cause a material adverse impact to our reputation, affect our ability to use collected data, conduct new studies and potentially disrupt our business.

We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. We also rely on our employees and consultants to safeguard their security credentials and follow our policies and procedures regarding use and access of computers and other devices that may contain our sensitive information. If we or our third-party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third-party providers could have difficulty preventing, detecting and controlling such cyber-attacks and any such attacks could result in losses described above as well as disputes with physicians, patients and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. Any failure by such third parties to prevent or mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business.

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.

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 contract manufacturer and other third parties upon whom we rely. For example, the COVID-19 pandemic presented a substantial public health and economic challenge around the world and affected employees, patients, communities and business operations, as well as the U.S. economy and financial markets.

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

We face an inherent risk of product liability as a result of the clinical testing of our vaccine and will face an even greater risk if we commercialize any products. For example, we may be sued if our vaccine or antibody 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 vaccine. 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 vaccine;
- 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 vaccine candidate; 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, including most recently as a result of the COVID-19 pandemic. 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 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 abroad 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.

The Tax Cuts and Jobs Act, or the Tax Act, could adversely affect our business and financial condition.

In December 2017, the Tax Act was signed into law. The Tax Act, among other things, contains significant changes to corporate taxation, including (i) changes to the expensing of research and development expenses for tax years beginning after December 31, 2021, (ii) reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, (iii) limitation of the tax deduction for interest expense to 30% of adjusted earnings (with certain exceptions, including for certain small businesses), (iv) limitation of the deduction for post-2017 net operating losses, or NOLs, to 80% of current-year taxable income and elimination of net operating loss carrybacks for post-2017 NOLs, (v) immediate deductions for certain new investments instead of deductions for depreciation expense over time and (vi) modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as "orphan drugs").

We continue to examine the impact the Tax Act may have on our business. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business, financial condition, results of operations and prospects could be adversely affected. We urge our stockholders, including purchasers of common stock in this offering, to consult with their legal and tax advisors with respect to the Tax Act and the tax consequences of investing in our common stock. Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited. We have incurred substantial losses since inception and do not expect to become profitable in the near future, if ever.

The Tax Act, among other things, includes changes to U.S. federal tax rates and the rules governing NOL carryforwards. For federal NOLs arising in tax years beginning after December 31, 2017, the Tax Act limits a taxpayer's ability to utilize NOL carryforwards to 80% of taxable income. In addition, federal NOLs arising in tax years beginning after December 31, 2017 can be carried forward indefinitely, but carryback is generally prohibited. Deferred tax assets for NOLs will need to be measured at the applicable tax rate in effect when the NOL is expected to be utilized. The new limitation on use of NOLs may significantly impact our ability to utilize our NOLs to offset taxable income in the future. Our insurance policies may be inadequate and potentially expose us to unrecoverable risks. Although we intend to maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any vaccine candidate. Insurance availability, coverage terms and pricing continue to vary with market conditions. We endeavor to obtain appropriate insurance coverage for insurable risks that we identify; however, we may fail to correctly anticipate or quantify insurable risks, we may not be able to obtain appropriate insurance coverage and insurers may not respond as we intend to cover insurable events that may occur. Conditions in the insurance markets relating to nearly all areas of traditional corporate insurance change rapidly and may result in higher premium costs, higher policy deductibles and lower coverage limits. For some risks, we may not have or maintain insurance coverage because of cost or availability.

Risks Related to Our Reliance on Third Parties

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 vaccine.

We currently do not have the ability to independently conduct preclinical or clinical studies that comply with the regulatory requirements known as good laboratory practices and 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. We and these third parties are required to comply with GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for vaccine in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There can be no assurance that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with biologic product produced under cGMPs and will require a large number of test patients. 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 vaccine. As a result, our financial results and the commercial prospects for our vaccine 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.

We rely on third parties, including Glycosyn and Lonza, to supply raw materials and manufacture our preclinical and clinical product supplies of our vaccine, and expect to rely on third parties to supply raw materials and produce and process our vaccine, if approved. The loss of these suppliers or their failure to comply with applicable regulatory requirements or provide us with sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.

We do not have nor do we plan to build or acquire the infrastructure or capability internally to manufacture supplies for our vaccine and antibody or the materials necessary to produce our vaccine for use in the conduct of our preclinical studies or clinical trials, and we lack the internal resources and the capability to manufacture any of our vaccine on a preclinical, clinical or commercial scale. We have entered into an agreement with Glycosyn to supply us the key component of our vaccine (the oligosaccharide) use in manufacturing non-clinical and clinical supplies. We have engaged Lonza to perform manufacturing process development and clinical manufacture and supply of the antibody. We also engaged Lonza to perform manufacturing process development and clinical manufacture and supply of F598 drug product. Our agreements with Lonza are denominated in Swiss Francs. Fluctuations in the exchange rate for Swiss Francs may increase our costs and affect our operating results.

In addition, our anticipated reliance on a limited number of third-party suppliers and manufacturers exposes us to the following risks:

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA may have questions regarding any replacement contractor. This may require new testing and regulatory interactions. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA questions, if any.
- Our third-party suppliers and manufacturers might be unable to timely formulate and manufacture or supply raw materials for our vaccine or produce the quantity and quality required to meet our clinical and commercial needs, if any.
- Contract manufacturers may not be able to execute our manufacturing procedures appropriately.
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.
- Manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.
- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our products.
- Our third-party suppliers and manufacturers could breach or terminate their agreement with us.

Each of these risks could delay our clinical trials, the approval, if any, of our vaccine by the FDA or the commercialization of our antibody and vaccine or result in higher costs or deprive us of potential product revenue. In addition, we will rely on third parties to perform release tests on our vaccine prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm.

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.

Risks Related to Government Regulation

The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug products, including biologics such as conjugate vaccines, are subject to extensive regulation by the FDA and other regulatory authorities in the United States. We expect that our vaccine and antibody candidates will be regulated by the FDA as biologics. We are not permitted to market any biological drug product in the United States until we receive approval of a Biologics License Application, or BLA, from the FDA. We have not previously submitted a BLA to the FDA, or similar approval filings to comparable foreign regulatory authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish the vaccine candidate's safety and effectiveness for each desired indication. Further, because our vaccine that are subject to regulation as biological drug products, we will need to demonstrate that they are safe, pure and potent for use in their target indications. The BLA must also include significant information regarding the CMC for the product, including with respect to chain of identity and chain of custody of the product.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies of our vaccine may not be predictive of the results of early-stage or later-stage clinical trials, and results of early clinical trials of our vaccine may not be predictive of the results of later-stage clinical trials. The results of clinical trials in one set of patients or disease indications may not be indicative of those obtained in another. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same vaccine candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. Vaccine or antibody candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most drugs that begin clinical trials are never approved by regulatory authorities for commercialization. In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit a BLA or other marketing application.

We may also experience delays in completing planned clinical trials for a variety of reasons, including delays related to:

- obtaining regulatory authorization to begin a trial, if applicable;
- the availability of financial resources to commence and complete the planned trials;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval at each clinical trial site by an independent IRB;
- recruiting suitable patients to participate in and complete a trial;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- addressing any safety concerns that arise during the course of a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of qualified materials under cGMPs and applying them on a patient-by-patient basis for use in clinical trials.

We could also encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our vaccine or antibody in lieu of using existing therapies that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a vaccine candidate, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial or based on a recommendation by the data safety monitoring board. If we experience termination of, or delays in the completion of, any clinical trial of our vaccine, the commercial prospects for our vaccine will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our vaccine.

The FDA may disagree with our regulatory plan, and we may fail to obtain regulatory approval of our vaccine and antibody.

The general approach for FDA approval of a new biologic or drug is for the sponsor to provide dispositive data from two Phase 3 clinical trials of the relevant biologic or drug in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and are time consuming. Based on our discussions with the FDA we believe our current clinical development approach will be positively received. But there can be no assurance that this approach will be sufficient for regulatory approval or that regulators will not require field efficacy trials.

We intend to seek accelerated approval from the FDA for our vaccine and antibody and, if granted, the FDA may require us to perform post-marketing studies as a condition of approval to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoints. If the results from such post-marketing studies are not positive or otherwise fail to show the predicted effect, the drug or biologic may be subject to expedited withdrawal procedures by the FDA. In addition, the standard of care may change with the approval of new products in the same disease areas that we are studying. This may result in the FDA or other regulatory agencies requesting additional studies to show that our vaccine candidate is non-inferior or superior to the new products.

Our clinical trial results may also not support approval. In addition, our vaccine and antibody could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our vaccine and antibody are safe and effective for any of their proposed disease areas;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that our vaccine's clinical and other benefits outweigh their safety risks;
- any vaccine to be approved in pediatric populations may need to undergo extensive vaccine-vaccine interference studies with the standard of care pediatric vaccine regimen;
- the need to perform superiority or field efficacy trials, which can be larger, longer and more costly, if an existing vaccine is approved for a disease indication;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our vaccine may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities will inspect the commercial manufacturing facilities we may utilize and may not approve such facilities; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Even if we receive regulatory approval of our vaccine or antibody, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our immune therapeutics.

Any regulatory approvals that we receive for our vaccine and antibody may also be subject to limitations on the approved indicated uses for which a product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including post-marketing clinical trials, and surveillance to monitor the safety and efficacy.

In addition, if the FDA or a comparable foreign regulatory authority approves our vaccine or antibody the manufacturing processes, labeling, packaging, distribution, adverse event reporting, conduct of post-marketing studies, storage, sampling, advertising, promotion, import, export and recordkeeping for our vaccine will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration and continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing application and previous responses to inspectional observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. In addition, the FDA could require us to conduct another study to obtain additional safety or biomarker information. Further, we will be required to comply with FDA promotion and advertising rules, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses (known as "off-label use"), limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet and social media. Later discovery of previously unknown problems with our vaccine, including side effects of unanticipated severity or frequency, or with our third-party suppliers or 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-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our vaccine, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;

- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of regulatory approvals;
- product seizure or detention, or refusal to permit the import or export of our vaccine; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our vaccine or antibody. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance and review and approval of marketing applications. It is difficult to predict how these orders will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

We expect the vaccine and antibody we develop will be regulated as biological products, or biologics, and therefore they may be subject to competition sooner than anticipated.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, was enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, ACA, to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until twelve years after the reference product was approved under a BLA. 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 intended to implement the BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that if the vaccine and antibody we develop is approved in the United States as a biological product under a BLA should qualify for the twelve-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 the subject vaccine to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the 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.

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 vaccine for which we 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 vaccine, 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;
- 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; and
- similar healthcare laws and regulations in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of certain protected information, such as the General Data Protection Regulation, or GDPR, which imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the EU (including health data).

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.

Insurance Coverage and reimbursement rates may be limited or unavailable in certain market segments for our vaccine and antibody, which could make it difficult for us to sell our therapeutics, if approved, profitably.

Successful sales of our vaccine and antibody, if approved, depend on the availability of coverage and adequate reimbursement from third-party payors including governmental healthcare programs, such as Medicare and Medicaid, managed care organizations and commercial payors, among others. Significant uncertainty exists as to the coverage and reimbursement status of any vaccine for which we obtain regulatory approval. Patients who receive vaccines and antibodies generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Obtaining coverage and adequate reimbursement from third-party payors is critical to new product acceptance. Third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. Even if we obtain coverage for a given product, if the resulting reimbursement rates are insufficient, hospitals may not approve our product for use in their facility or third-party payors may require co-payments that patients find unacceptably high. Patients are unlikely to use our vaccine unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our vaccine and antibody. Separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for administering the product. Further, from time to time, CMS revises the reimbursement systems used to reimburse health care providers, including the Medicare Physician Fee Schedule and Outpatient Prospective Payment System, which may result in reduced Medicare payments. In some cases, private third-party payors rely on all or portions of Medicare payment systems to determine payment rates.

Changes to government healthcare programs that reduce payments under these programs may negatively impact payments from third-party payors and reduce the willingness of physicians to use our vaccine. Certain ACA marketplace and other private payor plans are required to include coverage for certain preventative services, including vaccinations recommended by the ACIP without cost share obligations (i.e., co-payments, deductibles or co-insurance) for plan members. Children through 18 years of age without other health insurance coverage may be eligible to receive such vaccinations free-of-charge through the CDC's Vaccines for Children program. For Medicare beneficiaries, vaccines may be covered under either the Part B program or Part D depending on several criteria, including the type of vaccine and the beneficiary's coverage eligibility. If our vaccine, once approved, are covered only under the Part D program, physicians may be less willing to use our products because of the claims adjudication costs and time related to the claims adjudication process and collection of co-payments associated with the Part D program.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. 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. We intend to seek approval to market our vaccine and antibody in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our vaccine and antibody, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in Europe, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a vaccine candidate. Some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular vaccine to currently available vaccines. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any vaccine for which we receive regulatory approval for commercial sale may suffer if government and other third-party payors fail to provide coverage and adequate reimbursement. We expect downward pressure on pharmaceutical pricing to continue. Further, 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. Healthcare legislative reform measures may have a negative impact on our business, financial condition, results of operations and prospects. In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of vaccine, restrict or regulate post-approval activities and affect our ability to profitably sell any vaccine for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both governmental and private payors in the United States. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include:

- an annual, non-deductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, which is apportioned among these entities according to their market share in certain government healthcare programs;
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

- a requirement that certain ACA marketplace and other private payor plans include coverage for preventative services, including vaccinations recommended by the ACIP without cost share obligations (i.e., co-payments, deductibles or co-insurance) for plan members;
- 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
- establishment of a Center for Medicare Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

There have been executive, judicial and Congressional challenges to the ACA. For example, the Tax Act included a provision that repealed, effective January 1, 2019, 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, which is commonly referred to as the “individual mandate.” On June 17, 2021, the United States Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Thus, the ACA will remain in effect in its current form. Moreover, prior to the United States Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges, other litigation, and the healthcare reform measures of the Biden administration will impact the ACA.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and, due to subsequent legislative amendments to the statute, including the BBA and the Infrastructure Investment and Jobs Act, will remain in effect until 2031 unless additional Congressional action is taken. COVID-19 pandemic relief support legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2022. Under the current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several types of providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, Congress is considering additional healthcare reform measures as a part of the budget reconciliation process. In addition, Congress is considering additional healthcare reform measures as a part of the budget reconciliation process.

Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, which ended the use of the statutory formula for clinician payment and established a quality payment incentive program, also referred to as the Quality Payment Program. This program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models, or APMs, and the Merit-based Incentive Payment System, or MIPS. In November 2019, CMS issued a final rule finalizing the changes to the Quality Payment Program. At this time, the full impact of the introduction of the Medicare quality payment program on overall physician reimbursement remains unclear. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Further, in the United States there has 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 federal and state legislation designed to, among other things, bring more transparency to drug and biological product pricing, reduce the cost of prescription drugs and biological products under government payor programs and review the relationship between pricing and manufacturer patient programs. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration’s proposals. The FDA concurrently released a final rule and guidance in September 2020 providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The implementation of the rule has been delayed until January 1, 2027. On November 20, 2020, CMS issued an interim final rule implementing President Trump’s Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. As a result of litigation challenging the Most Favored Nation model, on December 27, 2021, CMS published a final rule that rescinded the Most Favored Nation Model interim final rule. In July 2021, the Biden administration released an executive order, “Promoting Competition in the American Economy,” with multiple provisions aimed at prescription drugs. In response to Biden’s executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. It is unclear whether these or similar policy initiatives will be implemented in the future. 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. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs, biological products and suppliers will be included in their healthcare programs. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our current or any future vaccine or additional pricing pressures. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing or new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our current or any future vaccine we may develop may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

We expect that 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 any approved product, which could have an adverse effect on demand for our vaccine and antibody. Any reduction in reimbursement from Medicare or other government 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. For additional information on healthcare reform, see the section entitled “Business—Government Regulation.”

Changes in funding for the FDA and other government agencies could hinder our 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, 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, including for 35 days beginning on December 22, 2018, 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.

Separately, in response to the global COVID-19 pandemic, the FDA has adopted a risk-based system for the conduct of inspections of manufacturing facilities. Additionally, the FDA is 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 outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 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.

We are also subject to a growing body of privacy, data security and data protection laws outside of the United States. For example, the EU has adopted the GDPR, which went into effect in May 2018 and introduced strict requirements for processing personal data. Among other obligations under the GDPR, we are required to give more detailed disclosures about how we collect, use and share personal data; contractually commit to data protection measures in our contracts with clients; maintain adequate data security measures; notify regulators and affected individuals of certain personal data breaches; meet extensive privacy governance and documentation requirements; and honor individuals' expanded data protection rights, including their rights to access, correct and delete their personal data. The processing of sensitive personal data, such as health data information, may impose heightened compliance burdens under the GDPR and is a subject of active interest among regulators. Companies that violate the GDPR can face private litigation, regulatory enforcement action, prohibitions on data processing and fines of up to the greater of 20 million Euros or 4% of their worldwide annual revenue.

European data protection laws, including the GDPR, generally restrict the transfer of personal data from Europe, including the European Economic Area, United Kingdom and Switzerland, to the United States and most other countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. Historically, to comply with these restrictions, we have generally relied on the Standard Contractual Clauses for personal data transfers approved by the European Commission. However, a July 2020 decision of the EU's highest court called into question whether the Standard Contractual Clauses can lawfully be used for transfers of personal data from the EU to the United States and most other non-EU countries. Authorities in Switzerland may similarly question the viability of the Standard Contractual Clauses as a mechanism for the lawful transfer of personal data from those countries to the United States or other countries. Further, the UK's decision to leave the EU, often referred to as Brexit, and ongoing developments in the UK have created uncertainty regarding data protection regulation in the UK. Following December 31, 2020, and the expiry of transitional arrangements between the UK and EU, the data protection obligations of the GDPR continue to apply to UK-related Processing of personal data in substantially unvaried form under the so-called 'UK GDPR'. However, going forward, there is increasing risk for divergence in application, interpretation and enforcement of the data protection laws as between the UK and EEA. Furthermore, the relationship between the UK and the EEA in relation to certain aspects of data protection law remains uncertain. For example, it is unclear whether transfers of personal data from the EEA to the UK will be permitted to take place on the basis of a future adequacy decision of the European Commission, or whether a 'transfer mechanism' such as the Standard Contractual Clauses will be required. If we are unable to lawfully transfer personal data from Europe via the Standard Contractual clauses or an alternative mechanism, we will face increased exposure to regulatory actions, substantial fines, and injunctions against processing personal information from Europe, and we may be required to increase our data processing capabilities in Europe at significant expense. Inability to import personal information from Europe may also restrict our clinical trials activities in Europe and limit our ability to collaborate with contract research organizations, service providers, contractors and other companies subject to European data protection laws. Additionally, other countries outside of Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of operating our business.

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. In addition, it is anticipated that the CCPA will be expanded on January 1, 2023, when the California Privacy Rights Act of 2020, or CPRA, becomes operative. 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 any of our product candidates are approved for marketing and we are found to have improperly promoted 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 any of our product candidates are approved and we are found to have improperly promoted 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 candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our vaccine and monoclonal antibody development programs. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to AV0328, F598 and any future candidates, as well as methods of making our vaccine and antibody and components thereof. We seek to protect our proprietary position by filing patent applications in the United States, and abroad related to our development programs. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

The patents and patent applications that we own or in-license may fail to result in issued patents with claims that protect AV0328, F598 or any future candidate in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application or be used to invalidate a patent. Even if patents do successfully issue and even if such patents cover AV0328, F598 or any future candidate, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any vaccine or companion diagnostic that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a vaccine candidate under patent protection could be reduced.

If the patent applications we hold or have in-licensed with respect to our development programs and vaccine fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for AV0328, F598 or any future candidate, it could dissuade companies from collaborating with us to develop vaccine and threaten our ability to commercialize future therapies. Any such outcome could have a materially adverse effect on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has been and will continue to be the subject of litigation and new legislation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, many countries restrict the patentability of methods of treatment of the human body. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

As a result of these and other factors, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or the USPTO, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings and litigation can be substantial and the outcome can be uncertain. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future vaccine.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. In certain instances, patent term can be adjusted to recapture a portion of delay by the USPTO in examining the patent application (patent term adjustment) or extended to account for term effectively lost as a result of the FDA regulatory review period (patent term extension), or both. The scope of patent protection may also be limited. Without patent protection for our current or future vaccine, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new vaccine, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we fail to comply with our obligations under any license, collaboration or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our vaccine.

We have licensed certain intellectual property rights related our PNAG platform from Brigham and Women's Hospital. If, for any reason, these agreements are terminated or we otherwise lose those rights, it could adversely affect our business. These agreements impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us and may affect future collaboration agreements. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor(s) may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. There are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering PNAG, our vaccine, antibody or any future candidate, our competitors might be able to enter the market, which would have an adverse effect on our business.

Third-party claims or litigation alleging infringement of patents or other proprietary rights or seeking to invalidate our patents or other proprietary rights, may delay or prevent the development and commercialization of our vaccine, antibody and any future candidate.

Our commercial success depends in part on our avoiding infringement and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, inter partes review and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing vaccine and monoclonal antibody candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our vaccine or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization.

Also, there may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our vaccine. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our vaccine may infringe. In addition, third parties may obtain patent rights in the future and claim that use of our technologies infringes upon rights. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our vaccine, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such vaccine candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable vaccine candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our therapeutics. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms.

Furthermore, as the vaccine patent landscape is crowded and highly competitive, even in the absence of litigation we may need to obtain licenses from third parties to advance our research or allow commercialization of our vaccine, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our therapeutics, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against vaccine resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties.

We may become involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. 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 patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, written description, or lack of patentable subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as *ex parte* reexaminations, inter-partes review or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future vaccine. Such a loss of patent protection could harm our business.

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.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

The United States has enacted and implemented wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future.

In 2018 Alopexx signed a Material Transfer Agreement (“MTA”) with Xenothera, a French biotechnology company that had developed genetically modified pigs capable of producing humanized antisera. Xenothera was interested to see if vaccination with vaccine AV0328 could induce anti-PNAG antisera in their pigs. Alopexx provided the vaccine at no cost and Xenothera did a preliminary vaccination study in their pigs at their expense. The MTA stated that those activities could not be considered a commitment by Alopexx to license its vaccine to Xenothera. Although the MTA expired in 2019, Xenothera continued to develop the vaccine AV0328-induced antisera. Their activities were outside the scope of MTA and occurred without Alopexx’s prior knowledge or consent. After learning of those activities in May 2022, Alopexx formally requested that Xenothera halt all work referable to AV0328 and provide Alopexx with a full accounting of the activities, including any results of trials. Instead of responding to the information request, Xenothera filed a lawsuit against Alopexx in Nantes, France claiming that their activities, performed under the MTA in 2018, obligated Alopexx to, among other things, provide a license to Xenothera for the vaccine AV0328 or in the alternative pay monetary damages of €120,000,000.

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 vaccine from those approved for marketing from the products of our competitors. We have not yet selected trademarks for our vaccine and have not yet begun the process of applying to register trademarks for our current or any future vaccine. 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 vaccine candidate 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.

We may not be able to protect our intellectual property rights throughout the world, which could impair our business

Filing, prosecuting and defending patents covering our current vaccine and any future vaccine candidate throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims, or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

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 AV0328 and F598 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 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

We do not know whether an active, liquid and orderly trading market will 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.

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 will be 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 particular, the COVID-19 pandemic has further heightened the volatility of the stock market for biopharmaceutical companies. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this prospectus, these factors include:

- the commencement, enrollment or results of our planned or future preclinical studies or clinical trials of our vaccine and those of our competitors;
- regulatory or legal developments in the United States and abroad;
- the success of competitive vaccines or technologies;
- the recruitment or departure of key personnel;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the level of expenses related to our vaccine or preclinical and clinical development programs;

- the results of our efforts to develop additional vaccine;
- 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 vaccine;
- our inability to obtain or delays in obtaining adequate supply for any approved vaccine 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 vaccine or monoclonal antibody;
- general economic, political and market conditions and overall fluctuations in the financial markets in the United States and abroad; and
- investors' general perception of us and our business.

In addition, the stock market in general, and 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, including very recently in connection with the COVID-19 pandemic, 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.

Certain recent initial public offerings of companies with public floats comparable to the anticipated public float of Alopexx have experienced extreme volatility that was seemingly unrelated to the underlying performance of the respective company. We may experience similar volatility, which may make it difficult for prospective investors to assess the value of our common stock.

In addition to the risks addressed above in “—The price of our stock may be volatile, and you could lose all or part of your investment,” our common stock may be subject to extreme volatility that is seemingly unrelated to the underlying performance of our business. Recently, companies with comparable public floats and initial public offering sizes have experienced instances of extreme stock price run-ups followed by rapid price declines, and such stock price volatility was seemingly unrelated to the respective company's underlying performance. Although the specific cause of such volatility is unclear, our anticipated public float may amplify the impact the actions taken by a few stockholders have on the price of our stock, which may cause our stock price to deviate, potentially significantly, from a price that better reflects the underlying performance of our business. Should our common stock experience run-ups and declines that are seemingly unrelated to our actual or expected operating performance and financial condition or prospects, prospective investors may have difficulty assessing the rapidly changing value of our common stock. In addition, investors of shares of our common stock may experience losses, which may be material, if the price of our common stock declines after this offering or if such investors purchase shares of our common stock prior to any price decline.

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.

Our principal stockholders and management 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 and could delay or prevent a change in corporate control.

Prior to this offering, our executive officers, directors and 5% stockholders beneficially owned approximately 100% of our voting stock as of January 8, 2025 and, upon the closing of this offering, that same group will continue to beneficially own approximately 67.4% of our outstanding voting stock. Accordingly, even after this offering, these stockholders will have the ability to influence us through this ownership position and significantly affect the outcome of all matters requiring stockholder approval. For example, these stockholders may be able to significantly affect the outcome of elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. In addition, these stockholders acquired their shares of common stock for substantially less than the price of the shares of common stock being acquired in this offering, and these stockholders may have interests, with respect to their common stock, that are different from those of investors in this offering and the concentration of voting power among these stockholders may have an adverse effect on the price of our common stock.

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 assumed initial public offering price of \$5.00 per share, you will experience immediate dilution of \$4.15 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. After this offering, we will also have outstanding options and a warrant to purchase common stock with exercise prices lower than the initial public offering price. To the extent these outstanding options or warrant are exercised, there will be further dilution to investors in this offering. See the section entitled “Dilution” for additional information.

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, or JOBS Act, enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we complete this offering, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which we have total annual gross revenue of at least \$1.235 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed \$700 million as of the prior June 30th, and (2) the date on which we have issued more than \$1 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company” which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply for a period of time with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or Sarbanes-Oxley Act, and reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have 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 we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

As a public company, we will be subject to more stringent federal and state 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 LLC, or 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 NYSE 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.

If our common stock is listed on the NYSE American, 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. We are currently in the process of hiring additional accounting and finance staff as we grow our business. 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.

We have identified a material weakness in our internal control over financial reporting, and the failure to remediate this material weakness 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. The material weakness we identified related to the lack of maintaining a sufficient complement of personnel commensurate with the accounting and financial reporting requirements in order to have adequate segregation of key duties and responsibilities, which affected the operation of controls over the recording of journal entries and the reconciliation of key accounts. This material weakness did not result in a material misstatement to the financial statements. We are in the process of implementing measures designed to improve internal control over financial reporting to remediate the control deficiencies that led to our material weakness by, among other things, hiring qualified personnel with appropriate expertise to perform specific functions, and designing and implementing improved processes and internal controls.

While we believe the remedial efforts we are taking and will take will improve our internal controls and address the underlying causes of the material weakness, we cannot be certain that these steps will be sufficient to remediate the control deficiencies that led to our material weakness in our internal controls over financial reporting or prevent future material weaknesses or control deficiencies from occurring. While we will work to remediate the material weakness as timely and efficiently as possible, at this time we cannot provide an estimate of costs expected to be incurred in connection with the implementation of our remediation actions, nor can we provide an estimate of the time it will take to complete our remediation actions. Neither our management nor an independent registered public accounting firm has performed an evaluation of our internal controls over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act because no such evaluation has been required.

If we fail to effectively remediate the material weakness in our internal controls over financial reporting described above, we may be unable to accurately or timely report our financial condition or results of operations. Such failure may adversely affect our business, investor confidence in our company, our financial condition and the market value of our common stock.

We are not currently required to comply with SEC rules that implement Section 404 of the Sarbanes-Oxley Act and are therefore not required to make a formal assessment of the effectiveness of our internal controls over financial reporting for that purpose. Upon becoming a public company, we will be required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which will require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of internal controls over financial reporting. Although we will be required to disclose changes that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting on a quarterly basis, we will not be required to make our first annual assessment of our internal controls over financial reporting pursuant to Section 404 until at least our second annual report required to be filed with the SEC, and we will not be required to have our independent registered public accounting firm formally assess our internal controls for as long as we remain an "emerging growth company" as defined in the JOBS Act.

When formally evaluating our internal controls over financial reporting, we may identify material weaknesses that we may not be able to remediate in time to meet the applicable deadline imposed upon us for compliance with the requirements of Section 404 of the Sarbanes-Oxley Act. In addition, if we fail to achieve and maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. We cannot be certain as to the timing of completion of our evaluation, testing and any remediation actions or the impact of the same on our operations. If we are not able to implement the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner or with adequate compliance, our independent registered public accounting firm may issue an adverse opinion due to ineffective internal controls over financial reporting, and we may be subject to sanctions or investigation by regulatory authorities, such as the SEC. As a result, there could be a negative reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. Any such action could have a significant and adverse effect on our business and reputation, which could negatively affect our results of operations or cash flows. In addition, we may be required to incur additional costs in improving our internal control system and the hiring of additional personnel.

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 September 30, 2024, upon the closing of this offering we will have a total of 7,596,769 shares of common stock outstanding (7,956,769 shares if the underwriters exercise their over-allotment option in full). Of these shares, only the 2,400,000 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 365 days from the date of this prospectus in the case of our directors and executive officers, and 180 days from the date of this prospectus in the case of our other stockholders. 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.

Provisions in our corporate charter 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.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the closing of this offering 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:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- prohibit our stockholders from calling a special meeting of our stockholders;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called “poison pill,” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 66 2/3% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

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 amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the closing of this offering will 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 amended and restated bylaws that will be in effect upon the closing of this offering will 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 amended and restated bylaws will 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 amended and restated certificate of incorporation and amended and restated bylaws 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 amended and restated certificate of incorporation that will become effective upon the closing of this offering provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation will provide that the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders;
- any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws;
- any action or proceeding to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; and
- any action asserting a claim against us by any of our directors, officers or other employees governed by the internal affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction. In addition, our amended and restated certificate of incorporation will provide that the federal district court for the District of Delaware will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act or the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Our decision to adopt a federal forum provision for suits arising under federal securities laws in our amended and restated certificate of incorporation followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. However, such provision may not be enforceable under Section 22 of the Securities Act, and it may be possible for us to be sued in applicable state and local courts notwithstanding such provision.

Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Accordingly, actions by our stockholders to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder must be brought in federal court. Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the regulations promulgated thereunder.

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 us or our directors, officers or other employees, which may discourage these types of lawsuits. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive-forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find the exclusive-forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business.

We are a "controlled company" within the meaning of the NYSE American rules and, as a result, qualify for, and may rely on, exemptions and relief from certain corporate governance requirements. If we rely on these exemptions, our stockholders will not have the same protections afforded to stockholders of companies that are subject to such requirements.

Following this offering, Daniel Vlock, our President and Chief Executive Officer, will beneficially own approximately 58.5% of the voting power of our common stock. As a result, we will be a "controlled company" within the meaning of the NYSE American corporate governance standards. Under these corporate governance standards, a company of which more than 50% of the voting power in the election of directors is held by an individual, group or another company is a "controlled company" and may elect not to comply with certain corporate governance requirements. For example, controlled companies are not required to have:

- a board that is composed of a majority of "independent directors," as defined under the NYSE rules;
- a compensation committee that is composed entirely of independent directors; and
- director nominations be made, or recommended to the full board of directors, by its independent directors, or by a nominations/governance committee that is composed entirely of independent directors.

While we do not intend to rely on the exemptions relating to being a "controlled company" within the meaning of the NYSE American rules, we may utilize these exemptions for as long as we continue to qualify as a "controlled company." Accordingly, our stockholders may not have the same protections afforded to stockholders of companies that are subject to all of the corporate governance requirements of the NYSE American. Investors may find our common stock less attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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;
- our expectations regarding the potential benefits, spectrum coverage and immunogenicity of our vaccine;
- our expectations regarding our preclinical study results potentially being predictive of clinical study results;
- our belief that our vaccine could receive regulatory approval based on a demonstration of efficacy using well-defined surrogate immune endpoints rather than requiring clinical field efficacy studies;
- 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 vaccine and antibody and successfully complete clinical trials;
- the commercialization of our vaccine and antibody, 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 vaccine and antibody, 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.

USE OF PROCEEDS

We estimate that we will receive net proceeds from this offering of approximately \$9.9 million (or approximately \$11.6 million if the underwriters exercise their option to purchase additional shares in full), based on the assumed initial public offering price of \$5.00 per share of common stock, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$5.00 per share of common stock would increase (decrease) the net proceeds to us from this offering by approximately \$2.2 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 100,000 shares in the number of shares of common stock offered by us would increase (decrease) the net proceeds to us from this offering by approximately \$0.5 million, assuming the assumed initial public offering price of \$5.00 per share of common stock remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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 currently intend to use the net proceeds we receive from this offering, together with our existing cash and cash equivalents, as follows:

- approximately \$4.0 million to initiate a proof-of-concept trial of vaccine AV0328, including manufacturing, and correlative laboratory studies;
- approximately \$3.0 million to initiate a proof-of-concept trial of our monoclonal antibody in ICU patients; and
- the remainder for general corporate purposes, including working capital, operating expenses and capital expenditures, as well as potential expansion of our research pipeline.

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 the vaccine development process, 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 and cash equivalents, 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 and cash equivalents, will not be sufficient for us to fund a pivotal clinical trial for any of our candidates, and we will need to raise additional capital to complete the development and commercialization of our vaccine. We expect to finance our cash needs through public or private equity or debt financings, government or other third-party funding, collaborations, strategic alliances and licensing arrangements, or a combination of these sources. 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.

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 and cash equivalents, total capitalization and indebtedness at September 30, 2024:

- on an actual basis;
- on a pro forma basis to reflect (i) the automatic conversion of all outstanding convertible notes into shares of common stock and (ii) the filing of the Amended and Restated Certificate of Incorporation; and
- on a pro forma as adjusted basis to give further effect to the sale and issuance by us of 2,400,000 shares of our common stock in this offering, at the assumed initial public offering price of \$5.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read the following table together with our financial statements and the related notes appearing at the end of this prospectus and the “Summary Financial Data,” “Management’s Discussion & Analysis of Financial Condition and Results of Operations” and “Description of Capital Stock” sections of this prospectus.

	Actual	Pro Forma	Pro Forma As Adjusted
Cash and cash equivalents	\$ 638,522	\$ 638,522	\$ 11,466,022
Convertible Notes Payable	950,000	—	—
Notes Payable	1,450,000	1,450,000	1,450,000
Accrued Interest	468,706	302,886	302,886
Stockholders’ deficit:			
Preferred Stock, \$.0001 par value - 10,000,000 shares authorized, no shares issued and outstanding	—	—	—
Common Stock, \$.0001 par value - 100,000,000 shares authorized, 4,899,218 shares issued and outstanding, 5,196,769 shares issued and outstanding pro forma, 7,596,769 shares issued and outstanding pro forma as adjusted	490	520	760
Additional paid-in capital	8,606,289	9,722,078	19,665,922
Accumulated deficit	(13,208,504)	(13,208,504)	(13,208,504)
Total Stockholders’ (deficit) equity	(4,601,725)	(3,485,906)	6,458,178
Total Capitalization	<u>\$ (1,733,019)</u>	<u>\$ (1,733,020)</u>	<u>\$ 8,211,064</u>

The number of shares of our common stock that will be outstanding after this offering is based on 4,899,218 shares of our common stock outstanding as of September 30, 2024, and includes the conversion into 297,551 shares of our common stock of the convertible notes currently outstanding upon the closing of this offering.

The number of shares of our common stock that will be outstanding after this offering excludes:

- 1,419,388 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock;
- 1,312,612 additional shares of our common stock to be reserved for future issuance under our 2023 Equity Incentive Plan.

The table above assumes:

- an initial public offering price of \$5.00 per share;
- no exercise of the outstanding options described above;
- no exercise of the underwriters’ option to purchase up to an additional 360,000 shares of our common stock;
- assumes no exercise of the representative’s warrants to be issued to the representative of the underwriters in this offering;

- the filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, each of which will occur prior to the closing of this offering; and
- the conversion of the convertible notes currently outstanding into 297,551 shares of our common stock upon the closing of this offering.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share and the pro forma as adjusted net tangible book value (deficit) per share of our common stock after this offering. The net tangible book value (deficit) of our common stock as of September 30, 2024 was \$(5.5 million), or \$(1.12) per share. Our historical net tangible book value (deficit) represents the amount of our total tangible assets less our total liabilities. Historical net tangible book value (deficit) per share represents historical net tangible book value (deficit) divided by the number of shares of our common stock outstanding as of September 30, 2024.

The pro forma net tangible book value (deficit) of our common stock as of September 30, 2024 was \$(4.4 million), or \$(0.84) per share, after giving effect to issuance of shares of our common stock as a result of the automatic conversion of all outstanding convertible notes into 297,551 shares of common stock and the filing of the Amended and Restated Certificate of Incorporation.

After giving further effect to the receipt of the net proceeds from our sale of 2,400,000 shares of common stock in this offering at an assumed public offering price of \$5.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value (deficit) as of September 30, 2024, would have been \$6.5 million, or \$0.85 per share. This represents an immediate increase in pro forma net tangible book value (deficit) of \$1.97 per share to our existing stockholders and an immediate dilution of \$4.15 per share to investors purchasing common stock in this offering.

Dilution per share to investors participating in this offering is determined by subtracting pro forma as adjusted net tangible book value (deficit) per share after this offering from the initial public offering price per share paid by investors participating in this offering. The following table illustrates this dilution (without giving effect to any exercise by the underwriters of their option to purchase additional shares):

Assumed public offering price per share	\$ 5.00
Historical net tangible book value (deficit) per share as of September 30, 2024	(1.12)
Pro forma net tangible book value (deficit) per share as of September 30, 2024	(0.84)
Pro forma as adjusted net tangible book value (deficit) per share of Common Stock as of September 30, 2024, to give effect to this offering	0.85
Dilution in pro forma as adjusted net tangible book value (deficit) per share in this offering	<u>\$ (4.15)</u>

The dilution information discussed above is illustrative and will change based on the actual initial public offering price and other terms of this offering determined at pricing. If the underwriters exercise their option to purchase additional shares in full, our pro forma as adjusted net tangible book value (deficit) per share after this offering would be approximately \$1.02 per share, and the dilution in pro forma as adjusted net tangible book value (deficit) per share to new investors participating in this offering would be \$3.98 per share.

A \$1.00 increase (decrease) in the assumed initial public offering price of \$5.00 per share would increase (decrease) the pro forma as adjusted net tangible book value (deficit) by \$0.29 per share and the dilution to investors participating in this offering by \$0.71 per share, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated expenses payable by us.

Similarly, each increase (decrease) of 100,000 shares in the number of shares offered by us in this offering would increase (decrease) the pro forma as adjusted net tangible book value (deficit) by \$0.01 per share and the dilution to investors participating in this offering by \$0.01 per share, assuming the assumed initial public offering price of \$5.00 per share remains the same, and after deducting estimated underwriting discounts and commissions and estimated expenses payable by us.

The following table summarizes, on a pro forma as adjusted basis as of September 30, 2024, the differences between the number of shares of common stock purchased from us, the total cash consideration and the average price per share paid to us by existing stockholders and by new investors purchasing shares in this offering at the assumed initial public offering price of \$5.00 per share, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. As the table shows, new investors purchasing shares of common stock in this offering will pay an average price per share substantially higher than our existing investors paid.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	5,196,769	68%	\$ 5,493,896	31%	\$ 1.06
New investors participating in this offering	2,400,000	32%	\$ 12,000,000	69%	\$ 5.00
Total	7,596,769	100%	\$ 17,493,896	100%	\$ 2.30

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 65% 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 35% 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

Alopecx, Inc. ("Alopecx" or the "Company") is a corporation organized and existing under the laws of the State of Delaware. Our executive office is located at 186 Alewife Brook Pkwy #1068, Cambridge, MA 02138, telephone 617-780-1598, www.alopexx.com.

Alopecx, Inc. is a clinical stage biotechnology company focusing on developing novel, broad-spectrum immune-mediated therapeutics for the prevention and treatment of a wide range of bacterial, fungal and parasitic microbial infections.

Technology and Patents

Alopecx has developed two immune therapeutics directed at PNAG – a monoclonal antibody and a vaccine. The potential efficacy of these immune therapeutics has been evaluated in studies of 14 pathogens in 20 animal models of infection. In all of those infection models a positive therapeutic effect was observed in preventing or treating infections. Whether the efficacy noted in animal models will be observed in humans remains to be determined. While the ultimate decision on the safety and efficacy of our therapeutics will be determined by the FDA and other health authorities, it is our management's assessment that the broad-spectrum potential of our therapeutics will allow them to be used for the prevention, treatment, and mitigation of a wide range of infections. Both therapeutics are now in human clinical trials in which, in our management's assessment, they have been found to be well-tolerated. Our therapeutics are:

- **Monoclonal antibody F598** - Phase 1 and pilot phase 2 trials of F598 have been completed. The antibody was found to be well tolerated, and no serious adverse events were observed. A single infusion was noted to provide sustained serum levels for 2-3 months. Unlike vaccines which may take several weeks or longer to induce protective immunity, administration of a monoclonal antibody provides immediate protection. Therefore, the antibody will be utilized in settings where an individual is at an immediate or near-term risk of developing an infection. Hospital-associated infections are one of the major settings where this occurs. Monoclonal antibody F598 will not replace antibiotics but will instead complement and augment their efficacy and by doing so reduce the development of antibiotic resistant organisms. Use of monoclonal antibody F598 in that setting offers the potential for it to become the first broad-spectrum therapeutic antibody. We will study this in a setting where the prevalence of acquired infections is very high – intensive care units. Demonstrating that monoclonal antibody F598 can reduce the morbidity/mortality related to microbial infections in ICU patients would constitute a major health advancement. We believe it would establish administration of F598 as part of the standard of care in that setting.
- **Vaccine AV0328** - a synthetic PNAG vaccine. A phase 1, first-in-man trial has been completed and the vaccine was found to be well-tolerated with only minor and transient injection site reactions observed. It induced antibodies that were capable, in laboratory studies, of killing a wide range of PNAG-expressing pathogens. *In vitro* efficacy in killing was noted against every pathogen tested which included over 10 different microbial species. While these do not assure that ultimate safety and efficacy of the vaccine it prompted, Alopecx will propose to the FDA that AV0328 be developed as a complement to currently approved *Streptococcus pneumoniae* vaccines (Prevnam and Pneumovax). Those vaccines, including the recently approved versions, cover at best 23 of the 100 known *Streptococcus pneumoniae* serotypes. AV0328 could provide protection against many of the remaining 80+ serotypes. Feedback from the FDA supported pursuing accelerated approval of AV0328 based on safety in vaccinated humans and utilization of a validated surrogate assay – opsonic killing mediated by the antibodies induced by the vaccine. The FDA's Accelerated Approval Program allows for earlier approval of drugs that treat serious conditions based on a surrogate endpoint. A surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. Management believes that this points to a development path comparable to those that have led to FDA approval of other vaccines for *Streptococcus pneumoniae* infections. However, the FDA has not yet approved the vaccine and there is no guarantee that the FDA will ultimately approve the vaccine.

The technology for both the vaccine and antibody is licensed from Brigham and Women's Hospital. Alopexx has full rights to all uses and indications pursuant to those licenses.

Our patent portfolio contains 4 patent families with coverage through 2040. This includes both composition of matter and use patents. We continue to seek to maximize the scope of our patent protection for all our programs. In addition to patents, synthesis of the PNAG oligosaccharide is covered by a trade secret agreement. The F598 monoclonal antibody is produced using a proprietary master cell bank.

Key Management

Dr. Daniel Vlock is the CEO of newly formed Alopexx, Inc. He was appointed CEO of the prior company, OneBioPharma, Inc. on November 17, 2020. He brings extensive pharmaceutical industry and academic experience in pharmaceutical drug development. Previously as CEO of Alopexx Pharmaceuticals and Alopexx Vaccine he and Dr. Gerald Pier developed F598, a human monoclonal antibody directed against *S. aureus*. Vaccine AV0328 was also developed by Dr. Vlock and Dr. Pier. Dr. Vlock has held senior-level medical and research positions at GPC Biotech, Inc., Pharmacia Corporation, Ethicon Endo-Surgery (a subsidiary of Johnson & Johnson Company), and Boehringer Ingelheim Pharmaceuticals, Inc., where he was involved in the development of numerous oncology drugs, medical devices and drug-device combinations. While at Pharmacia he ran the Celebrex Oncology Group. While at other companies he ran programs which successfully developed and introduced monoclonal antibodies into clinical trials.

Thomas T. Thomas was appointed as CFO on August 30, 2021. From November 2016, he has served as an Independent Director of Opiant Pharmaceuticals (NASDAQ: OPNT), where he served as Chairman of the Audit Committee and a member of the Compensation Committee through March 2023. He has over 35 years of experience as a financial executive, consultant and entrepreneur in biotechnology, packaged goods, wine production, financial services and non-profit organizations. He is the former Interim Chief Executive Officer of the Stupski Foundation (2009 – 2010). He joined the foundation in 2009 as its Chief Financial Officer and in 2010 was promoted to Chief Operating Officer and subsequently asked to serve as the Foundation's interim CEO. Prior to joining the Stupski Foundation, Thomas spent twelve years (1994 – 2006) at Genentech, Inc, a bio-pharmaceutical company, in various financial roles serving as the company's Corporate Treasurer from 2001 through 2006. His executive responsibilities included Treasury Operations and Investments, Corporate Finance, Global Procurement, Enterprise Risk Management and Insurance, Business Continuity and Real Estate. As Treasurer, he led Genentech's Corporate Investment Program, implemented and led an Enterprise Risk Management program to holistically assess and mitigate company risks, partnered with Business Development in the financing of Genentech's Drug Collaborations and also executed large corporate transactions in support of Genentech's growth, including the \$2 billion Global Public Debt Offering and the financing and construction of Genentech's 870 thousand sq. ft. South Campus Research Center expansion.

Christine de los Reyes has served as our Chief Business Officer since June 2021. She has over 30 years of pharmaceutical experience and most recently was founder and Managing Director of Biotech Partnering Solutions, a business development consulting firm that advises life science companies on partnering strategy, search for potential partners, coordination of technical evaluation and due diligence, deal structure and transaction negotiation. In this capacity, she has had numerous clients and executed several licensing transactions. Christine also spent 12 years on the advisory board of the Neurotechnology Industry Organization, a non-profit trade association that represents companies involved in neuroscience, academic neuroscience research centers and brain-illness advocacy groups.

Company History

Alopexx has undergone a significant reorganization over the past year in anticipation of the IPO. This has been a culmination of a number of events over the past 3 years. Briefly, until 2019 monoclonal antibody F598 and vaccine AV0328 were licensed to Alopexx Pharmaceuticals, LLC and Alopexx Vaccine, LLC. Dr. Daniel Vlock was CEO of both of those entities. The research and development performed by those entities was responsible for bringing both the antibody and vaccine into clinical trials. A proprietary process for the vaccine's synthesis was developed and a first-in-man trial successfully completed. Plans for a phase 2 program and interactions with the FDA were initiated. Funding for these companies was funded solely by a high-net-worth U.S. family (the "Family Office") with ties to the Vlock family.

In late 2017, the Family Office made a decision to exit from a large number of investments, including the Alopexx F598 antibody and AV0328 vaccine programs.

For the F598 antibody and AV0328 vaccine an outside development group was engaged to continue the programs. To permit that group to independently pursue development it was elected to have both assets assigned to a new entity founded March 23, 2019 – OneBioPharma, Inc (OBP). The licenses from Brigham and Women’s Hospital for human use of the vaccine and antibody were assigned to OBP. After 18 months the parties then-responsible for OBP’s activities resigned from the company and board.

The Family Office remained committed to its desire to exit from the programs as part of their global strategy. Rather than close the programs entirely, the Family Office appointed Daniel Vlock as CEO of the newly re-named Alopexx, Inc. (formerly known as OneBioPharma) on November 17, 2020. The equity portion held by the Family Office was transferred to the new CEO in December 2020. The Family Office relinquished all rights and ownership.

To streamline and simplify equity ownership a cash-out merger occurred on June 14, 2021 and the intellectual property (among other assets) of the vaccine and antibody were merged into a new entity – OneBioPharma Acquisition Corp – which was subsequently renamed Alopexx, Inc.

Path Forward

Alopexx’s goal is to develop a broad-spectrum, non-antibiotic therapeutic platform for the treatment and prevention of microbial infections. These immune therapeutics offer the promise of greatly limiting the burden of bacterial infections in the world and reliance on antibiotics and the development of antimicrobial resistance.

Based on Phase 1 results Alopexx proposed to the FDA that AV0328 be developed as a complement to currently approved *Streptococcus pneumoniae* vaccines (Pneumovax, Pneumovax and Vaxneuvance). Those vaccines, including the recently approved versions, cover at best 23 of the 100 known *Streptococcus pneumoniae* serotypes. AV0328 could provide protection against the remaining 80+ serotypes. Feedback from the FDA supported pursuing accelerated approval of AV0328 based on safety in vaccinated humans and utilization of a validated surrogate assay – opsonic killing mediated by the antibodies induced by the vaccine. The FDA’s Accelerated Approval Program allows for earlier approval of drugs that treat serious conditions based on a surrogate endpoint. A surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Management believes that this points to a development path comparable to those that have led to FDA approval of other vaccines for *Streptococcus pneumoniae* infections. However, our vaccine has not been approved by the FDA and there is no guarantee that the FDA will ultimately approve the vaccine.

Unlike vaccines that may take several weeks or longer to induce protective immunity, administration of a monoclonal antibody F598 provides immediate protection. Therefore, the antibody can be utilized in settings where an individual is at an immediate or near-term risk of developing an infection. Hospital-associated infections are one of the major settings where this occurs. This will not replace antibiotics but will instead complement and augment their efficacy and by doing so reduce the development of antibiotic resistant organisms. Use of monoclonal antibody F598 in that setting offers the potential for it to become the first broad-spectrum therapeutic antibody. We will study this in a setting where the prevalence of acquired infections is very high – intensive care units. Demonstrating that monoclonal antibody F598 can reduce the morbidity/mortality related to microbial infections in ICU patients would constitute a major health advancement. It would establish administration of F598 as part of the standard of care in that setting.

In the view of Alopexx’s management, the immune-mediated anti-infective therapeutics being developed by Alopexx are unique. No other immune therapeutics offer such broad-spectrum potential. The initial target indications being pursued will permit development of anti-PNAG therapeutics in a focused fashion and, if successful, can establish Alopexx’s therapeutic platform to prevent and treat a wide range of disorders.

Results of operations for the years ended December 31, 2023 and 2022

	For the Years Ended	
	December 31, 2023	December 31, 2022
OPERATING EXPENSES:		
Research and development	\$ 357,234	\$ 471,326
General and administrative	3,223,999	1,760,501
TOTAL OPERATING EXPENSES	3,581,233	2,231,827
LOSS FROM OPERATIONS	(3,581,233)	(2,231,827)
Interest expense	(198,956)	(86,237)
NET LOSS BEFORE INCOME TAX	(3,780,189)	(2,318,064)
Income tax expense	—	—
NET LOSS	\$ (3,780,189)	\$ (2,318,064)
Loss per common share – basic and diluted	\$ (0.81)	\$ (0.50)
Weighted Average common shares outstanding – basic and diluted	4,689,460	4,640,000

Research and Development

This category includes costs incurred mainly for development activities and clinical trials. Research and development expenses decreased by approximately \$114 thousand from a total of \$471 thousand during 2022 to a total of \$357 thousand during 2023. This decrease is largely attributable to a decrease in storage expenses of \$161 thousand. Costs incurred in the years ended December 31, 2023 and December 31, 2022 were largely related to the development and clinical trials of the vaccine AV0328 and the monoclonal therapeutic F598.

General and Administrative Expense

General and administrative expense (“G&A”) included only general and administrative expenses in both 2023 and 2022 as the company currently has no sales or selling expenses. General and Administrative expenses were approximately \$1,463 thousand higher in 2023 relative to 2022 due to a \$1,923 thousand increase in stock-based compensation expense from the 2023 stock option grants.

Interest Expense

Interest expense is primarily related to the notes payable and convertible notes payable used to fund the Company’s operations in 2023 and 2022. Interest expense increased from approximately \$86 thousand in 2022 to approximately \$199 thousand during the year ended December 31, 2023. The increase in interest expenses was due to higher average outstanding debt in 2023 compared to 2022.

Net Loss

Net Loss for year ended December 31, 2023 was approximately \$3,780 thousand, an increase of approximately \$1.5 million from the approximately \$2,318 thousand incurred during the year ended December 31, 2022. The increase in the loss was largely due to the \$1,923 increase in stock-based compensation, offset by a decrease in storage and legal expenses.

Results of operations for the nine months ended September 30, 2024 and 2023

	For the Nine Months Ended	
	September 30, 2024	September 30, 2023
OPERATING EXPENSES:		
Research and development	\$ 177,605	\$ 290,000
General and administrative	1,806,561	2,557,685
TOTAL OPERATING EXPENSES	1,984,166	2,847,685
LOSS FROM OPERATIONS	(1,984,166)	(2,847,685)
Interest expense	(180,403)	(147,653)
NET LOSS BEFORE INCOME TAX	(2,164,569)	(2,995,338)
Provision for income taxes	—	—
NET LOSS	\$ (2,164,569)	\$ (2,995,338)
Loss per common share – basic and diluted	\$ (0.44)	\$ (0.64)
Weighted Average common shares outstanding – basic and diluted	4,865,557	4,659,812

Research and Development

This category includes costs incurred mainly for development activities and clinical trials. Research and development expenses decreased by approximately \$112 thousand from a total of \$290 thousand during 2023 to a total of \$178 thousand during 2024. This decrease is largely attributable to a decrease in storage costs of \$41 thousand and legal and professional services related to intellectual property of \$74 thousand.

General and Administrative Expense

General and administrative expense ("G&A") included only general and administrative expenses as the company currently has no sales or selling expenses. General and Administrative expenses were approximately \$751 thousand lower in 2024 relative to 2023 due to a \$437 thousand decrease in stock-based compensation expense from the 2023 stock option grants and a \$280 thousand decrease in contractor services, partially offset by an increase in franchise taxes of approximately \$11 thousand.

Interest Expense

Interest expense is primarily related to the notes payable and convertible notes payable used to fund the Company's operations in 2024 and 2023. Interest expense increased from approximately \$148 thousand in 2023 to approximately \$180 thousand during the nine months ended September 30, 2024. The increase in interest expenses was due to higher average outstanding debt in the first three quarters of 2024 compared to that of 2023.

Net Loss

Net Loss for nine months ended September 30, 2024 was approximately \$2.16 million, a decrease of approximately \$831 thousand from the approximately \$3.00 million incurred during the nine months ended September 30, 2023.

Liquidity and Capital Resources**Overview**

Our liquidity requirements are primarily to fund our business operations, including capital expenditures and working capital requirements. Our primary sources of liquidity are additional capital investment and debt.

The source, timing and availability of any future financing will depend principally upon market conditions, and, more specifically, on the progress of our clinical development program. Funding may not be available when needed, at all, or on terms acceptable to us. Lack of necessary funds may require us to, among other things, delay, scale back or eliminate expenses including some or all of our planned development, including our clinical trials. These factors, among others, raise substantial doubt about our ability to continue as a going concern.

Cash Flow Analysis

The Company had cash of approximately \$639 thousand at September 30, 2024 compared to \$44 thousand at September 30, 2023. The Company had cash of approximately \$50 thousand at December 31, 2023 compared to approximately \$39 thousand at December 31, 2022.

Cash Used in Operating Activities

Cash used in operating activities during the nine months ended September 30, 2024, was approximately \$111 thousand. Operating activities for the period ended consisted primarily of the net loss of approximately \$2.16 million, stock-based compensation of approximately \$1.11 million, an increase of accounts payable and accrued expenses of approximately \$115 thousand, an increase in deferred offering costs of \$24 thousand, and an increase in deferred revenue of \$667 thousand. Operating activities also included an increase in total accrued interest of \$180 thousand.

Cash used in operating activities during the nine months ended September 30, 2023, was approximately \$645 thousand. Operating activities for the period ended consisted primarily of the net loss of approximately \$3.00 million, stock-based compensation of approximately \$1.55 million, an increase of accounts payable and accrued expenses of approximately \$710 thousand, and an increase in deferred offering costs of \$59 thousand. Operating activities also included an increase in total accrued interest of \$147 thousand.

Cash used in operating activities during the year ended December 31, 2023, was approximately \$1,306 thousand. Operating activities for the year ended 2023 consisted primarily of the net loss of approximately \$3,780 thousand for the year ended, stock-based compensation of approximately \$1,923 thousand, an increase of accounts payable and accrued expenses of approximately \$562 thousand, and an increase in deferred offering costs of \$210 thousand. Operating activities also included an increase in total accrued interest of \$199 thousand.

Cash used in operating activities during the year ended December 31, 2022 was approximately \$1,551 thousand. Operating activities for the year ended 2022 consisted primarily of the net loss of approximately \$2,318 thousand for the year ended, an increase of accounts payable and accrued expenses of approximately \$1,222 thousand, and an increase in deferred offering costs of \$543 thousand. Operating activities also included a decrease in other current assets of \$1 thousand and an increase in total accrued interest of \$86 thousand.

Cash Flows from Financing Activities

Cash provided by financing activities during the nine months ended September 30, 2024 was \$700 thousand. This consisted of proceeds from issuance of common stock to a related party of approximately \$500 thousand and proceeds from convertible notes payable – related parties of approximately \$200 thousand.

Cash provided by financing activities during the nine months ended September 30, 2023 was \$650 thousand. This consisted of proceeds from issuance of common stock to a related party of approximately \$400 thousand and proceeds from notes payable – related party of \$250 thousand.

Cash provided by financing activities during the year ended December 31, 2023 was \$1,316 thousand. This consisted of proceeds from notes payable – related party of \$450 thousand, and proceeds from issuance of common stock – related party of approximately \$866 thousand.

Cash provided by financing activities during the year ended December 31, 2022 was \$1,550 thousand. This consisted of proceeds from notes payable – related party of \$1,000 thousand, proceeds from convertible notes payable of \$50 thousand, and proceeds from long term convertible notes payable – related party of \$500 thousand.

Certain Significant Relationships

Brigham and Women's Hospital

The initial discovery and development of our PNAG therapeutic platform came out of Dr. Gerald Pier's laboratory at Brigham and Women's Hospital and Harvard Medical School. Alopexx has a licensing agreement with Brigham and Women's Hospital (BWH). Under this license, we received an exclusive, worldwide, royalty bearing license relating to development, utilization and commercialization of all therapeutics and diagnostics targeting PNAG. In consideration for the licenses granted under the agreement, we must pay BWH annual license fees prior to the first commercial sale of a licensed product that range in the mid-five-digit to low six-digit figures, and a low single digit royalty on net sales of licensed products beginning with the first commercial sale of a licensed product in any country during the term of the agreement. In the event we commercialize a product in the therapeutic space, we are also required to make certain drug-approval regulatory and commercialization milestone payments to BWH of up to a low seven-digit figure in the aggregate for licensed products. In the event we sublicense any of the licensed intellectual property, we must pay BWH a percentage of any sublicense income received by us, which on a going-forward basis will be in the low double digits. The aggregate milestone payments under the 2 patent license agreements are up to \$2,325,000 and \$1,850,000 for vaccine AV0328 and antibody F598 respectively for a total of \$4,175,000.

Components of Results of Operations

Operating Expenses

Research and Development

Research and development expenses represent costs incurred in performing research, development and manufacturing activities in support of our own product development efforts and include personnel-related costs (such as salaries, employee benefits and stock-based compensation) for our personnel in research and development functions; costs related to acquiring, developing and manufacturing supplies for preclinical studies, clinical trials and other studies, including fees paid to contract manufacturing organizations; costs and expenses related to agreements with contract research organizations, investigative sites and consultants to conduct non-clinical and preclinical studies and clinical trials; professional and consulting services costs; research and development consumables costs; laboratory supplies and equipment costs; and facility and other allocated costs.

Research and development expenses are expensed as incurred. Non-refundable advance payments for services that will be used or rendered for future research and development activities are recorded as prepaid expenses and recognized as expenses as the related services are performed.

We expect our research and development expenses to increase substantially in absolute dollars for the foreseeable future as we advance our candidates through clinical trials and pursue regulatory approval.

The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success may be affected by a variety of factors, including the safety and efficacy of our therapeutic candidates, early clinical data, investment in our clinical programs, competition, manufacturing capability and commercial viability. We may never succeed in achieving regulatory approval for any of our therapeutic candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or if, when and to what extent we will generate revenue from the commercialization and sale of our immune therapeutics.

Our clinical development costs may vary significantly based on factors such as:

- the costs and timing of our CMC activities, including fulfilling GMP-related standards and compliance;
- the cost of clinical trials being greater than we anticipate;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- delays in adding a sufficient number of trial sites and recruiting suitable patients to participate in our clinical trials;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- patients dropping out of a study;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing our vaccine and antibody;
- the phase of development of our vaccine and antibody; and
- the efficacy and safety profile of our vaccine and antibody.

Future Funding Requirements

Our primary uses of cash are to fund our operations, which consist primarily of research and development expenditures related to our programs and, to a lesser extent, general and administrative expenditures. We anticipate that we will continue to incur significant expenses for the foreseeable future as we continue to advance our therapeutic candidates, expand our corporate infrastructure, including the costs associated with being a public company, further our research and development initiatives for our vaccine, scale our laboratory and manufacturing operations, and incur marketing costs associated with potential commercialization. We are subject to all of the risks typically related to the development of new drug candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We anticipate that we will need substantial additional funding in connection with our continuing operations.

We believe that our existing cash and cash equivalents as of the date of this prospectus, together with the net proceeds from this offering, will fund our current operating plans through at least the next 12 months from the date of this offering. However, we will need to raise additional capital prior to commencing pivotal trials for our vaccine and antibody. Until we can generate a sufficient amount of revenue from the commercialization of our vaccine and antibody or from collaboration agreements with third parties, if ever, we expect to finance our future 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. The sale of equity or convertible debt securities may result in dilution to our stockholders, and, in the case of preferred equity securities or convertible debt, those securities could provide for rights, preferences or privileges senior to those of our common stock. Debt financings may subject us to covenant limitations or restrictions on our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Our ability to raise additional funds may be adversely impacted by deteriorating global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the COVID-19 pandemic. There can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable or acceptable to us. If we are unable to obtain adequate financing when needed or on terms favorable or acceptable to us, we may be forced to delay, reduce the scope of or eliminate one or more of our research and development programs.

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 and non-clinical
- studies and clinical trials;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform field efficacy studies for our vaccine, require more studies than those that we currently expect or change their requirements regarding the data required to support a marketing application;
- the cost of building a sales force in anticipation of any product commercialization;
- the costs of future commercialization activities, including product manufacturing, marketing, sales, royalties and distribution, for any of our vaccine for which we receive marketing approval;
- 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 revenue, if any, received from commercial sales, or sales to foreign governments, of our vaccine for which we may receive marketing approval; and
- 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 our patents or other intellectual property rights.

A change in the outcome of any of these or other variables could significantly change the costs and timing associated with the development of our therapeutics. Furthermore, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such change.

Legal Contingencies

From time to time, we may become involved in legal proceedings arising from the ordinary course of business. We record a liability for such matters when it is probable that future losses will be incurred and that such losses can be reasonably estimated. Significant judgment by us is required to determine both probability and the estimated amount.

Off-Balance Sheet Arrangements

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Accrued Research and Development Expenses

We have entered into various agreements with contract manufacturing organizations, or CMOs, and may enter into contracts with clinical research organizations, or CROs, in the future. As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel and third parties to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. We make estimates of our accrued research and development expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments, if necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced.

We accrue for costs related to research and development activities based on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors, including CMOs, that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received. Services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received. We make significant judgments and estimates in determining accrued research and development liabilities as of each reporting period based on the estimated time period over which services will be performed and the level of effort to be expended. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Stock-Based Compensation Expense

Stock-based compensation expense represents the cost of the grant date fair value of equity awards recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis. We estimate the fair value of equity awards using the Black-Scholes option pricing model and recognize forfeitures as they occur. Estimating the fair value of equity awards as of the grant date using valuation models, such as the Black-Scholes option pricing model, is affected by assumptions regarding a number of variables, including:

- *Fair Value of Common Stock*—See the subsection entitled “—Common Stock Valuations” for more information.
- *Expected Term*—Expected term represents the period that our stock-based awards are expected to be outstanding. For employee options, the expected term is calculated using the simplified method where there is insufficient historical data about exercise patterns and post-vesting employment termination behavior. The simplified method is based on the vesting period and the contractual term for each grant, or for each vesting-tranche for awards with graded vesting. The mid-point between the vesting date and the maximum contractual expiration date is used as the expected term under this method. For awards with multiple vesting-tranches, the time from grant until the mid-points for each of the tranches may be averaged to provide an overall expected term. The expected term for options issued to nonemployees is the remaining contractual term.
- *Expected Volatility*—Expected volatility is estimated from the average historical volatilities of publicly traded companies within the life sciences industry that are considered to be comparable to our business over a period approximately equal to the expected term for employees’ options and the remaining contractual life for non-employees’ options. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.
- *Expected Dividend*—We have not paid and do not anticipate paying any dividends in the near future. Accordingly, we have estimated the dividend yield to be zero.
- *Risk-Free Interest Rate*—The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero-coupon notes with remaining terms corresponding with the expected term of the option.

Changes in the assumptions can materially affect the fair value and ultimately how much stock-based compensation expense is recognized. These inputs are subjective and generally require significant analysis and judgment to develop.

Common Stock Valuations

We are required to estimate the fair value of the common stock underlying our equity awards when performing fair value calculations. The fair value of the common stock underlying our equity awards will be approved on each grant date by our board of directors. The fair value of our common stock will be determined by management, considering input from independent third-party valuation analyses. All options to purchase shares of our common stock are intended to be granted with an exercise price per share no less than the fair value per share of our common stock underlying those options on the date of grant, based on the information known to us on the date of grant. In the absence of a public trading market for our common stock, on each grant date we develop an estimate of the fair value of our common stock in order to determine an exercise price for the option grants. Our determinations of the fair value of our common stock were made using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants Accounting and Valuation Guide: Valuation of Privately Held Company Equity Securities Issued as Compensation, or the Practice Aid. Because our common stock shares are not publicly traded, estimating their fair values can be highly complex and subjective.

Management will consider various objective and subjective factors to determine the fair value of our common stock, including:

- valuations of our common stock performed with the assistance of independent third-party valuation specialists;
- our stage of development and business strategy, including the status of research and development efforts of our vaccine, and the material risks related to our business and industry;
- our results of operations and financial position, including our levels of available capital resources;
- the valuation of publicly traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of peer companies;
- the lack of marketability of our common stock;

- the likelihood of achieving a liquidity event for the holders of our common stock, such as an initial public offering or a sale of our company, given prevailing market conditions;
- trends and developments in our industry; and
- external market conditions affecting the life sciences and biotechnology industry sectors.

The Practice Aid prescribes several valuation approaches for setting the value of an enterprise, such as the cost, income and market approaches, and various methodologies for allocating the value of an enterprise to its common stock. The cost approach establishes the value of an enterprise based on the cost of reproducing or replacing the property less depreciation and functional or economic obsolescence, if present. The income approach establishes the value of an enterprise based on the present value of future cash flows that are reasonably reflective of our future operations, discounting to the present value with an appropriate risk adjusted discount rate or capitalization rate. The market approach is based on the assumption that the value of an asset is equal to the value of a substitute asset with the same characteristics.

Following the completion of this offering, the fair value of our common stock will be based on the closing quoted market price of our common stock as reported on the date of grant on the primary stock exchange on which our common stock is traded. Estimating the fair value of our common stock will not be necessary to determine the fair values of new awards once the underlying shares begin trading.

Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Our cash and cash equivalents as of September 30, 2024 of approximately \$639 thousand consisted of readily available checking and money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial condition or results of operations. We believe that our exposure to interest rate risks is not significant and that a hypothetical 10% movement in market interest rates would not have a significant impact on the total value of our portfolio or our interest income. In addition, we do not believe that our cash and cash equivalents have significant risk of default or illiquidity.

Foreign Currency Risk

We may be exposed to market risk related to changes in foreign currency exchange rates, mainly relating to our contract with Lonza, our CMO in the UK. We have also entered into a limited number of contracts with other parties with payments denominated in foreign currencies. Payments under these contracts are made in foreign currencies and are subject to fluctuations in foreign currency rates. We do not currently have a formal program in place to hedge foreign currency risks. To date, foreign currency transaction gains and losses have not been material to our financial statements. A 10% increase or decrease in current exchange rates would not have a material effect on our financial results. As our foreign currency risk increases in the future, we will evaluate alternative strategies, including hedging, to mitigate our foreign currency exposure.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and research and development contract costs. We do not believe inflation had a material effect on our results of operations during the periods presented.

Emerging Growth Company Status

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay the adoption of new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for emerging growth companies include presentation of only two years of audited financial statements in a registration statement for an initial public offering, an exemption from the requirement to provide an auditor's report on internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, as amended, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation and less extensive disclosure about our executive compensation arrangements. 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 (i) we are no longer an emerging growth company or (ii) we affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. However as described in Note 3 to our financial statements included elsewhere in this prospectus, we early adopted certain accounting standards, as the JOBS Act does not preclude an emerging growth company from adopting a new or revised accounting standard earlier than the time that such standard applies to private companies to the extent early adoption is permitted. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

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 SEC, which means the market value of equity securities that is held by non-affiliates exceeds \$700.0 million as of the prior September 30th 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.

Recently Adopted Accounting Pronouncements

See Note 2 to our financial statements included elsewhere in this prospectus for more information.

Internal Control Over Financial Reporting

The process of improving our internal controls has required and will continue to require us to expend significant resources to design, implement and maintain a system of internal controls that is adequate to satisfy our reporting obligations as a public company. There can be no assurance that any actions we take will be completely successful. We will continue to evaluate the effectiveness of our disclosure controls and procedures and internal control over financial reporting on an ongoing basis.

We have not begun testing or documenting our internal control procedures in order to comply with the requirements of Section 404 of SOX. Section 404(a) requires annual management assessments of the effectiveness of our internal control over financial reporting and Section 404(b) requires a report by our independent auditors addressing these assessments. We must comply with Section 404(a) immediately and we must comply with Section 404(b) no later than the time we file our annual report for fiscal 2026 with the SEC, assuming we complete this offering in the current period. As part of this process, we may identify specific internal controls as being deficient. We anticipate retaining additional personnel to assist us in complying with our Section 404 obligations. We are currently evaluating whether such personnel will be retained as consultants or as our employees.

However, based on this evaluation, our principal executive officer and principal financial and accounting officer have concluded that during the period covered by this report, our disclosure controls and procedures were not effective due to a material weakness over timely review of financial reporting. To address material weakness, management has devoted, and plans to continue to devote, significant effort and resources to the remediation and improvement of its internal control over financial reporting and to provide processes and controls over the internal communications within the Company, financial advisors and independent registered public accounting firm.

BUSINESS

Overview

We are a clinical stage biotechnology company focusing on developing novel, broad-spectrum immune-mediated therapeutics for the prevention, treatment and mitigation of a wide range of bacterial, fungal and parasitic microbial infections. The target of our therapeutics, Poly *N*-acetyl glucosamine or PNAG, is a conserved molecule expressed on the surface of a wide range of non-viral microbes. The target of Alopexx's therapeutics was identified by Dr. Gerald Pier and his team at Harvard Medical School and Brigham and Women's Hospital.

Conventional immune-mediated therapeutics for infectious diseases are highly specific. Current approaches target a component or antigen that is unique to a subset of the microbial species causing an infection. The pneumococcal vaccine Prevnar 13 provides protection against only 13 of the 100+ known subsets or serotypes of the microbe that causes that infection. To broaden that coverage, the conventional approach has been to include additional serotype-specific components into newer vaccines, e.g., Prevnar-20.1 That approach is limited in that a multi-component serotype-specific vaccine cannot hope to contain the over 100 serotype-specific antigens to provide full protection. In addition, while current vaccines have reduced the incidence of the specific strains, infections caused by non-vaccine serotypes have increased, reducing the net effectiveness of the vaccine. This is a phenomenon known as serotype replacement.

There are other limitations associated with developing and utilizing a multi-component serotype-specific vaccine. Incorporation of additional serotypes into a single vaccine formulation has been noted to lower immune (or opsonic) titers elicited by Prevnar 20 compared to Prevnar 13. This was also observed in infants when the immune titers elicited by Prevnar 13 were compared to Prevnar 7. Adding to the challenge of developing new serotype-specific vaccines has been the recognition that serotype replacement is not occurring uniformly. A recent report noted that the efficacy of current serotype-specific vaccines has resulted in the rise of a diverse and less uniform number and distribution of serotypes that may not be as effectively addressed by newer serotype-specific vaccines. Taken as whole it points to the limitations and complexity of providing broad spectrum coverage by adding more serotype-specific components.

An alternative approach would be utilization of a single antigen that is common to most if not all pneumococcal and potentially many other microbial infections – a non-serotype specific vaccine. PNAG offers that promise. It is a surface polysaccharide produced by major bacterial and fungal species, and protozoan parasites. Over 75 microbes have been found to express PNAG, including anti-microbial resistant organisms. This suggests that PNAG could serve as a therapeutic target against many different microbes.

Alopexx has developed two immune therapeutics directed at PNAG – a monoclonal antibody and a vaccine. The potential efficacy of these immune therapeutics has been evaluated in studies of 14 pathogens in 20 animal models of infection. In all of those infection models a positive therapeutic effect was observed in preventing or treating infections. Whether the efficacy noted in animal models will be observed in humans remains to be determined. While the ultimate decision on the safety and efficacy of our therapeutics will be determined by the FDA and other health authorities, it is our management's assessment that the broad-spectrum potential of our therapeutics will allow them to be used for the prevention, treatment, and mitigation of a wide range of infections. Both therapeutics are now in human clinical trials in which, in our management's assessment, they have been found to be well-tolerated. Our therapeutics are:

- **Vaccine AV0328** - a synthetic PNAG vaccine. A phase 1, first-in-man trial has been completed and the vaccine was found to be well tolerated, and no serious adverse events were observed. It induced antibodies that were capable of killing a wide range of PNAG-expressing pathogens. In vitro efficacy in killing was noted against every pathogen tested which included over 10 different microbial species. Based on those results, Alopexx proposed to the FDA that AV0328 be developed as a complement to currently approved *Streptococcus pneumoniae* vaccines (Prevnar, Pneumovax and Vaxneuvance). Those vaccines, including the recently approved versions, cover at best 23 of the 100 known *Streptococcus pneumoniae* serotypes. AV0328 could provide protection against many of the remaining 80+ serotypes. Feedback from the FDA supported pursuing accelerated approval of AV0328 based on safety in vaccinated humans and utilization of a validated surrogate assay – opsonic killing mediated by the antibodies induced by the vaccine. The FDA's Accelerated Approval Program allows for earlier approval of drugs that treat serious conditions based on a surrogate endpoint. A surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. Management believes that this points to a development path comparable to those that have led to FDA approval of other vaccines for *Streptococcus pneumoniae* infections. However, the FDA has not yet approved the vaccine and there is no guarantee that the FDA will ultimately approve the vaccine.
- **Monoclonal antibody F598** - Phase 1 and pilot phase 2 trials of F598 have been completed. The antibody was found to be well tolerated, and no serious adverse events were observed. A single infusion was noted to provide sustained serum levels for 2-3 months. Unlike vaccines which may take several weeks or longer to induce protective immunity, administration of a monoclonal antibody provides immediate protection. Therefore, the antibody will be utilized in settings where an individual is at an immediate or near-term risk of developing an infection. Hospital-associated infections are one of the major settings where this occurs. Monoclonal antibody F598 will not replace antibiotics but will instead complement and augment their efficacy and by doing so reduce the development of antibiotic resistant organisms. Use of monoclonal antibody F598 in that setting offers the potential for it to become the first broad-spectrum therapeutic antibody. We will study this in a setting where the prevalence of acquired infections is very high – intensive care units. Demonstrating that monoclonal antibody F598 can reduce the morbidity/mortality related to microbial infections in ICU patients would constitute a major health advancement. We believe it would establish administration of F598 as part of the standard of care in that setting.

The Problem

Infections caused by bacteria, fungi and parasites continue to be a major cause of death and disability worldwide. The Global Burden of Diseases, Injuries, and Risk Factors Study (GBD) found that pneumonia or bronchiolitis are leading causes of mortality and morbidity worldwide. Nearly 2.38 million deaths resulted from lower respiratory infections in 2016, making these infections the sixth leading cause of mortality for all ages and the leading cause of death among children younger than 5 years. *Streptococcus pneumoniae*, an initial focus of the Company, is the leading cause of pneumonia mortality globally. The World Health Organization (WHO) estimates that *Streptococcus pneumoniae* kills close to half a million children under 5 years old worldwide every year with most of these deaths occurring in developing countries.

The discovery of antibiotics had a major impact on human and animal health. As has been widely reported in the public media (such as ABC News), antibiotics, along with vaccines, are widely considered to be among the greatest health advances in human history. Following their introduction in the 1940's over 100 antibiotics have been approved and the world witnessed a decrease in many bacterial infections - so much so that a belief commonly held by many senior scientists, was that antibiotics could effectively control every important infectious disease. Others were less optimistic, including the discoverer of penicillin, Alexander Fleming, who in 1945 predicted the development of resistant organisms. Unfortunately, Fleming's fears have been borne out and less than a century since their introduction the benefits of antibiotics are facing a crisis. The overuse of antibiotics in healthcare and agriculture (over 22 million pounds are used in the United States alone), as well as inappropriate waste management and environmental transmission, have led to substantially increased antimicrobial resistance according to the New England Journal of Medicine. Bacteria have a rapid doubling time (approximately 20 - 30 minutes) and it is estimated by the CDC that resistance to a specific antibiotic takes an average of 1 year to emerge after it becomes commercially available. The risk of anti-microbial resistance by bacteria has been prominently featured in the lay press as well such as Time Magazine and the Economist.

In the United States in 2015 it was estimated that more than 2 million people suffered from anti-microbial resistant (AMR) infections and about 23,000 died as a direct result of these infections. In the European Union, taking data from 2007, it has been estimated that AMR infections cause about 25,000 deaths annually and generate an overall cost of about €1500 million per year. In the United States the CDC estimates that U.S. costs of AMR are \$55 billion per year, of which \$20 billion is attributed to healthcare and \$35 billion is attributed to loss of productivity. More broadly, a report commissioned by the UK Government and the Wellcome Trust estimated that by 2050 the cumulative cost to global economic output could be \$100 trillion. The global death toll from AMR infections, estimated to be at least 700,000 annually, is expected to reach into the millions by 2050. In 2022, the first detailed analysis estimating the worldwide burden of AMR in 204 countries and territories was reported in The Lancet. That analysis found a far higher incidence of AMR-related deaths than had been previously reported. The analysis found an estimated 4.95 million deaths associated with bacterial AMR in 2019, including 1.27 million deaths attributable to bacterial AMR. Compared with all underlying causes of death, they found that AMR was the third leading cause of death after ischemic heart disease and stroke.

The Solution

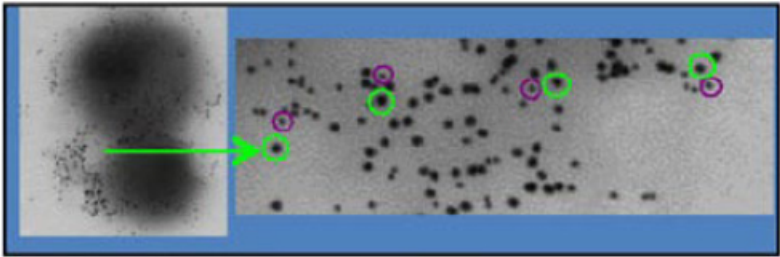
Given the rise in AMR infections there is an urgent need to develop anti-microbial therapeutics that will not lead to selection for resistance. We have developed two immune therapeutics capable of preventing and treating microbial infections without the use of antibiotics, including AMR organisms. Alopexx has developed a vaccine and monoclonal antibody capable of targeting a wide range of microbial infections. Unlike antibiotics, immune therapeutics are not associated with the development of resistance as they make use of the host's innate immune system to clear the microbes, without putting pressure on the pathogen to survive in a hostile environment. Antibodies remain within the host and are therefore not like antibiotics excreted into the environment at low levels that promote the development of antimicrobial resistance.

PNAG - a unique broad spectrum anti-microbial target

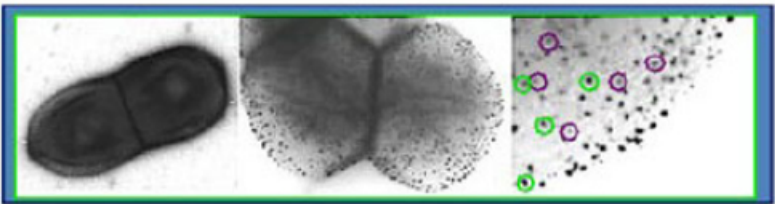
The products comprising Alopexx's therapeutics were developed by Dr. Gerald Pier and his team at Harvard Medical School and Brigham and Women's Hospital. PNAG has been identified by a large number of independent investigators as a conserved surface polysaccharide produced by major bacterial and fungal species, and protozoan parasites. For bacterial pathogens, surface capsules, often composed of highly varied carbohydrate polymers, have been used successfully to vaccinate humans against *Streptococcus pneumoniae*, *Hemophilus influenzae* type b, *Neisseria meningitidis* and *Salmonella enterica* serovar Typhi. However, efficacy is limited to the capsule types included in vaccines or targeted by monoclonal antibodies. Over the past several years the occurrence of the β -1 $\rightarrow$ 6-linked PNAG polysaccharide has been discovered to be a component of the bacterial surfaces of many bacterial, fungal and other eukaryotic pathogens. The synthesis of PNAG by all of these pathogens suggests an important role for this molecule in microbial biology.

PNAG co-localizes on the microbial surface with other capsular antigens that have been shown to be effective vaccine targets. As shown in the photomicrographs below, PNAG is spatially located in the same area as *N. meningitidis* capsular antigens serogroup A and *S. pneumoniae* serogroup 19A.

Co-localization with Capsular Antigens



N. Meningitidis serogroup A
Anti-PNAG + Anti- Serogroup A



S. pneumoniae serogroup 19A
Anti-PNAG + Anti- Serogroup 19A



N. meningitidis serogroup A and *S. pneumoniae* serotype 19 cells were reacted with either mouse IgG antibody specific to the respective capsule or human monoclonal antibody to PNAG and then further reacted with anti-mouse IgG conjugated to 10 nm gold particles or anti-human IgG conjugated to 15 nm gold particles. Electron microscopy was used to detect the antibody-labeled antigens.

PNAG has been shown in many cases to be a critical factor for pathogen survival and virulence. This suggests that it could serve as a therapeutic target against many different microbes. As summarized in the table below, positive detection of expression of PNAG has been obtained with over 75 distinct species of microbes, encompassing Gram-positive and Gram-negative bacteria, spirochetes such as those causing Lyme disease, fungi, protozoan parasites such as those causing trichomonas, malaria, leishmaniasis and toxoplasmosis and filarial worms that cause heartworm in dogs and filariasis in humans.

Among strains within species tested for PNAG expression, we detected the antigen among 100% of 50 strains of *Staphylococcus aureus*, 100% of 12 strains of *Neisseria* spp. including representatives of all capsular serotypes of *N. meningitidis*, 100% of 36 strains of *Streptococcus pneumoniae*, and 100% of 38 strains of different species of antibiotic-resistant Gram-negative bacteria. Only among a minority of isolates of *E. coli* have we found some strains not expressing PNAG (5 of 30 negative) and expression of PNAG by clinical isolates of *Staphylococcus epidermidis*, a cause of device-related infection, has been reported by multiple groups to range from 30%-60%. Among common causes of infection that we have tested, only *Pseudomonas aeruginosa* and *Proteus mirabilis* did not express PNAG. Overall, close to 250 distinct microbial strains have been analyzed for PNAG expression with >90% positive for antigen production.

- | | | |
|---|---|--|
| <ul style="list-style-type: none">● <i>Staphylococcus aureus</i> including MRSA● <i>Staphylococcus epidermidis</i> and other coagulase-negative staphylococci● <i>Escherichia coli</i> including 0157 and other Shiga-toxin producers● <i>Ammonifex degensii</i>● <i>Bordetella pertussis</i> | <ul style="list-style-type: none">● <i>Coxiella burnettii</i>● <i>Cutibacterium (Propionobacterium) acnes</i>● <i>Dirofilaria immitis</i>● <i>Ehrlichia canis</i>● <i>Ehrlichia chaffeensis</i>● <i>Francisella tularensis</i> | <ul style="list-style-type: none">● <i>Streptococcus pneumoniae</i>● <i>Vibrio cholerae</i>● <i>Fusobacterium nucleatum</i>● <i>Helicobacter pylori</i>● <i>Hemophilus ducreyi</i>● <i>Hemophilus influenzae</i>● <i>Hemophilus parvus</i> |
|---|---|--|

● <i>Bordetella parapertussis</i> ● <i>Bordetella bronchiseptica</i> ● <i>Burkholderia cenocepacia</i> ● <i>Enterobacter</i> spp. ● <i>Enterococcus faecalis</i> ● <i>Klebsiella</i> spp. ● <i>Shigella</i> spp. ● <i>Staphylococcus pseudintermedius</i> ● <i>Stenotrophomonas maltophilia</i> ● <i>Babesia bovis</i> ● <i>Bacteroides fragilis</i> ● <i>Borrelia burgdorferi</i> ● <i>Brucella abortus</i> ● <i>Brucella melitensis</i> ● <i>Brugia malayi</i> ● <i>Burkholderia mallei</i> ● <i>Burkholderia pseudomallei</i> ● <i>Clostridium difficile</i> ● <i>Campylobacter jejuni</i> ● <i>Chlamydia trachomatis</i>	● <i>Fungal pathogens</i> ● <i>Candida albicans</i> ● <i>Cryptococcus neoformans</i> ● <i>Cryptococcus gattii</i> ● <i>Aspergillus fumigatus</i> ● <i>Aspergillus flavus</i> ● <i>Fusarium solani</i> ● <i>Yersinia pestis</i> ● <i>Aggregatibacter actinomycetemcomitans</i> ● <i>Actinobacillus pleuropneumoniae</i> ● <i>Acinetobacter baumannii</i> ● <i>Vibrio parahaemolyticus</i> ● <i>Bacillus subtilis</i> ● <i>Streptomyces coelicolor</i> ● <i>Yersinia enterocolitica</i> ● <i>Yersinia pseudotuberculosis</i> ● <i>Salmonella enterica</i> serovar Typhi ● <i>Salmonella enterica</i> (multiple serovars) ● <i>Streptococcus pyogenes</i> Group A streptococci ● <i>Streptococcus agalactiae</i> (Group B streptococcus)	● <i>Leptospira interrogans</i> ● <i>Listeria monocytogenes</i> ● <i>Mannheimia haemolytica</i> ● <i>Mycobacterium avium</i> and other NTB ● <i>Mycobacterium tuberculosis</i> ● <i>Neisseria gonorrhoeae</i> ● <i>Neisseria meningitidis</i> ● <i>Plasmodium species</i> ● <i>Rhodococcus equi</i> ● <i>Streptococcus equi</i> ● <i>Streptococcus pyogenes</i> ● <i>Streptococcus suis</i> ● <i>Streptococcus uberis</i> ● <i>Theileria equi</i> ● <i>Toxoplasma cruzi</i> ● <i>Trypanosoma cruzi</i> ● <i>Trichomonas vaginalis</i> ● <i>Tritrichomonas foetus</i>
---	--	---

PNAG Has a Critical Role in Bacterial Virulence

Beyond its wide distribution, another key component of PNAG as a target antigen is its critical role in bacterial virulence. Studies in Dr. Pier's laboratory have shown that laboratory-created mutant variants of *S. aureus* that cannot produce PNAG have a significantly reduced ability to cause infections in mice. Laboratory studies with other bacterial species have similarly shown that loss of PNAG production decreases a given microbe's virulence. The broad expression of PNAG among such a diverse range of microbes strongly implicates PNAG as critical factor for basic microbial biology and thus the existence of strong selective pressures to maintain PNAG as an essential component of microbial cell survival.

PNAG is not expressed in mammalian tissues

PNAG has not, to date, been described to occur in mammalian species. Therefore, immune targeting of PNAG is not expected to cross react with human tissue or organs. Immunohistochemistry studies of the binding of monoclonal antibody F598 to human and non-human primate tissues, were performed using frozen normal human and cynomolgus monkey tissue specimens to identify any cross-reactivity with normal tissue and therefore evaluate whether any potential off-target binding might occur. In a panel of 32 cynomolgus and 33 human normal tissues from three separate donors, there was no F598-specific reactivity detected, indicating that F598 has little to no potential for off-target binding. This is supported by clinical studies of monoclonal antibody F598 in humans and vaccine AV0328 in multiple animal species and humans where no significant adverse effects were noted.

Natural antibody to PNAG is common but does not provide immune protection

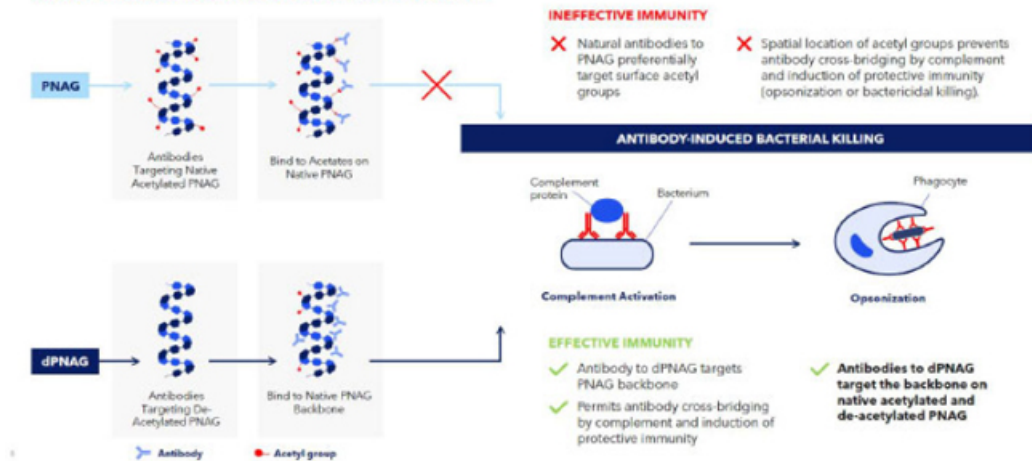
Natural antibody to PNAG is common in humans and many animal species but these antibodies do not routinely have robust opsonic killing or immune protection against PNAG-producing microbes. Those natural antibodies are unable to fully engage the host innate serum complement co-factor system which is needed for optimal protective immunity. Thus, broad-based immunity to this antigen rarely develops naturally in human or animal populations. Microbial colonization or infection does not usually induce effective antibody responses to PNAG. As detailed below, a key advance in the development of Alopexx's immune therapeutics has been the recognition of the role acetylation plays in preventing the induction of protective immunity.

The Role of Acetylation of PNAG in Immune Evasion and Antibody Responses

Alopexx's major proprietary advance was the recognition that this ineffective natural immunity was due to the high degree of acetylation of the native PNAG molecule. As illustrated in the figure below, natural PNAG has many acetyl groups on its surface. Those surface acetyl groups are responsible for inducing a natural but ineffective immune response. The acetyl groups can be removed by chemically altering PNAG. This results in a strong protective immunogen that now targets the backbone of PNAG and avoids participation from the acetyl groups. As illustrated in the lower figure, targeting the backbone of PNAG leads to the induction of antibody-mediated bacterial killing. Alopexx's vaccine and antibody target the backbone on native PNAG and provide an effective immune response.

Targeting dPNAG

IMPACT OF DE-ACETYLATION AND MECHANISM OF ACTION



Investigations have shown that the functional antibodies that target the PNAG backbone are able to bind to the native, acetylated molecule. Antibodies raised to deacetylated PNAG (which we will collectively refer to as dPNAG) and the fully human immunoglobulin G1 monoclonal antibody that binds to both native and poorly acetylated glycoforms of PNAG, mediate complement-dependent opsonic and microbial killing. They have been found to protect against local and/or systemic infections by a wide array of bacterial and fungal agents.

In Vivo Efficacy Studies targeting dPNAG

A summary of the protective immunity targeting PNAG in 20 different animal models is shown in the table below. These data suggest that a dPNAG vaccine or monoclonal antibody could be used to protect against a broad range of pathogens that produce surface PNAG.

In Vivo Efficacy Studies

Pathogen	Infection Model	Animal
<i>S. aureus</i>	• Lethal peritonitis • Bacteremia • Skin infection • Corneal Keratitis • Lethal systemic infection	Mouse
<i>E. coli</i>	• Lethal peritonitis • Oral infection with Shiga-toxin producing strains	
<i>Burkholderia</i>	• Lethal peritonitis	
<i>A. baumannii</i>	• Bacteremia • Pneumonia	
<i>N. meningitidis</i> serogroup B	• Neonatal infection	
<i>N. gonorrhoeae</i>	• Conjunctivitis	
<i>S. pyogenes</i>	• Lethal infections	
<i>L. monocytogenes</i>	• Lethal infections	
<i>S. pneumoniae</i>	• Pneumonia • Corneal infections	
<i>K. pneumoniae</i>	• Pneumonia	
<i>C. albicans</i>	• Keratitis	
<i>P. berghei</i>	• Malaria	
<i>R. equi</i>	• Pneumonia	Horse
<i>S. aureus</i>	• Mastitis • Lethal infection	Sheep
<i>A. pleuropneumoniae</i>	• Pneumonia	Pig

Therapeutic Potential and Initial Indications

As summarized in the table below, the broad distribution of PNAG allows for an expansive range of targets and indications to be pursued. These immune therapeutics will be effective whether or not the microbe is resistant to antibiotics. A key aspect of the company's plan is to initially focus on areas we believe have an increased potential for regulatory approval. Success there would justify and support pursuit of several other indications.

As is detailed in the sections that follow, we plan to initially focus on two indications - prevention of infections caused by *S. pneumoniae* for vaccine AV0328 and ICU infections for monoclonal antibody F598. However, the data generated in pre-clinical studies and the completed phase 1 and 2 trials supports pursuit of other indications as well. That is reflected in the developmental pipeline figure where the status of other indications is illustrated. The rationale for those additional indications is briefly mentioned below.

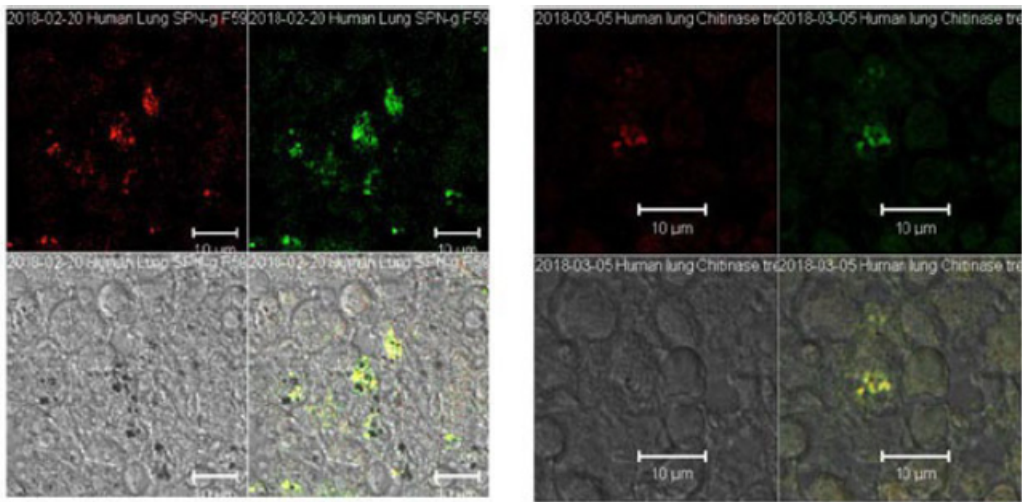
Of note, there is growing evidence to suggest that PNAG-positive microbes may be critical factors in a wide range of diseases not usually associated with infections. Ineffective removal of PNAG-expressing microbes or their fragments can contribute to the development of diabetes, Alzheimer's disease and other chronic debilitating conditions. There are an increasing number of conditions where an infection has been identified as the initial trigger for inflammation and associated tissue destruction. While not the initial focus of the Company, these are areas that have great future potential.

	Setting	Relevant Diseases/Rationale
Infectious Diseases	Expansion of existing vaccines	• Pneumococcal pneumonia • Meningitis
	Antibiotic resistant organisms	World Health Organization identified threat organisms • 12 families of bacteria that pose the greatest threat to human health Antibody could be combined with antibiotics to treat these resistant infections
	Prevention in high-risk populations	Use of the monoclonal antibody could reduce development of infections in multiple high-risk settings • ICU patients • Emergency abdominal surgery • Neonatal infections • Burn patients • Trauma patients
	Sexually Transmitted Diseases	• Gonorrhea • Chlamydia
	Chronic and Difficult to treat Infections	• Chronic Lyme disease • Recurrent urinary tract infections • Eye infections • Prosthetic joint infections
Diseases where alterations in the microbiome or prior infection have been implicated	• Alzheimer's Disease • Graft vs Host Disease • Traumatic brain injury • Diabetes • Cancer	Strong preliminary data has implicated PNAG-positive microbes in the development of a wide range of chronic diseases, associated with inflammation and tissue injury. Many tumors harbor PNAG-positive microbes making microbial antigens potential anti-tumor antigens

PNAG Expression and S. pneumoniae

PNAG expression has been evaluated in 36 *S. pneumoniae* serotypes. One-hundred percent of serotypes evaluated have been found to express PNAG. This includes serotypes contained in PREVNAR13 (PCV13), PREVNAR20 (PCV20) and PNEUMOVAX23 (PPSV23). Consistent with our results with other pathogens, we expect that the majority of remaining pneumococcal serotypes will be positive as well. We have further sought to confirm the relevance of PNAG expression by examining tissues from patients infected with *S. pneumoniae*. As can be seen in the photomicrographs below, confocal microscopy of a lung section from one patient with a positive *S. pneumoniae* lung culture demonstrated PNAG expression during this human infection (shown in green). Staining with an anti-*S. pneumoniae* antibody (shown in red) confirmed that PNAG was located on the bacteria. This demonstrates that PNAG expression occurs in infected human lung tissue and points to its likely relevance as a therapeutic target in pneumococcal pneumonia.

Demonstration of PNAG Expression on *S.pneumoniae* Infected Human Lung Tissue



Confocal microscopy of human lung sections from two patients with a positive *S. pneumoniae* lung culture to assess PNAG expression *in vivo*. Formalin fixed, paraffin-embedded tissue sections were deparaffinized. Samples were incubated with either 5.2 ug/ml of F598 (antibody to PNAG) conjugated to Alexa Fluor 568 (red) or anti-*S. pneumoniae* conjugated to FITC (green) for 4 hours at room temp in 0.5% BSA/PBS pH 7.4. Samples were washed and mounted for confocal microscopic analysis. A higher magnification is shown in the right photomicrograph demonstrating binding to individual *S. pneumoniae* diplococci.

Upper left	Anti PNAG monoclonal antibody (Red)
Upper right	<i>S. pneumoniae</i> specific antibody (Green)
Lower left	Phase contrast
Lower right	Composite of red & green channels showing co-localization (yellow)

Preclinical Proof of Concept Studies

Several preclinical models, summarized below, have been used to demonstrate proof of concept for protection induced by vaccine AV0328 and monoclonal antibody F598:

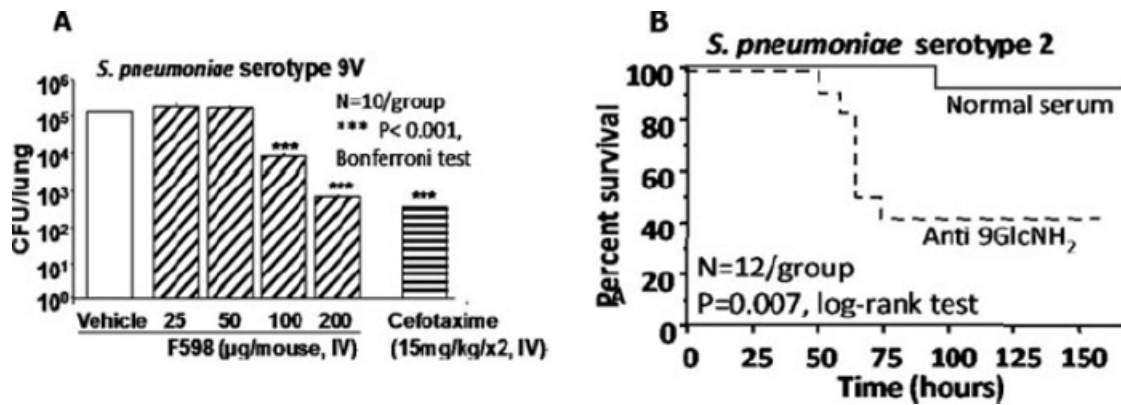
- Rabbits vaccinated with AV0328 and assayed for *in vitro* opsonizing antibodies
- Monoclonal antibodies administered to mice who were subsequently challenged with *S. pneumoniae*
- Pigs vaccinated and challenged with a species-relevant pulmonary pathogen *Actinobacillus pleuropneumoniae*
- Maternal transfer of immunity by horses vaccinated with AV0328 to foals challenged with a species-relevant pulmonary pathogen *Rhodococcus equi*.

The data from these diverse models, including infections leading to serious lung disease, consistently show high-level protection by antibody to PNAG, and are highly supportive of the likely efficacy of vaccine AV0328 in preventing pneumococcal disease in humans.

Protection Against *S. pneumoniae*-Induced Pneumonia

In a *S. pneumoniae* lung infection model, the monoclonal antibody to PNAG, F598, was administrated intravenously to mice 4 hours before bacterial challenge and reduced the recovered bacterial levels in a dose-dependent manner. As illustrated below, protection was observed starting from 25 µg/mouse (~0.8 mg/kg) with a maximum effect at 200 µg/mouse (~7 mg/kg). At 200 µg/mouse, the effect of F598 on bacterial load reduction was comparable to curative treatment with 30 mg/kg of a standard antibiotic, cefotaxime, administered following the bacterial infection.

Protection Against *S. pneumoniae*-Induced Lung Infection by Anti-PNAG Monoclonal Antibody F598



A: Colony-forming units of *S. pneumoniae* serotype 9V recovered 24 hours after infection of mice treated with either vehicle (PBS), varying doses of monoclonal antibody F598 to PNAG, or cefotaxime. Overall ANOVA P value<0.001.

B: Survival of CBA/N mice infected intranasally with *S. pneumoniae* serotype 2 following injection of 0.2 ml of either non-immune or PNAG-immune antisera raised in rabbits immunized with the 9GlcNH₂-TT vaccine.

Note: The p-values cited here refer to statistical significance for this pre-clinical study. p-values are widely used in both the social and natural sciences to quantify the statistical significance of observed results. A small number as is reported here is an indication that the observed results did not occur by random chance. These p-values refer to the results of this experiment alone. A separate statistical analysis plan will need to be developed and approved by the FDA for the clinical studies that will be used to support regulatory approval.

Rhodococcus equi Infection in Horses

R. equi is a Gram-positive coccobacillus that is an important cause of pneumonia in foals. The organism is commonly found in dry and dusty soil and is also a causative agent of infection in other domesticated animals. The frequency of foal infection can reach near 60% on some breeding farms. It is an intracellular parasite that mimics human disease caused by *Mycobacterium tuberculosis* (TB). Its close association with TB suggests that it may be a good model for that disease.

Alopxx is collaborating with Dr. Noah Cohen, Professor of Veterinary Medicine in the Department of Large Animal Clinical Sciences at Texas A&M to study the vaccine's efficacy in protecting foals from an intra-bronchial challenge with *R. equi*. As foals are primarily susceptible to infection early in life, pregnant mares were immunized 3 and 6 weeks prior to parturition with AV0328 (the same vaccine used in human trials) plus 10% Specol adjuvant. This resulted in the transfer of maternal antibodies to the foal via the colostrum (horses do not have transplacental transfer of maternal antibody – transfer is via colostrum during the first 48 hours of life).

Two studies were performed during the annual foaling seasons in 2015 and 2016. Combining the results, 11/12 or 92% of immune foals remained healthy and did not develop any signs of pneumonia due to *R. equi* infection, whereas 6 of 7 non-immune foals became infected and developed signs of severe pneumonia requiring treatment with azithromycin (P = 0.0017; Fisher's exact test; Protected fraction=84% (95% C.I. 42% to 97%, Koopman asymptotic score analysis).

An additional study was conducted in 2017 wherein horse foals were transfused on day 1 of life with 2 liters of either a normal horse plasma or anti-PNAG hyperimmune plasma, prepared from adult horse sera via immunization with the 5GlcNH₂-TT vaccine AV0328. Transfusion was followed by an intrabronchial challenge on day 28 with live *R. equi*. 100% protection was seen in 5 foals receiving the PNAG-hyperimmune plasma, whereas all 4 foals receiving normal horse plasma were clinically diagnosed with *R. equi* pneumonia.

In total, 16 of 17 horse foals receiving antibodies to PNAG by either passive colostral transfer or hyperimmune plasma infusion were protected against *R. equi* pneumonia following challenge, whereas 10 of 11 controls became ill (P<0.0001, Fisher's exact test, protected fraction 90%, (95% C.I. 59%-98%, Koopman asymptotic score).

Our Other Programs

Prevention of meningococcal infections

Meningococcal disease is caused by the bacterium *Neisseria meningitidis*. According to the Centers for Disease Control and Prevention (CDC), 1,000 to 2,600 people contract meningococcal disease each year in the United States. According to the CDC, one in 10 of these cases results in death and may also cause serious health problems in 11 to 19 percent of survivors such as loss of limbs, deafness, nervous system problems, mental retardation, seizures and strokes. While rare it is highly contagious. The majority of U.S. states have mandated immunization for populations at risk - infants, people with certain medical conditions, college freshmen living in dorms, and teenagers, according to the NCSL. Because of the rarity and severity of the disease approval of meningococcal vaccines are based on serologic assays – the serum bactericidal assay (SBA). Six serogroups account for most disease cases worldwide. As shown in the table below, while there are several vaccines approved in the United States none covers all six serogroups. Serologic results from the clinical phase 1 study (See “*Summary of In Vitro Activity*” on page 105) have shown vaccination with AV0328 to induce bactericidal killing as measured by SBA of all six serogroups and could either complement or replace current vaccines.

Vaccine	Company	Serogroup					
		A	B	C	W135	X	Y
Menactra	Sanofi	X		X	X		X
Menomune	Sanofi	X		X	X		X
Menveo	GSK	X		X	X		X
Bexsero	GSK		X				
Trumenba	Pfizer		X				
AV0328	Alopecx	X	X	X	X	X	X

Prevention of Infections following Emergency Abdominal Surgery

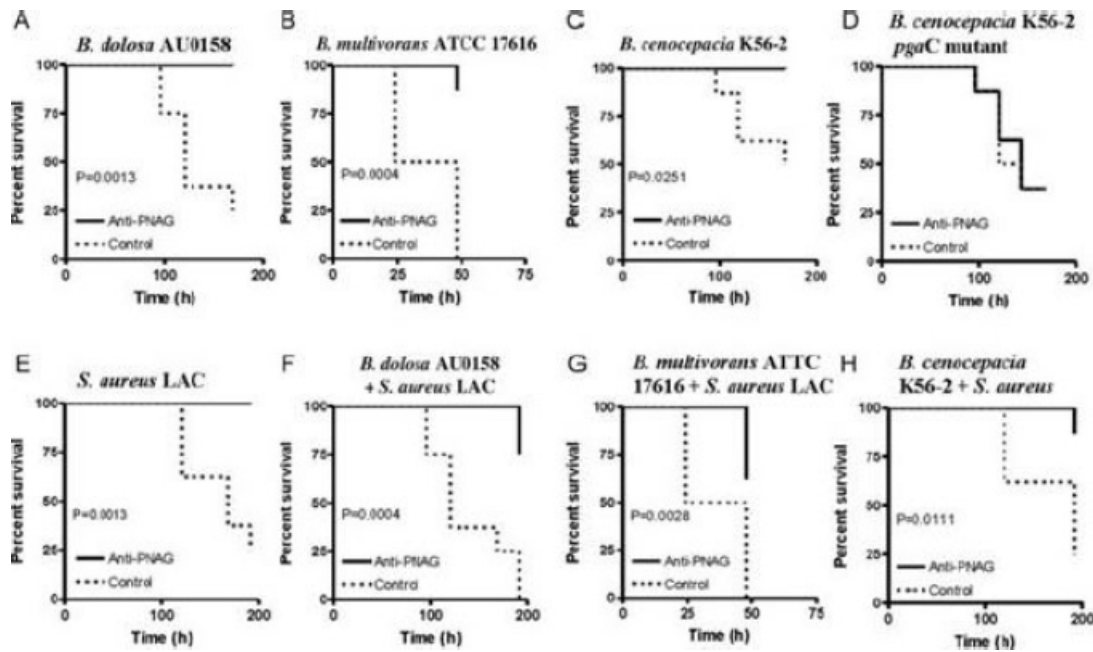
Rationale

Preoperative antibiotics for elective abdominal operations are essential in decreasing surgical site infections (SSIs) such that the timely and appropriate administration of antimicrobials is a well-established standard of care. However, their role in emergency surgery for intestinal perforation is controversial. The incidence of SSIs and other infections following hollow viscus injury is high. As noted in numerous publications, despite perioperative antimicrobial administration, an infection rate ranging from 4% to 31% has been observed and the extended use of antibiotics in this setting has not reduced the incidence of post-operative infections. It has been postulated that microscopic leakage of gastrointestinal contents continues for a period of time following surgical repair. That would be consistent with the observation, in one study published in the World Journal of Surgery, that the mean time to develop a surgical site infection was 9.8 days following surgery. Under those circumstances a short course of antibiotics would not prevent those infections. At the same time, it is not advisable to have patients receive a prolonged exposure to antibiotics as that would lead to the development of resistant infections and other toxicities associated with those drugs.

Use of mAb F598

An alternative therapy, such as F598, could provide prolonged protection without the sequelae associated prolonged antibiotic exposure. This is based on several observations and preclinical studies performed in the laboratory of Dr. Gerald Pier, an advisor of Alopecx. To begin, the major causative organisms associated with SSIs have been noted to be Enterobacteriaceae that have been isolated from both surgical and non-surgical sites of infection. These include *Escherichia coli*, *Enterobacter cloacae*, and *Klebsiella pneumoniae*, all of which have been found to express PNAG.

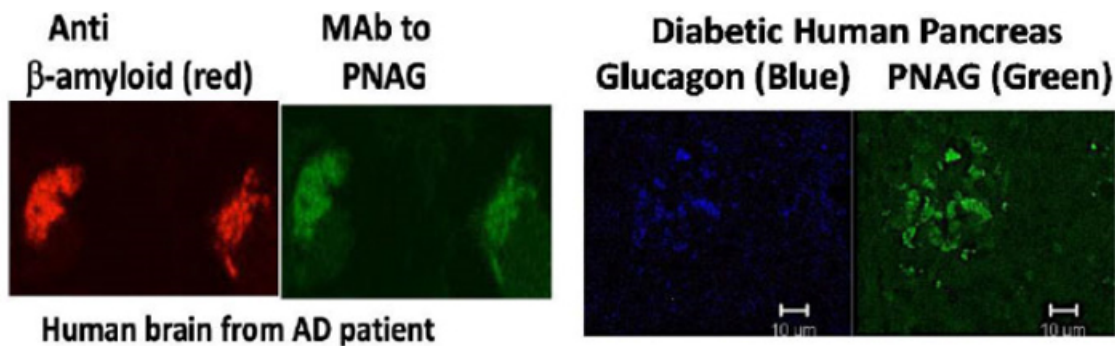
Beyond the high incidence of PNAG-expressing pathogens associated with SSIs, mAb F598 has been noted to prevent intra-abdominal infections. In studies performed in Dr. Pier's laboratory and as illustrated in the figure below, antibodies against PNAG were able to protect against infections caused by a number of pathogens in a lethal peritonitis model including methicillin-resistant *S. aureus* and a number of other PNAG-expressing pathogens. The peritonitis model used is consistent with what occurs following abdominal trauma where microbes residing within the GI tract contaminate the abdominal or peritoneal cavity. Based on these results it is management's belief that administration of mAb F598 at the time of emergency abdominal surgery may prevent the development of infections following emergency abdominal surgery.



Antibodies to PNAG protect against lethal peritonitis from PNAG-producing *Burkholderia cepacia* complex (BCC) even during coinfection with methicillin-resistant *Staphylococcus aureus*. Note: The p-values cited here refer to statistical significance for this pre-clinical study. p-values are widely used in both the social and natural sciences to quantify the statistical significance of observed results. A small number as is reported here is an indication that the observed results did not occur by random chance. These p-values refer to the results of this experiment alone. A separate statistical analysis plan will need to be developed and approved by the FDA for the clinical studies that will be used to support regulatory approval.

PNAG in the development of chronic diseases – the role of sterile inflammation and potential role in the development of Alzheimer’s Disease (AD) and Type 1 Diabetes (T1D)

We have been investigating the role of PNAG-containing microbial cells and fragments in chronic debilitating conditions not usually thought to be associated with an infectious cause. We have found that PNAG is present in the brains of patients with Alzheimer’s disease (AD) and pancreas of individuals with type 1 diabetes (T1D), despite the fact that viable microbial pathogens cannot usually be isolated or grown from those tissues. While viable pathogens cannot routinely be detected, there is clear evidence of inflammation associated with disease progression. Those observations are shown in the photomicrographs below, where PNAG fragments were found in patients with AD to co-localize with b-amyloid, the main component of the amyloid plaques found in the brains of individuals with Alzheimer’s disease. PNAG deposits were not observed in brains of individuals who did not have AD. We have observed a similar association of PNAG-positive microbial fragments and destroyed insulin-producing beta cells in the pancreas of individuals with T1D, while pancreata from non-diabetic human have no detectable PNAG via immunohistochemical analysis. The presence of glucagon identifies a destroyed islet in the diabetic pancreas.



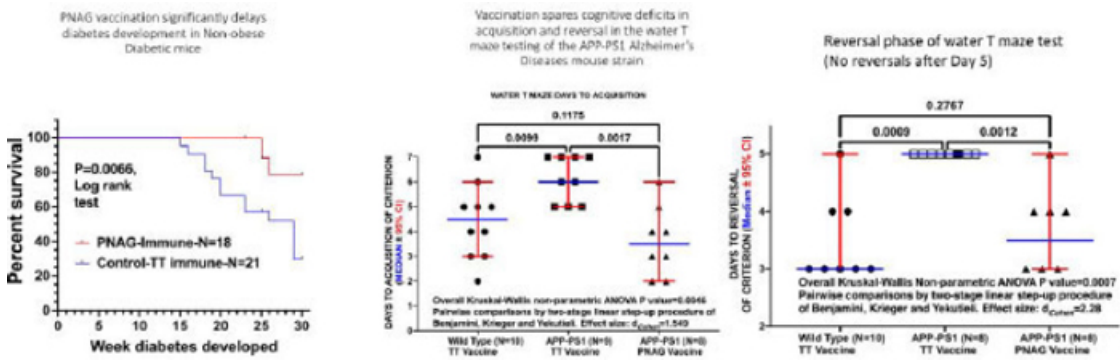
These observations led us to hypothesize that an unrecognized causative factor in these diseases is inflammation resulting from the persistence of undegraded microbial cells or fragments in affected tissues instead of viable microorganisms themselves. These nonviable, undegraded microbial remnants persist in tissues and act as an inflammatory nidus of chronic inflammation. This might lead to sterile inflammation, a form of pathogen-free inflammation.

It seems likely that the source of these PNAG-containing fragments occurs following disruption of nasal, oral, skin, GI and blood-brain barriers, which results in microbes or microbial fragments, known as extracellular vesicles, from the host's own microbiota entering the bloodstream. The loss of barrier function may be due to a fall, trauma, environmental exposure, medications, or aging. The escaping microbes or fragments are usually degraded and disposed of by host defenses. However, in association with genetic, environmental and other factors such as changes in the host microbiota, these microbes or microbial fragments are not effectively disposed of and can remain in tissues and contribute to inflammation and associated tissue destruction.

Impact of Targeting PNAG in the prevention of AD and T1D

If PNAG-containing fragments are a causative factor in the development of AD and T1D then targeting PNAG via immunotherapeutic interventions may reduce incidence or severity of those diseases. To test this hypothesis, studies were performed in mouse models of diabetes and Alzheimer's Disease. For the diabetes study, the AV0328 vaccine was provided to Dr. Aleksandar Kostis, Assistant Professor at Harvard Medical School and the Joslin Diabetes Center, for use in a mouse diabetes model. Vaccination against PNAG resulted in a drastic reduction in diabetes incidence from 70% of 21 controls to 17% of 18 PNAG-immune mice (as published at diabetesjournals.org). Similarly, Dr. Pier's laboratory has shown that immunization against the PNAG antigen prevents behavioral and cognitive decline in preclinical mouse models of Alzheimer's disease (as published at alzjournals.onlinelibrary.wiley.com).

Those observations in T1D and AD are illustrated in the figures below.



Left – Delay in the development of diabetes in non-obese diabetic mice immunized with vaccine AV0328.

Middle and Right – Sparing on cognitive deficits in APP-PS1 Alzheimer Disease mice following vaccination with AV0328 as measured by the water T maze.

Note: The p-values cited here refer to statistical significance for this pre-clinical study. p-values are widely used in both the social and natural sciences to quantify the statistical significance of observed results. A small number as is reported here is an indication that the observed results did not occur by random chance. These p-values refer to the results of this experiment alone. A separate statistical analysis plan will need to be developed and approved by the FDA for the clinical studies that will be used to support regulatory approval.

It is management's belief that our vaccine may be capable of inducing antibodies that recognize these PNAG-containing microbial cells and fragments and, by binding to them, engage the host's immune system to effectively clear PNAG-containing microbial fragments. Under these conditions, progression of symptoms associated with tissue destruction in diseases like Alzheimer's and T1D can be prevented. While not the initial focus of the company, it points to the broad promise these therapeutics offer. Dr. Pier's laboratory **was recently** awarded a grant from the Cure Alzheimer's Fund to explore the relationship between immunity to PNAG and the development of Alzheimer's Disease in additional mouse models.

Our Pipeline

Vaccine AV0328

AV0328 is a novel vaccine candidate comprised of a synthetic pentamer of the oligosaccharide β 1-6-glucosamine [(GlcNH₂)₅] conjugated to tetanus toxoid (TT) protein through a linker. The conjugate vaccine induces antibodies to the glucosamine backbone of naturally occurring PNAG.



Phase 1 Clinical Studies

A Phase 1 clinical study evaluating the safety, tolerability, pharmacodynamics and preliminary efficacy of AV0328 in 16 healthy volunteers has been completed. As assessed by the management, AV0328 was found to be well-tolerated with only minor and transient injection site reactions observed even after the second dose. At the two highest doses, clear increases were noted in antibody titers against PNAG, as well as a positive indication of a major correlate of protective immunity, complement activation and binding of C1q to the PNAG antigen. As can be seen below, sera from subjects immunized with AV0328 resulted in the killing of 100% of PNAG-positive microbial species and strains tested.

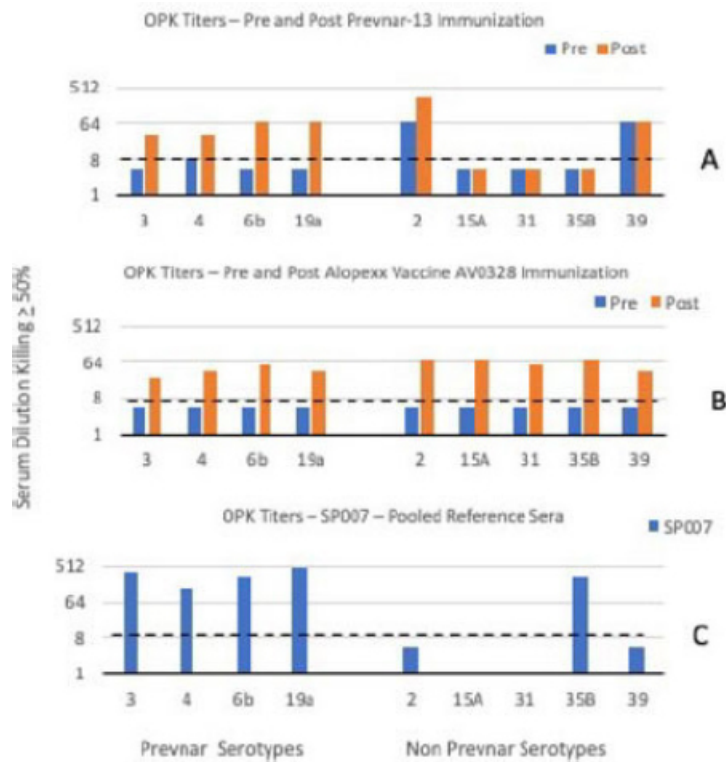
Summary of In Vitro Activity

Microbe	Strain	Assay	Outcome	Microbe	Strain	Assay	Outcome
<i>N. gonorrhoeae</i>	UNC25A	SBA	POS	<i>S. pneumoniae</i>	TX68 4 (4)	OPA	POS
	442089		POS		Spn 6B (6B)	Pneumococcal Serotype	POS
	35253		POS		296 (34)		POS
	HO41		POS		EF3030 (19F)	Pneumococcal Serotype	POS
	CTR SPAIN		POS		11865 (9V)		POS
<i>N. meningitidis</i> Serogroup A	Z2087	SBA	POS	<i>S. pneumoniae</i>	Spn 212 (23F)	Pneumococcal Serotype	POS
<i>N. meningitidis</i> Serogroup B	B16B6	SBA	POS		Spn 255 (33B)		POS
	M2996		POS		Spn 080 (8)	Neisser	POS
	NM8		POS	<i>S. aureus</i>	MNR (CP8)	OPA	POS
	H84/75		POS	MRSA	USA300 (No CP)		POS
	M981		POS		USA300 (CP5)	OPA	POS
<i>N. meningitidis</i> Serogroup C	B9-1	SBA	POS		Sanger 256 (CP8)		POS
<i>N. meningitidis</i> Serogroup W	W171	SBA	POS	<i>E. coli</i>	NDM1	OPA	POS
<i>N. meningitidis</i> Serogroup X	IF	SBA	POS	<i>K. pneumoniae</i>	MCR1		POS
<i>N. meningitidis</i> Serogroup Y	Y2220	SBA	POS		KPN-NDM 1	OPA	POS
<i>A. baumannii</i>	S1	SBA	POS	<i>S. Typhi</i>	KPN-KPC		POS
<i>C. albicans</i>	SC5314	OPA	POS		TY2	OPA	POS

SBA – Serum bactericidal assay OPA – Opsonophagocytic killing POS – at least 4 fold increase in titer in all subjects tested

We also sought to compare the immune response induced to AV0328 with those elicited by immunization with Prevnar 13 against Prevnar and non-Prevnar *S. pneumoniae* serotypes. As shown in the 3 figures below, OPK activity was measured before and after Prevnar immunization (Fig A) and AV0328 immunization (Fig B). Results with a pooled reference sera SP007 are shown in Figure C. As SP007 is a pooled reference sera there is no pre-immunization sera. Based on the accepted titer threshold (see dotted line in figures) of 1:8 killing $\geq 50\%$ of the bacterial cells, indicative of protection, AV0328 was able to induce protective levels of antibody as reflected in the opsonic killing titers against all tested *S. pneumoniae* serotypes.

There was activity by SP007 against one non-Prevnar serotype. The Prevnar-vaccinated human also had pre-existing antibody to two non-Prevnar serotypes. We think this may reflect prior exposure of individuals whose sera was used to make the standard serum pool and the vaccinated individual to those serotypes as opposed to cross reactivity.



Comparing maximum OPK titers from vaccines targeting different antigens must be viewed cautiously. Antigen expression can vary significantly *in vitro* depending on growth conditions, the serotype and other factors. Nor does the ratio of antigen expression *in vitro* reflect what occurs in an infected individual where one antigen may be more highly expressed. What is more relevant, in an *in vitro* OPK assay, is achieving a consistent titer at or above the protective threshold against all serotypes. By that definition AV0328 demonstrated consistent killing against all *S. pneumoniae* serotypes tested (as well as multiple other microbes). As PNAG is likely expressed on the vast majority *S. pneumoniae* serotypes we anticipate we will be able to achieve broad spectrum protective immunity.

Initial indication for the Use of Vaccine AV0328 - Prevention of Pneumococcal Disease

The current vaccine standard of care for pneumococcal disease includes the combination of Merck’s Pneumovax 23 and Pfizer’s Prevnar 13 for adults, and Pfizer’s Prevnar 13 for infants. Pneumovax 23 is a polysaccharide vaccine that protects against 23 strains of pneumococcus but is not thought to protect against pneumonia, provides only transient protection against bacteremia in adults and is not effective in children under two years of age. Prevnar 13 is a pneumococcal conjugate polysaccharide vaccine (PCV) that protects against only 13 strains of pneumococcus, but offers significantly better immunogenicity, protects against pneumonia and is suitable for both adults and infants. Routine immunization with PCVs has been effective in dramatically lowering the incidence of invasive pneumococcal disease (IPD) in both adults and children in the United States and other industrialized nations.

Both Prevnar 13 and Pneumovax 23 are serotype-specific and require combining 13 or 23 components into a single vaccine. However, there are over 100 pneumococcal strains and as current vaccines have reduced the incidence of the specific strains, covered strains that are not covered by existing vaccines are increasing in prevalence. While the overall incidence of IPD has not changed, infections caused by non-vaccine serotypes has reduced the net effectiveness of the vaccines for both vaccinated and unvaccinated adult individuals in countries with high vaccine coverage. This is a phenomenon known as serotype replacement.

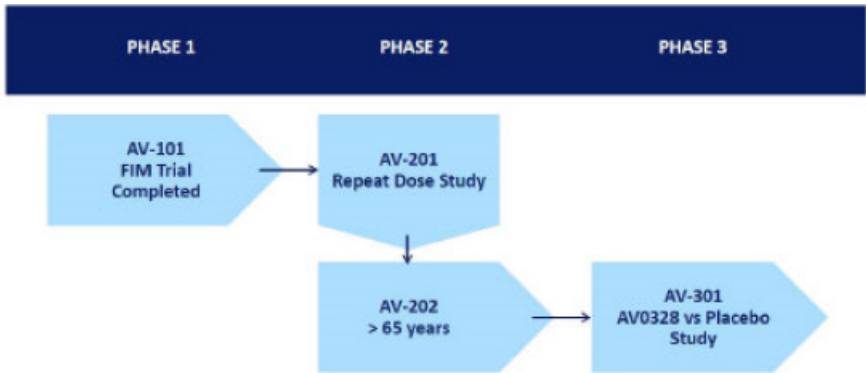
Efforts to improve the current standard of care vaccines have focused on expanding the number of serotypes covered by serotype-specific vaccines. The 15-valent (Merck), 20-valent (Pfizer) vaccines have recently been approved. Twenty-four-valent (Affinivax) and 30-valent (VaxCyte) vaccines are in development. The problem with all of those approaches is that they will inevitably lead to serotype replacement and the rise of infections not covered by those newer vaccines.

Adding to the challenge of developing new serotype-specific vaccines has been the recognition that serotype replacement is not occurring uniformly. The serotypes selected for inclusion in the 7- and then 13 valent vaccines were based on their high prevalence in the US and Europe. However, a recent report has noted that the efficacy of current serotype-specific vaccines has resulted in the rise of a diverse and less uniform number and distribution of serotypes that may not be as effectively addressed by newer serotype-specific vaccines. The authors noted that although there are common emerging serotypes between countries and within age groups, there has not been a dominating serotype following the introduction of Prevnar as there was before. They conclude that continuing reliance on serotype-specific vaccines may require different vaccine serotype formulations for different locations, as well as distinct vaccine serotype formulations that attempt to anticipate and prevent the next expected serotype replacement.

PNAG has been noted to be expressed by 100% of the 36 pneumococcal strains tested to date. That includes all serotypes contained in Pneumovax and the recently approved Prevnar 20. As detailed previously, of the close to 250 distinct microbial strains that have been analyzed for PNAG expression >90% were positive. Consistent with our results with other pathogens, we expect that the majority of remaining pneumococcal serotypes will be positive as well. AV0328 has the potential to be a single, non-serotype specific, polysaccharide vaccine capable of covering most if not all serotypes. In management's opinion no other currently available serotype-specific pneumococcal vaccine or any others in development are capable of offering this degree of coverage.

This broad-spectrum potential has led us to follow a unique regulatory approval approach. As an initial indication we plan to have AV0328 serve as a complementary vaccine that can expand coverage to many of the remaining 80+ *S. pneumoniae* serotypes not covered by current vaccines. This approach could also apply to many of the newer pneumococcal vaccines under development. Most critically, we have been in contact with the FDA where we proposed this complementary approach. Feedback from the FDA has been supportive of the utilization of AV0328 as a complementary vaccine. In addition, the FDA supported pursuing accelerated approval of AV0328 based on safety and utilization of a validated surrogate assay – opsonic killing mediated by antibodies induced by AV0328. The FDA's Accelerated Approval Program allows for earlier approval of drugs that treat serious conditions based on a surrogate endpoint. A surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Management believes that this points to a development path comparable to those that have led to FDA approval of other vaccines for *Streptococcus pneumoniae* infections. However, the FDA has not yet approved our vaccine and there is no guarantee that the FDA will ultimately approve the vaccine.

Below is a schema of the overall clinical development of AV0328 in adults for the prevention of pneumococcal disease. We anticipate that the trial can be initiated after the completion of this Offering and completed 12 months later. The duration of the trial is less due to patient accrual than the time needed to assess the durability of the immune response to the vaccine.



As can be seen in the figure, following the completed phase 1 trial, two phase 2 studies are envisioned. AV-201 is a repeat dose trial in healthy volunteers that seeks to confirm and optimize the dose and schedule of AV0328. In parallel with that trial, we plan on performing a study in adults > 65 years old – the population that would receive the vaccine. Each of those trial would involve ~ 100 subjects and should accrue quite quickly as they are healthy volunteer studies. They will each take about a year to complete as we will need to follow the subjects to assess the duration of protection. The efficacy end point will not need to rely on reduction in pneumococcal infections but, as we have discussed with the FDA, will employ a surrogate endpoint (opsonic killing) similar to what is used by other pneumococcal vaccines.

The results of those studies will be a major inflection point. Assuming that we continue to the same degree of safety and efficacy we would then plan to mount a phase 3 registration trial in adults along with supportive studies that would permit utilization of the vaccine in infants and children. It should be noted that because we will be seeking use of AV0328 as a complementarity vaccine, there is no need to compare our results with currently available vaccines.

Although we believe that our vaccine has the potential to be widely adopted, we have not received regulatory approval. In order to obtain regulatory approval and commercialize our vaccine, the U.S. Food and Drug Administration, or FDA, European Medicines Agency, or EMA, or other regulatory agencies will need to determine that our vaccine are safe and effective. Obtaining such approval will require that we successfully complete additional studies and there can be no assurance that the results of such studies will be similar to our earlier studies. As such, we may not obtain regulatory approval for our vaccine.

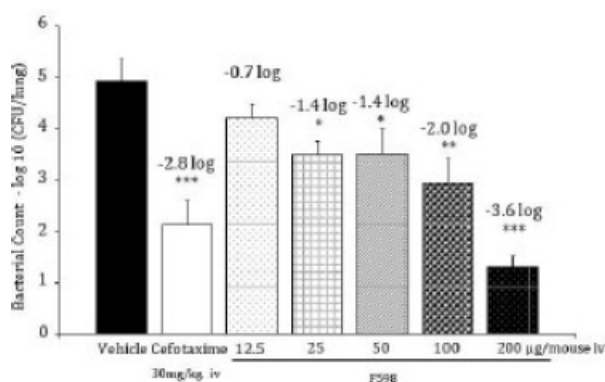
Manufacturing and Supply – Vaccine AV0328

Unlike any other vaccine, the immunogenic component for PNAG in AV0328 is chemically synthesized. This offers a major advantage in that we are not reliant on isolating the key vaccine component from a variable microbial source. We have partnered with Glycosyn, Inc., a New Zealand-based company with expertise in carbohydrate synthesis, to produce the key antigen component of the vaccine – the carbohydrate oligosaccharide. They have developed a scalable manufacturing process capable of producing supplies sufficient for clinical development and commercialization. Beyond the patent portfolio, we have built synthesis of the vaccine is also covered by a trade secret agreement that prevents publication of the multi-step process used to synthesize our proprietary antigen.

The other key component is a protein carrier to which the carbohydrate is linked. This is a well-established process to augment the immune response to the antigen. Prevnar-13 is a pneumococcal conjugate polysaccharide vaccine or PCV which uses a similar approach. In our case, we have found that tetanus toxoid can serve as an excellent protein carrier. As tetanus toxoid is routinely administered to people to prevent tetanus it has a well-established safety profile and is readily available. Taken as a whole, we believe our vaccine can be produced at a cost of <\$0.50/dose – far lower than any other vaccine in development.

Monoclonal Antibody F598

F598 is a fully human IgG1 monoclonal antibody selected for its ability to target PNAG. While no assurances exist we can duplicate these results in man, animal studies administration of monoclonal antibody F598 has been shown reduce the impact of microbial challenges in several models, using a number of different microbes, as measured by reductions in mortality or the development of pneumonia, peritonitis, corneal infection and other evidence of a local or systemic infection. As can be seen in the figure below, F598 administered intravenously 4 hours before intranasal bacterial challenge with *S. pneumoniae* (10^8 cfu/mouse), dose-dependently prevented the development of infection in mice. A significant effect was observed starting from 25 μ g/mouse (~0.8 mg/kg) with a maximum effect at 200 μ g/mouse (~7 mg/kg). At 200 μ g/mouse, the effect of F598 on bacterial load reduction was comparable to curative treatment with 30 mg/kg of a standard antibiotic, cefotaxime, administered following the bacterial load.



Results are expressed as the mean $\pm$ SEM, n = 6-8 animals per group, comparison versus vehicle group

* p < 0.001 (student's t-test)

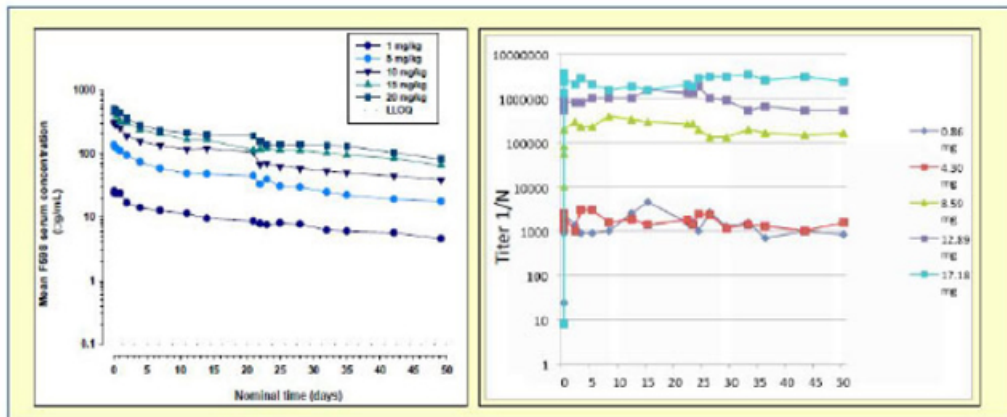
** p < 0.05 (one-way ANOVA followed by Dunnett's adjustment)

*** p < 0.001 (one-way ANOVA followed by Dunnett's adjustment)

Note: The p-values cited here refer to statistical significance for this pre-clinical study, and such values will not be used to justify regulatory approval by the FDA or other regulatory authorities.

Clinical Experience with F598

A Phase 1 trial of F598 was performed by Alopexx. In that study, a single infusion of F598 was administered to 20 healthy adults. Pharmacokinetic analysis showed long elimination half-lives (~20-30 days), low systemic clearance, a low volume of distribution and a dose-dependent increase in serum monoclonal antibody levels. No relevant immunogenicity related to study compound (as measured by detection of antibodies against F598 in human serum) was observed. Overall, the antibody was found to be well tolerated, and no serious adverse events were observed. As shown below, dose-dependent and high levels of functional activity of the antibody as measured by opsonophagocytic assays against *S. aureus* were maintained at all doses up to Day 50, the last time point in the study. This suggests that single administration of F598 could provide protection for a prolonged period of time.



Because of concerns that the antibody might elicit an untoward inflammatory response, a pilot study was performed in patients with an active infection. F598 was administered to individuals with latent and newly diagnosed tuberculosis. This was a phase 2 open-label trial to evaluate the safety, tolerability and early bactericidal activity of F598 in adults with latent tuberculosis or newly diagnosed, smear-positive pulmonary tuberculosis. A total of 25 subjects received a single infusion of F598. No serious or unexpected adverse events were observed in any of the participants. The short duration (2 weeks) of the study precluded observation of bactericidal activity however, it did demonstrate that F598 could be administered to individuals with a documented, active infection.

Prevention of Hospital-Acquired Infections

Unlike vaccines which may take several weeks or longer to induce protective immunity administration of a monoclonal antibody provides immediate protection. In previous studies we have found that F598 is not only well tolerated but has a long half-life which may provide protection for 2-3 months after a single administration. Therefore, the antibody will be utilized in settings where an individual is at an immediate or near-term risk of developing an infection. Healthcare associated infections are one of the major settings where this occurs.

In 2007, the Centers for Disease Control and Prevention estimated that roughly 1.7 million Healthcare-Associated infections, from all types of microorganisms, including bacteria and fungi combined, cause or contribute to 99,000 deaths each year in the United States (see also a study by Kievers in 2002). A follow-up analysis in 2016 noted that while the overall incidence of infection had fallen from 4% to 3.2% there was no change in pneumonia and gastrointestinal infections. Hospital-acquired or nosocomial infections can cause severe pneumonia and infections of the urinary tract, bloodstream and other parts of the body. Many types display antimicrobial resistance, which can complicate treatment.

While overall hospital-acquired infections are relatively uncommon, that is not the case in intensive care units (ICUs). Although ICUs account for fewer than 10 percent of total beds in most hospitals, more than 20 percent of all nosocomial infections are acquired in ICUs. ICU-acquired infections account for substantial morbidity, mortality, and expense. Infections and sepsis are the leading cause of death in noncardiac ICUs and account for 40 percent of all ICU expenditures. Despite the advances in modern medicine and intensive care, the incidence of sepsis in intensive care units (ICUs) continues to rise. In a 2006 international study of 1265 ICUs, (EPIC II) 60 percent of ICU patients at the time of survey were considered infected, with infection being a strong independent predictor for mortality. The risks of infection in general and with a resistant pathogen, in particular, increased with the length of patient stay in the ICU. These results have recently been updated and in 2017 a survey of 1150 centers in 88 countries (EPIC III) it was found that 54% of ICU patients had a suspected or proven infection, including 22% with an ICU-acquired infection. Infection rates remained high whether or not the ICU was located in a low (57.8%) or high (50.2%) income country or geographically (North America 47.7%, Western Europe 50.7%, Asia/Middle East 60.1%).

In an effort to reduce the incidence of HAIs, in 2008 Medicare initiated the Hospital-Acquired Condition (HAC) Reduction Program. Under the program the Centers for Medicare and Medicaid Services' (CMS') reduced overall Medicare payments for hospitals that rank in the worst-performing quartile of all hospitals on measures of hospital-acquired conditions, including HAIs. The hope was that financial penalties would encourage hospitals to initiate programs that would reduce the incidence of HAIs. Because Medicare relies on hospitals to self-report infection rates, the HAC policy may have affected a hospital's incentive to identify and report the exact origin of infections in a manner that increases reimbursement or avoids financial penalties. This may have an impact on therapies seeking to treat documented HAIs as it would require hospitals to report those infections and risk financial penalties.

Utilization of monoclonal antibody F598 should not be affected by that issue. As detailed below F598 will be employed upon admission to an intensive care unit as a means to prevent or ameliorate any subsequent HAIs. It would be consistent with Medicare's goal to reduce HAIs and would not require a hospital to identify an HAI in advance of administering the antibody.

PNAG is produced by many pathogens causing hospital-acquired infections. The table below shows the gram-positive bacteria, gram-negative bacteria and fungi, listed by the CDC, as associated with HAIs. As can be seen with the exception of *Pseudomonas aeruginosa* all tested organisms express PNAG (*Clostridium sordellii* has not been tested).

Organism	PNAG Expression
<i>Acinetobacter</i>	Positive
<i>Burkholderia cepacia</i>	Positive
<i>Candida auris</i>	Positive
<i>Clostridioides difficile</i>	Positive
<i>Clostridium sordellii</i>	NT
<i>Enterobacterales</i> (carbapenem-resistance)	Positive
ESBL-producing <i>Enterobacterales</i> (extended-spectrum β -lactamase-producing)	Positive
<i>Escherichia coli</i>	Positive
<i>Klebsiella pneumoniae</i>	Positive
Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA)	Positive
Non-tuberculous <i>Mycobacteria</i> (NTM)	Positive
<i>Pseudomonas aeruginosa</i>	Negative
<i>Staphylococcus aureus</i>	Positive
<i>Mycobacteria tuberculosis</i> (TB)	Positive
Vancomycin-intermediate <i>Staphylococcus aureus</i>	Positive
Vancomycin-resistant <i>Staphylococcus aureus</i>	Positive
Vancomycin-resistant <i>Enterococci</i> (VRE)	Positive

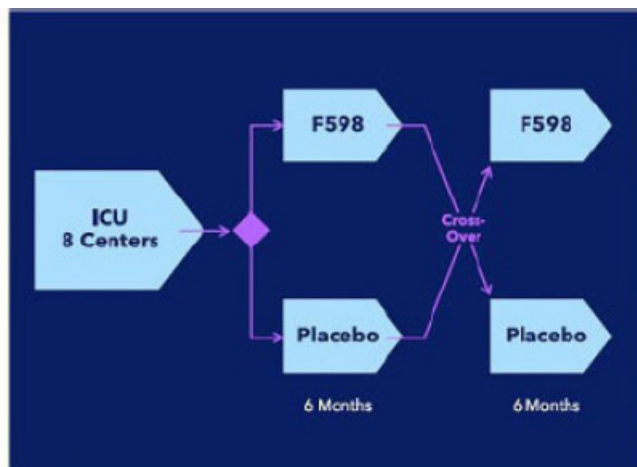
Use of monoclonal antibody F598 offers the potential for it to become the first broad-spectrum therapeutic antibody for microbial infections. To pursue this, we propose to study this in a setting where the prevalence of acquired infections is very high – intensive care units. Demonstrating that monoclonal antibody F598 can reduce the morbidity/mortality related to microbial infections in ICU patients would constitute a major health advancement. Administration of F598 in that setting could become the part of the standard of care.

Alopexx is uniquely positioned to perform a large proof-of-concept study in this setting. We have developed a collaboration with Europe's largest health care system, which has agreed to perform a 1,600-patient phase 2 intensive care unit study. The Assistance Publique-Hôpitaux de Paris (AP-HP) is the largest hospital system in Europe and one of the largest in the world. It provides healthcare, teaching, research and emergency medical services in 44 hospitals and sees more than 5.8 million patient visits annually. The impetus for this collaboration has been our relationship with Professor Dr. David Skurnik. Dr. Skurnik was a member of Dr. Pier's laboratory at Harvard Medical School from 2007-2017 where he studied the clinical and microbiological diagnosis and management of bacterial infections and sepsis and the emergence and dissemination of antibiotic resistance. He was also closely involved in the development and evaluation of Alopexx's PNAG immune therapeutics. Dr. Skurnik became Professor of Medicine at the Necker Hospital, part of the AP-HP system. Dr. Skurnik was able to obtain the commitment and collaboration of eight AP-HP hospitals to perform the ICU study outlined below as an institutional investigation. As a consequence, the clinical cost of performing this 1,600-patient study is estimated to be approximately \$4 million – a fraction of what an industry-sponsored trial would cost. Beyond the cost savings, this represents the strong interest of the consortium to test this important hypothesis, which can be viewed as an endorsement of the promise and potential of Alopexx's anti-infective immune therapeutics.

While it would be possible to perform this study in the United States, the collaboration with Dr. Skurnik and his relationship with AP-HP are major reasons to perform the study in Paris. We adhere to Good Clinical Practice (GCP) guidelines in all of our trials. GCP is an international quality standard, which governments can then transpose into regulations for clinical trials involving human subjects. GCP follows the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and enforces tight guidelines on ethical aspects of clinical research.

We anticipate that a positive result in this phase 2 proof-of-concept trial will not be sufficient for regulatory approval and that a confirmatory, company-sponsored registration study will be required. A positive result in this study would justify performing a confirmatory, company-sponsored registration study that will involve medical centers in the United States. Should that confirmatory trial be positive it will be used to seek regulatory approval.

The figure below illustrates the study design that has been endorsed by our collaborators in Paris. In this study it is the institution not the individual patient that will be randomized and the overall impact on morbidity and mortality will be assessed. The study has received initial approval by their institutions and can be quickly initiated. Patients entering the ICU will receive either F598 or a placebo in addition to the standard of care. To control for variations in different ICU settings, at the end of six months, there will be a cross-over so ICUs that had received F598 will receive placebo and vice versa. We will then observe patients for a reduction in morbidity and mortality due to infections caused by microbes that express PNAG. We anticipate that the trial can be initiated in the first quarter of 2023 and completed 18 months later. The duration of the trial is less due to patient accrual, which with eight participating ICUs should be fairly rapid, than the need to match the time at which the cross-over occurs to control for seasonal variations in ICU admissions.



Manufacturing and Supply – Monoclonal Antibody F598

We have strategically aligned with our contract manufacturer, Lonza Ltd., or Lonza, a globally recognized contract development and manufacturing organization based in Switzerland. We have developed a robust cell line capable of producing the antibody at a commercial scale. The cell line is able to produce our antibody at a scale and cost equivalent or better than other commercially available Monoclonal antibodies. Antibodies produced using this cell line have already been used in clinical trials.

Our Strategy

The key elements of our strategy are:

- Advance vaccine AV0328 and monoclonal antibody F598 through key proof-of-concept clinical trials.
- Create a long-lasting franchise by offering the broadest-spectrum vaccine available for prevention of a wide range of microbial infections
- Establish monoclonal antibody F598 as part of the standard of care in preventing and treating microbial infections in individuals at immediate risk (i.e., ICU patients)
- Explore utilization of the vaccine and antibody in medical indication not classically thought to be associated with microbial infections – diabetes, Alzheimer’s Disease, cancer and other conditions.
- Continue to build a robust intellectual property portfolio.

Competition

Vaccine AV0238

The global vaccine market is highly concentrated among a small number of multinational pharmaceutical companies. Pfizer, Merck, GlaxoSmithKline and Sanofi together control approximately 75% of the global vaccine market. Other pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions are also working towards new solutions given the continuing global unmet need.

Within the current pneumococcal vaccine market, Pfizer, Merck and GlaxoSmithKline dominate. Global sales of these three products were approximately \$7.45B, with Pfizer's Prevnar 13, Merck's Pneumovax 23 and GlaxoSmithKline's Synflorix representing approximately 78%, 15% and 7%, respectively, of these sales. While Prevnar 13 covers fewer pneumococcal strains than Pneumovax 23, it delivers a stronger and more durable immune response than Pneumovax 23. Prevnar 13 is the current standard of care in children and the first vaccine offered under the current standard of care in adults.

Existing vaccine makers, as well as new entrants, are competing to develop the next generation of pneumococcal vaccines. Both Pfizer and Merck have pneumococcal vaccine candidates that have recently been approved and could surpass the performance of Prevnar 13. Pfizer's PF-06482077 is a 20-valent vaccine while Merck's V114 is a 15-valent vaccine. Sanofi and SK Chemicals have partnered to develop a pneumococcal vaccine. Separately, Affinivax and Astellas have partnered to develop an affinity-bound pneumococcal vaccine that includes 24 pneumococcal serotypes. VaxCytex is developing 24- and 30-valent vaccines utilizing their proprietary conjugate platform.

Other companies have similar business models to us. For example, Immunome, Inc., TFF Pharmaceuticals, Inc., Adagio Therapeutics, Inc. and AbCellera Biologics, Inc. are focused on human monoclonal antibodies for commercialization. Some of these companies are pre-clinical and some have approved drugs. Companies pursuing vaccines include Vaxcyte, Inc., CureVac N.V., Inovio Pharmaceuticals, Inc. and more well-known companies like Novavax, Inc. and Moderna, Inc. Some companies are in different clinical stages while others have approved drugs on the market.

To our knowledge, there is only one other company that is developing a universal pneumococcal vaccine. ImmBio's PnuBioVax seeks to target heat shock proteins as a universal pneumococcal vaccine. Vaccines targeting a protein that do not include a toxoid component have never been shown to be effective in a randomized clinical trial. Every human vaccine that has been licensed on the basis of clinical trial data target surface carbohydrates, as does the PNAG vaccine. Because we are seeking to develop AV0328 as a complement to serotype-specific specific vaccines, none of them would preclude addition of our vaccine to the current or future standard of care.

As mentioned above we believe AV0328 can be produced at a cost of less than \$0.50 per dose. As noted below in our market analysis we assumed a price of \$60 per dose, which is considerably lower than the current average price of Prevnar, which is \$211.86. This will facilitate our ability to add our vaccine to current or future serotype-specific vaccines whose cost is far greater than AV0328. The table below summarizes the current price of approved vaccines for pneumococcal disease and meningitis and has been taken into consideration as part of the initial market analysis discussed below.

Vaccine	Price/Dose	
	CDC	Private Sector
Prevnar 13	\$ 137.22	\$ 226.43
Prevnar 20	\$ 173.69	\$ 249.00
Pneumovax 23	\$ 74.50	\$ 117.08
Vaxneuvance	\$ 149.90	\$ 216.09
Bexero	\$ 111.40	\$ 191.75
Menactra	\$ 80.73	\$ 134.77

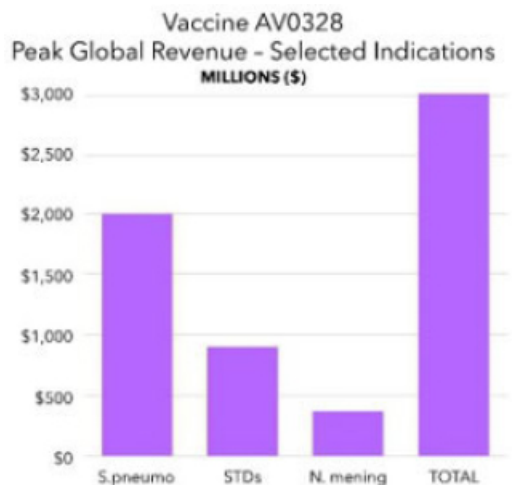
CDC Vaccine Price List March 2022

Monoclonal Antibody F598

There have been two monoclonal antibodies approved for the treatment of bacterial infections and both target toxins and do not have anti-bacterial effects – Anthim to prevent inhalational anthrax and bezlotoxumab for *Clostridioides difficile* infections. There are 14 anti-microbial monoclonal antibodies in development. All but one targets a specific organism. One monoclonal antibody, TRL1068 (Trellis Bioscience), targets bacterial biofilms but in pre-clinical trials it is ineffective unless used with antibiotics. While not a competitor, monoclonal antibodies targeting respiratory syncytial virus and more recently COVID-19 have been shown to be effective and points to potential utility of F598 against microbial infections.

Initial Market Analysis

We have performed independent commercial assessments for the initial indications we intend to pursue – use of the vaccine as a complement to currently approved *Streptococcus pneumoniae* vaccines and use of the mAb to reduce the morbidity/mortality related to microbial infections in ICU patients. We also explored the market potential for 2 other indications for our vaccine – prevention of *Neisseria meningitidis* systemic infection and for sexually transmitted diseases (STDs) as shown on the chart below.



For our vaccine, the assumption was that AV0328 would be added as a complement to current *Streptococcus pneumoniae* vaccines. The relevant population would be the same adult and pediatric patients who currently receive approved *Streptococcus pneumoniae* vaccines. We evaluated Prevnar data for our model since it is currently the most widely used pneumococcal vaccine.

For this analysis the initial target market segment included adults who had received existing Prevnar vaccines as well as *de novo* Prevnar vaccines and pediatric patients who would receive Prevnar as part of their standard vaccination schedule. Our base case assumed a peak market share of 60% and 65% of Prevnar vaccinations in pediatric and adults over 65, respectively. We also assumed a price of \$60 per dose (with a range of \$45 - 90 per dose), which is considerably lower than the current private sector price of Prevnar 13, which is \$226.43. Based on these key assumptions the peak expected global revenue for the *Streptococcus pneumoniae* indication alone is expected to be over \$2.0 billion per year.

For sexually treated diseases, gonorrhea and chlamydia, we assumed a peak annual vaccination rate in existing sexually-active adults between 18-34 years old of 3%, cumulatively reaching 40% over 10 years and a peak annual vaccination rate of 40% of the incoming cohort of 18-year-olds, ramping up linearly from 10% at launch over 7 years.

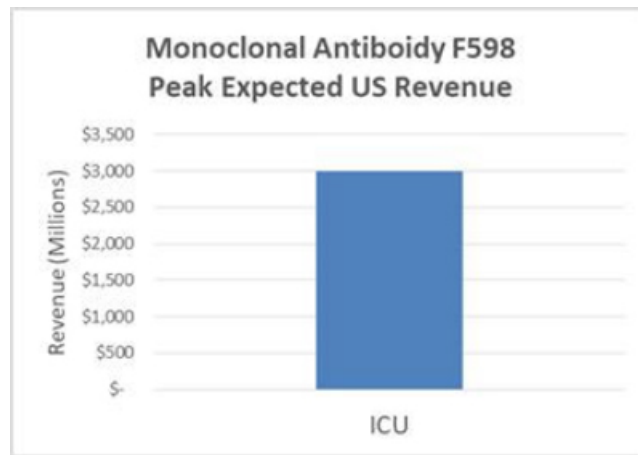
The potential meningococcus pediatric segment is almost completely cannibalized by the pre-existing *S. pneumoniae* indication, as this segment would not need to be treated twice. In freshman students we assumed a peak annual vaccination rate of 40% will be achieved, ramping up linearly from launch over 7 years. For at-risk adults (nurses, physicians, military new recruits) a peak annual vaccination rate of 5% will be achieved, also ramping up linearly from launch over 7 years.

For both the sexually transmitted diseases and the meningococcus indications we assumed a price of \$60 per dose.

Our market analysis of monoclonal antibody F598 was limited to U.S. sales as that is where we have data on yearly ICU admissions. F598 would be added to existing standard of care. F598 will be indicated for all ICU patients.

There are approximately 5 million ICU admissions/year in the U.S. We assumed a price lower than other recently approved anti-infective mAbs of \$1,000. The COVID mAbs were priced at ~ \$2,000 per treatment. Even if this becomes part of the standard of care, we conservatively assumed a market penetration of 60%. While the price may vary in different geographies with a COGS of \$100-\$200 per treatment, we have significant flexibility in pricing.

This is less expensive than the newer antibiotics which can range between \$2,900 and \$18,000 for a 14-day course of therapy. Based on that analysis, we estimated peak U.S. sales of \$3.0 billion per year.



Intellectual Property

Our success depends in part on our ability to obtain and maintain intellectual property protection for our products and technology. We use a variety of intellectual property protection strategies, including patents, trade secrets and other methods of protecting proprietary information.

As of September 30, 2024, our owned patents and patent applications, if issued, are expected to expire between 2040 and 2042, in each case without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

Such patent portfolio owned by us includes:

- A pending PCT application directed to PNAG composition of matter featuring high oligo loading.
- An issued U.S. patent and pending PCT and U.S. applications directed to low contaminant PNAG composition
- An issued U.S. and pending U.S. application directed to treating biofilm
- A pending PCT application directed to a method of combination therapy with antibody plus PNAG vaccine

We exclusively license four issued U.S. and PCT patents from BWH, as of September 30, 2024. These patents cover the vaccine and methods of use thereof, the F598 monoclonal antibody and variants thereof and the methods of use of the vaccine and/or the anti-PNAG antibody. Our in-licensed patents are expected to expire between 2025 and 2033, in each case without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

For further information on the license agreement with BWH, see the section titled “Business — License Agreements.”

We intend to pursue additional intellectual property protection to the extent we believe it would be beneficial and cost-effective. Our ability to stop third parties from making, using, selling, offering to sell, importing, or otherwise commercializing any of our patented inventions, either directly or indirectly, will depend in part on our success in obtaining, defending, and enforcing patent claims that cover our technology, inventions, and improvements. With respect to both our owned and in-licensed intellectual property, we cannot provide any assurance that any of our current or future patent applications will result in the issuance of patents in any particular jurisdiction, or that any of our current or future issued patents will effectively protect any of our products or technology from infringement or prevent others from commercializing infringing products or technology. Even if our pending patent applications are granted as issued patents, those patents may be challenged, circumvented, or invalidated by third parties. Consequently, we may not obtain or maintain adequate patent protection for any of our products or technologies.

In addition to our reliance on patent protection for our inventions, products, and technologies, we also rely on trade secrets, know-how, confidentiality agreements and continuing technological innovation to develop and maintain our competitive position. For example, some elements of manufacturing processes, analytics techniques, and processes, are based on unpatented trade secrets and know-how that are not publicly disclosed. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees, advisors and consultants, these agreements may be breached, and we may not have adequate remedies for any breach. In addition, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. As a result, we may not be able to meaningfully protect our trade secrets. For further discussion of the risks relating to intellectual property, see the section titled “Risk factors—Risks Related to our Intellectual Property.”

Brigham and Women's Hospital License Agreements

In December 2007 and March 2012, we entered into exclusive patent license agreements with BWH, pursuant to which we obtained an exclusive, royalty-bearing, sublicensable (with approval from BWH) license to certain U.S. and foreign patents related to the vaccine and methods of use thereof, the F598 monoclonal antibody and variants thereof and the methods of use of the vaccine and/or the anti-PNAG antibody. We may sublicense the patent rights licensed under the agreement subject to certain conditions, including obtaining the review and approval by BWH of such sublicense and any such sublicense must be consistent with and subject to the terms of the agreement.

Under the agreements, we must pay BWH combined annual license fees of \$165,000. Total expense incurred under the Licenses to BWH by the Company from 2019 through the end of the 2021 fiscal year is \$625,000. Combined regulatory milestone payments of \$675,000 will be due following initiation of phase 2 and 3 clinical studies and submission of an NDA. In the event we commercialize a product in the therapeutic space, we are also required to make certain drug-approval regulatory and commercialization milestone payments to BWH totaling \$3,500,000. In the event we sublicense any of the licensed intellectual property, we must pay BWH a percentage of any sublicense income received by us, which on a going-forward basis will be in the low double digits. Royalty payments in the low single digits will be paid on net sales. Aggregate milestone payments under the two patent license agreements are up to \$2,325,000 and \$1,850,000 for vaccine AV0328 and antibody F598, respectively, for a total of \$4,175,000.

Under the terms of the agreement, we are required to use commercially reasonable efforts to develop and commercialize the licensed products, including in accordance with certain developmental, funding, regulatory and commercialization milestones. BWH controls the prosecution, maintenance and enforcement of all licensed patents and patent applications under the agreement. Subject to an applicable cure period, BWH may terminate the agreement if we fail to comply with applicable payments or diligence obligations or upon a breach of our obligation under the agreement, or for certain insolvency-related events.

Unless earlier terminated, the agreement continues until the expiration of the last to expire patent right licensed under the agreement. Subject to an applicable cure period, BWH may terminate the agreement if we fail to comply with applicable payments or diligence obligations or upon a breach of our obligation under the agreement, or for certain insolvency-related events.

Other Partners

In addition to those listed above, we seek to partner with various academic, governmental and public or private research institutions as needed to advance the discovery or development of our therapeutics.

Collaboration and License Agreement

On September 5, 2024, the Company and Biotech Consortia, Inc (“BCI”), an affiliate of Bharat Biotech International Limited (“BBIL”), entered into a Collaboration and License Agreement (the “License Agreement”), which was subsequently amended effective December 27, 2024.

Pursuant to the License Agreement, the Company agreed to grant an exclusive royalty-bearing license to BCI to certain intellectual property rights controlled by the Company related to its proprietary broad-spectrum anti-microbial vaccine, AV0328, for the prevention of infections caused by *Streptococcus pneumoniae*; and two additional target indications in India and other countries classified as “low” and “lower-middle-income” countries, as set forth in the License Agreement, subject to certain retained rights by Alopexx. In addition, the License Agreement provides for the grant to the Company of a limited non-exclusive, non-royalty bearing, non-sublicensable license to certain patent and technology rights of BCI, as set forth in the License Agreement, to conduct certain development activities as part of the collaboration contemplated by the License Agreement.

Under the terms of the License Agreement, BCI will co-develop and commercialize AV0328, a synthetic vaccine targeting poly N-acetyl glucosamine (PNAG) (the “Licensed Product”), in India and other licensed territories. In addition, Alopexx will be entitled to upfront, development and milestone payments, including royalties on sales of AV0328 in the licensed territories.

Pursuant to the terms of the License Agreement, the Company has received an initial upfront payment of \$666,666 and will receive additional upfront payments in the aggregate amount of approximately \$1.3 million upon the occurrence of certain events. In addition, pursuant to the terms of the License Agreement, the Company may receive an aggregate of up to \$3 million in consideration of the Company's preclinical work and upon achievement of certain milestones. In addition, the Company may receive royalty payments in the single digits percent on net sales of each product (as defined in the License Agreement) in the public market and in the low teens on net sales in the private market. Public market includes sales of the vaccine to individuals or groups with limited financial resources as would be encountered in low and low-middle income countries. The private market includes sales to individuals and groups better able to afford the full cost of the vaccine.

Unless earlier terminated, the License Agreement continues from the date of the License Agreement through the commercial life of the last Licensed Product under the License Agreement. Either party may terminate the License Agreement by providing notice in writing to the other party (i) if the other party is in material breach of the License Agreement, and in the case of a breach that is curable within 60 days, that is not cured in such time period upon notice from the other party, (ii) in the event the other party challenges or assist in a third party in challenging any technology controlled by such party, or (iii) the other party makes a general assignment for the benefit of creditors, files a voluntary petition in bankruptcy, an involuntary petition in bankruptcy is undismissed for a period of more than 60 days. In addition, the Company may terminate the License Agreement in the event BCI ceases development of the Licensed Product (subject to certain exceptions for normal pauses or gaps between clinical studies).

Upon termination of the License Agreement, BCI shall have the right to sell, use or dispose of any unsold or unused product for a period of 18 months after termination, provided it remains in compliance with all other provisions of the License Agreement.

If the License Agreement is terminated by the Company upon the expiration of a 60 days' notice of default, the licenses granted to BCI under the License Agreement will terminate and be of no further effect and BCI shall assign to the Company all regulatory filings, as such term is defined in the License Agreement. Further, within 45 days after termination, BCI will provide a summary of the status and results of its development, manufacturing and commercialization activities for the product prior to the effective date of the termination. In addition, BCI shall use commercially reasonable efforts to transition to the Company all development, manufacturing and commercialization activities and responsibilities for the product as in existence as of the date of termination and upon the request of the Company grant to the Company a fully paid-up, non-royalty bearing, perpetual license under BCI's right in the joint program technology and joint program patent rights.

If the License Agreement is terminated by BCI upon the expiration of a 60 days' notice of default then the licenses granted to BCI shall continue to be valid in accordance with the License Agreement, provided that BCI continues to pay amounts due to the Company for the balance of the term.

The last patent subject to the License Agreement is set to expire in 2040.

The foregoing description of the License Agreement does not purport to be complete and is qualified in its entirety by the provisions of the License Agreement, which is attached hereto as Exhibit 10.8.

Coverage and Reimbursement

Sales of our products in the United States will depend, in part, on the extent to which the costs of the products are covered by third-party payors, such as government health programs, commercial insurance and managed health care organizations. The process for determining whether a third-party payor will provide coverage for a pharmaceutical or biological product is typically separate from the process for setting the price of such a product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved. As a result, a third-party payor's decision to provide coverage for a pharmaceutical or biological product does not imply that the reimbursement rate will be adequate. Certain ACA marketplace and other private payor plans are required to include coverage for certain preventative services, including vaccinations recommended by the ACIP without cost share obligations (i.e., co-payments, deductibles or co-insurance) for plan members. Children through 18 years of age without other health insurance coverage may be eligible to receive such vaccinations free-of-charge through the CDC's Vaccines for Children program. For Medicare beneficiaries, vaccines may be covered under either the Part B program or Part D depending on several criteria, including the type of vaccine and the beneficiary's coverage eligibility. If our vaccine, once approved, are covered only under the Part D program, physicians may be less willing to use our products because of the claims adjudication costs and time related to the claims adjudication process and collection of co-payments associated with the Part D program.

Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. As such, one third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service or will provide coverage at an adequate reimbursement rate. Further, 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 that receives regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, safety, effectiveness, manufacture, quality control, approval, post-approval monitoring and reporting, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of products such as those we are developing. A new biological product must be licensed by the FDA through the approval of a Biologics License Application, or BLA, before it may be legally marketed in the United States.

In the United States, pharmaceutical products are regulated by the FDA under the Federal Food, Drug and Cosmetic Act and other laws, including, in the case of biologics, the Public Health Service Act, or PHS Act. We expect our products to be regulated by the FDA as biologics and to be reviewed by the FDA's Center for Biologics Evaluation and Research.

We anticipate our vaccine and antibody will require the submission of a BLA and approval by the FDA before being marketed in the United States. Failure to comply with FDA requirements, both before and after product approval, may subject us or our partners, contract manufacturers and suppliers to administrative or judicial sanctions, including FDA refusal to approve applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, fines and/or criminal prosecution.

The steps required before a biologic may be approved for marketing of an indication in the United States generally include:

- completion of preclinical laboratory tests, animal studies, formulation studies conducted in accordance with good laboratory practices and other applicable regulations;
- submission to the FDA of an IND application, which must be active before human clinical trial commencement;
- approval by an institutional review board, or IRB, or ethics committee at each clinical site before a clinical trial is commenced;
- completion of adequate and well-controlled human clinical trials in accordance with good clinical practice, or GCP, requirements to establish that the biological product is "safe, pure and potent," which is analogous to the safety and efficacy approval standard for a chemical drug product for its intended use;
- preparation and submission to the FDA of a BLA for marketing approval that includes substantive evidence of safety, purity and potency from results of nonclinical testing and clinical trials;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with applicable current good manufacturing practices, or cGMPs, to assure that the facilities, methods and controls are adequate to preserve the products identity, strength, quality and purity;
- potential FDA audit of the nonclinical and clinical trial sites that generated the data in support of the BLA; and
- FDA review of the BLA and issuance of a biologics license, which is the approval necessary to market a vaccine.

Before conducting studies in humans, laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and efficacy of the biologic candidate, must be conducted. Preclinical toxicology studies in animals must be conducted in compliance with FDA regulations.

The results of the preclinical tests, together with manufacturing information, known as CMC, and analytical data, are submitted to the FDA as part of an IND application. Some preclinical testing may continue even after the IND application is submitted. In addition to including the results of the preclinical testing, the IND application will also include a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the first phase or phases of the clinical trial lend themselves to an efficacy determination. The IND application will automatically become effective 30 days after receipt by the FDA unless the FDA within the 30-day time period places the IND application on clinical hold because of safety concerns about the vaccine candidate or the conduct of the trial described in the clinical protocol included in the IND application. The IND application sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. Submission of an IND application therefore may or may not result in FDA authorization to begin a clinical trial.

All clinical trials for new drugs and biologics must be conducted under the supervision of one or more qualified principal investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. They must be conducted under protocols detailing, among other things, the objectives of the applicable phase of the trial, dosing procedures, research subject selection, exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND application, and progress reports detailing the status of the clinical trials must be submitted to the FDA annually. Sponsors must also report to the FDA within specified timeframes, serious and unexpected adverse reactions, any clinically significant increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator's brochure or any findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the vaccine candidate. An IRB at each institution participating in the clinical trial must review and approve the protocol before a clinical trial commences at that institution, approve the information regarding the trial and the consent form that must be provided to each research subject or the subject's legal representative and monitor the trial until completed.

Clinical trials are typically conducted in three sequential phases, but the phases may overlap, and different trials may be initiated with the same candidate within the same phase of development in similar or differing patient populations.

- Phase 1: Clinical trials may be conducted in a limited number of patients or healthy volunteers, as appropriate. The vaccine or antibody is initially tested for safety and immunogenicity.
- Phase 2: The vaccine or antibody is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- Phase 3: Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may also be made a condition to approval of the BLA. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND application safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human subjects or any clinically relevant increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND application safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients.

Assuming successful completion of all required testing in accordance with applicable regulatory requirements, the results of the preclinical studies and clinical trials, together with other detailed information, including information on the manufacture and composition of the vaccine candidate, are submitted to the FDA as part of a BLA requesting approval to market the vaccine candidate for a proposed indication or indications. The BLA must include all relevant data available from preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's CMC and proposed labeling, among other things. Under the Prescription Drug User Fee Act, the fees payable to the FDA for reviewing a BLA, as well as annual program user fees for approved products, can be substantial but are subject to certain limited deferrals, waivers and reductions that may be available. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication. Each BLA submitted to the FDA for approval is reviewed for administrative completeness and reviewability within 60 days following receipt by the FDA of the application. If the BLA is found complete, the FDA will file the BLA, triggering a full review of the application. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission. The FDA's established goal is to review 90% of priority BLAs within six months after the application is accepted for filing and 90% of standard BLAs within 10 months of the acceptance date, whereupon a review decision is to be made. Priority review will direct overall attention and resources to the evaluation of applications for products that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis or prevention of serious conditions. In both standard and priority reviews, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may also convene an advisory committee to provide clinical insight on application review questions. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions regarding approval.

Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. 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, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response Letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response Letter without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. In issuing the Complete Response Letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor the safety or efficacy of a product.

If a product is approved, the approval may impose limitations on the uses for which the product may be marketed, may require that warning statements be included in the product labeling, may require that additional studies be conducted following approval as a condition of the approval and may impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a Risk Evaluation and Mitigation Strategy, or REMS, or otherwise limit the scope of any approval. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine 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. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. In most cases, the FDA must approve a BLA supplement or a new BLA before a product may be marketed for other uses or before specific manufacturing or other changes may be made to the approved product. As a condition of approval, the FDA may also require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies. Also, product approvals may be withdrawn if compliance with regulatory standards is not maintained or if safety or manufacturing problems occur following initial marketing. In addition, new government requirements may be established that could delay or prevent regulatory approval of our vaccine under development.

Both before and after the FDA approves a product, the manufacturer and the holder or holders of the BLA for the product are subject to comprehensive regulatory oversight. For example, quality control and manufacturing procedures must conform, on an ongoing basis, to cGMP requirements, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to spend time, money and effort to maintain cGMP compliance.

Post-Approval Requirements

Any drug products manufactured or distributed by us or our partners pursuant to FDA approvals will be subject to pervasive and continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the drug, providing the FDA with updated safety and efficacy information, distribution requirements, complying with individual electronic records and signature requirements and complying with FDA promotion and advertising requirements. Once approval is granted, the FDA may withdraw the approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. After approval, most changes to the approved product, such as adding new indications, specific manufacturing changes and additional labeling claims, are subject to further FDA review and approval. Biologic manufacturers, their subcontractors and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP regulations and other laws and regulations. Changes to the manufacturing process are strictly regulated and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

Discovery of previously unknown problems, including adverse events of unanticipated severity or frequency, or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal or suspension of an approval or license, clinical holds, warning or untitled letters, product recalls, product seizures, safety alerts, Dear Healthcare Provider letters, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, consent decrees or civil or criminal penalties.

The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market and imposes requirements and restrictions on drug manufacturers, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or inpatient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities and promotional activities involving the internet. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict the manufacturer's communications on the subject of off-label use of their products.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including biological products, are required to register and disclose certain clinical trial information on clinicaltrials.gov. Information related to the product, patient population, phase of the investigation, trial sites and investigators and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Additional Controls for Biologics

To help reduce the increased risk of the introduction of adventitious agents, the PHS Act emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHS Act also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

After a BLA is approved, the product will also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform specific tests on each lot of the product before it is released for distribution. If the product is subject to an official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of the manufacture of the lot and the results of all the manufacturer's tests performed on the lot. The FDA may also perform specific confirmatory tests on lots of some products, such as vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency and effectiveness of biological products. As with drugs, after approval of biologics, manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing and are subject to periodic inspection after approval.

Expedited Development and Review Programs

A sponsor may seek approval of its vaccine candidate under programs designed to accelerate the FDA's review and approval of new drugs and biological products that meet certain criteria. Specifically, new drugs and biological 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. For a fast-track product, the FDA may consider sections of the BLA for review on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application. A fast-track designated vaccine candidate may also qualify for priority review, under which the FDA sets the target date for FDA action on the BLA at six months after the FDA accepts the application for filing. Priority review is granted when there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious disease or condition. If criteria are not met for priority review, the application is subject to the standard FDA review period of 10 months after FDA accepts the application for filing. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Under the accelerated approval program, the FDA may approve a BLA on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Post-marketing studies or completion of ongoing studies after marketing approval are generally required to verify the biologic's clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. FDA may withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product.

In addition, a sponsor may seek FDA designation of its vaccine candidate as a breakthrough therapy if the vaccine candidate is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If the FDA designates a product as a breakthrough therapy, it may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the therapy; providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and considering alternative clinical trial designs when scientifically appropriate, which may result in smaller trials or more efficient trials that require less time to complete and may minimize the number of patients exposed to a potentially less efficacious treatment. Breakthrough therapy designation comes with all of the benefits of fast-track designation.

Even if a drug or biologic qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for FDA review or approval will be shortened.

Biosimilars and Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, 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. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical trial or trials. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that 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. 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 that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact and implementation of the BPCIA are subject to significant uncertainty.

In the United States, there has been and continues to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval, restrict or regulate post-approval activities and affect the profitable sales of our vaccine and monoclonal antibody.

Among policymakers and payors in the United States, 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, in March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both the government and private insurers and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things: (1) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations; (2) created a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics that are inhaled, infused, instilled, implanted or injected; (3) established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in specific government healthcare programs; (4) expanded the eligibility criteria for Medicaid programs; (5) 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; (6) created a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and (7) established a Center for Medicare & Medicaid Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drugs.

There have been judicial and political challenges to certain aspects of the ACA. By way of example, the Tax Cuts and Jobs Act of 2017, or the Tax Act, was signed into law and included a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on specific individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." The Bipartisan Budget Act of 2018, among other things, amends the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Prior to the U.S. Supreme Court ruling on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is also unclear how the Supreme Court ruling, other such litigation and the healthcare reform measures of the Biden administration will impact the ACA and our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. For example, on August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, resulted in aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the Infrastructure Investment and Jobs Act, will remain in effect through 2031, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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, presidential executive orders and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, President Trump announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, the FDA concurrently released a final rule and guidance in September providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. As a result of litigation challenging the Most Favored Nation model, on December 27, 2021, CMS published a final rule that rescinded the Most Favored Nation model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of other reform initiatives. However, it is unclear whether these or similar policy initiatives will be implemented in the future. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on specific product access and marketing cost disclosure and transparency measures and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Federal and state healthcare laws and regulations restrict certain business practices in the biopharmaceutical industry, including anti-kickback and false claims laws and regulations, data privacy and security laws and regulations and transparency laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, individuals or entities from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in-kind to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation.

The federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, prohibit, among other things, any individual or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. Private individuals, commonly known as “whistleblowers,” can bring civil False Claims Act qui tam actions, on behalf of the government and such individuals and may share in amounts paid by the entity to the government in recovery or settlement. In addition, the government may assert that 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 civil False Claims Act.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal civil and criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program. Similar to 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. In addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, imposes specific requirements relating to the privacy, security and transmission of protected health information on HIPAA covered entities, which include certain healthcare providers, health plans and healthcare clearinghouses and their business associates and covered subcontractors who conduct certain activities for or on their behalf involving protected health information on their behalf.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, with specific exceptions, to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members.

Similar state, local and foreign healthcare laws and regulations may also restrict business practices in the pharmaceutical industry, such as state anti-kickback and false claims laws, which may apply to business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by patients themselves; state 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 healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information or which require tracking gifts and other remuneration and items of value provided to physicians, other healthcare providers and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state and local laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure compliance with applicable healthcare laws and regulations can involve substantial costs. Violations of healthcare laws can result in significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other U.S. healthcare programs, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of operations.

Foreign Regulation

In addition to regulations in the United States, we expect to be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our vaccine. Whether or not we obtain FDA approval for a vaccine candidate, we must obtain approval from the comparable regulatory authorities of foreign countries or economic areas, such as the European Union, before we may commence clinical trials or market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Certain countries outside of the United States have a process that requires the submission of a clinical trial application, much like an IND prior to the commencement of human clinical trials. In Europe, for example, a clinical trial application, or CTA, must be submitted to the competent national health authority and to independent ethics committees in each country in which a company intends to conduct clinical trials. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed in that country. In all cases, the clinical trials must be conducted in accordance with GCPs and other applicable regulatory requirements.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

Under European Union regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure is compulsory for medicinal products produced by biotechnology or those medicinal products containing new active substances for specific indications such as the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, viral diseases and designated orphan medicines, and optional for other medicines which are highly innovative. Under the centralized procedure, a marketing application is submitted to the European Medicines Agency, or EMA, where it will be evaluated by the Committee for Medicinal Products for Human Use, and a favorable opinion typically results in the grant by the European Commission of a single marketing authorization that is valid for all European Union member states within 67 days of receipt of the opinion. The initial marketing authorization is valid for five years, but once renewed is usually valid for an unlimited period.

To market a medicinal product in the European Economic Area, or EEA, (which is comprised of the 28 Member States of the EU plus Norway, Iceland and Liechtenstein), we must obtain a Marketing Authorization, or MA. There are two types of marketing authorizations:

- The Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use of the EMA, and which is valid throughout the entire territory of the European Economic Area, or EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced therapy products and medicinal products containing a new active substance indicated for the treatment certain diseases, such as AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU; and
- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in the various Member States through the Decentralized Procedure.

Under the above-described procedures, before granting the MA, the EMA, or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Additional Regulation

We are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential federal, state or local regulations. These and other laws govern our use, handling and disposal of various biological and chemical substances used in, and waste generated by our operations. Our research and development involve the controlled use of hazardous materials, chemicals, bacteria and viruses. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources.

There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biological products, government control and other changes to the healthcare system of the United States. It is uncertain what legislative proposals will be adopted or what actions federal, state or private payers for medical goods and services may take in response to any healthcare reform proposals or legislation. We cannot predict the effect medical, or healthcare reforms may have on our business, and no assurance can be given that any such reforms will not have a material adverse effect.

Privacy and Data Protection Laws

We are also subject to laws and regulations in non-U.S. countries covering data privacy and the protection of health-related and other personal information. EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. Laws and regulations in these jurisdictions apply broadly to the collection, use, storage, disclosure, processing and security of personal information that identifies or may be used to identify an individual, such as names, contact information and sensitive personal data such as health data. These laws and regulations are subject to frequent revisions and differing interpretations and have generally become more stringent over time.

As of May 25, 2018, Regulation 2016/676, known as the General Data Protection Regulation, or GDPR, replaced the Data Protection Directive with respect to the processing of personal data in the European Union. The GDPR imposes many requirements for controllers and processors of personal data, including, for example, higher standards for obtaining consent from individuals to process their personal data, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention and secondary use of information, increased requirements pertaining to health data and pseudonymized (i.e., key-coded) data and additional obligations when we contract third-party processors in connection with the processing of the personal data. The GDPR allows EU member states to make new laws and regulations further limiting the processing of genetic, biometric, or health data. Failure to comply with the requirements of GDPR and the applicable national data protection laws of the EU member states may result in fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties.

Employees and Human Capital

We currently have three officers and do not intend to have any full-time employees prior to the completion of the IPO. Members of our management team intend to devote as much of their time as they deem reasonably necessary to our affairs. The management team works with the Compensation Committee to design and implement incentive compensation programs that are designed to allow Alopexx to attract, develop and retain personnel. We currently do not have any full-time officers or employees dedicated solely to human resources.

Properties and Facilities

We currently maintain our executive offices at 186 Alewife Brook Pkwy #1068, Cambridge, MA 02138, and our telephone number is 617-780-1598. We consider our current office space adequate for our current operations.

Legal Proceedings

From time to time, we may be involved in legal proceedings or subject to claims incident to the ordinary course of business. Regardless of the outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

Material Transfer Agreement with Xenothera and resulting litigation

In 2018, Alopexx signed a Material Transfer Agreement (“MTA”) with Xenothera, a French biotechnology company that had developed genetically modified pigs capable of producing humanized antisera. Xenothera was interested to see if vaccination with vaccine AV0328 could induce anti-PNAG antisera in their pigs. Alopexx provided the vaccine at no cost and Xenothera did a preliminary vaccination study in their pigs at their expense. The MTA stated that those activities could not be considered a commitment by Alopexx to license its vaccine to Xenothera.

Although the MTA expired in 2019, Xenothera continued to develop the vaccine AV0328-induced antisera. Their activities were outside the scope of the MTA and occurred without Alopexx’s prior knowledge or consent. After learning the full extent of those activities in May 2022, Alopexx formally requested that Xenothera halt all work referable to AV0328 and provide Alopexx with a full accounting of the activities, including any results of trials. Instead of responding to the information request, Xenothera filed a lawsuit against Alopexx on June 8, 2022 in the Commercial Court of Nantes in Nantes, France claiming that their activities, performed under the MTA in 2018, obligated Alopexx to, among other things, provide a license to Xenothera for the vaccine AV0328 or in the alternative pay monetary damages of €120,000,000. The current status of Xenothera’s litigation against Alopexx is that the case was referred to the Paris Judicial Court on June 20, 2023, and since then, Alopexx has been waiting for a procedural timetable to be set.

Xenothera never obtained a license from Alopexx for use of its proprietary vaccine AV0328. In addition, Alopexx has never provided either verbally or in writing any commitment to grant a license to Xenothera.

Management believes that Xenothera’s lawsuit has no merit and intends to vigorously defend itself against the lawsuit. In addition, Alopexx has retained Covington & Burling, LLP and initiated litigation on July 6, 2022 in United States District Court, District of Massachusetts seeking a declaratory judgment, and associated damages, that Xenothera has no right to use Alopexx’s proprietary vaccine without Alopexx’s consent and damages for Xenothera’s breach of the MTA. That lawsuit remains pending. Alopexx has retained special counsel in France in addition to the United States to protect its interests.

MANAGEMENT

Directors, Director Nominees and Executive Officers

Our directors, director nominees and officers are as follows:

Name	Age	Position
Executive Officers		
Daniel R Vlock, MD	72	President, Chief Executive Officer and Director
Thomas T. Thomas	67	Chief Financial Officer
Christine de los Reyes, PharmD, MBA	70	Chief Business Officer, Chief Commercialization Officer
Non-Employee Directors		
Gail H. Cassell, PhD	78	Director Nominee
Richard Cohen ⁽¹⁾	73	Director Nominee
Ann MacDougall ⁽²⁾⁽³⁾	70	Director Nominee
William W. Chin, MD	76	Senior Strategic Advisor, Director Nominee

(1) Chair of the audit committee.

(2) Chair of the compensation committee.

(3) Chair of the nominating and governance committee.

Executive Officers and Directors

Daniel R. Vlock, MD – Co-Founder, President, Chief Executive Officer, Director

Dr. Vlock brings extensive pharmaceutical industry and academic experience in pharmaceutical drug development. As CEO of Alopexx Pharmaceuticals (founded in 2006), he and Dr. Gerald Pier developed F598, a human monoclonal antibody directed against S. aureus. Vaccine AV0328 was also developed by Drs. Vlock and Pier. Dr. Vlock has held his current position in Alopexx since 2021 and he has held similar positions in Alopexx’s predecessor companies.

Previously, Dr. Vlock held senior-level medical and research positions at GPC Biotech, Inc. (2004 to 2005), Pharmacia Corporation (2002 to 2004), Ethicon Endo-Surgery (1999 to 2002) (a subsidiary of Johnson & Johnson Company), and Boehringer Ingelheim Pharmaceuticals, Inc. (1996 to 1999), where he was involved in the development of numerous oncology drugs, medical devices and drug-device combinations. While at Pharmacia he ran the Celebrex Oncology Group. While at other companies he ran programs which successfully developed and introduced monoclonal antibodies into clinical trials. Prior to moving to industry, Dr. Vlock was on the faculty at Harvard Medical School, University of Pittsburgh School of Medicine and Yale University School of Medicine, where he led laboratory and clinical programs in tumor immunology.

Dr. Vlock received his A.B. from Cornell University and an M.D. from Baylor College of Medicine. He completed a research fellowship in clinical immunology at Baylor College of Medicine, an internship and medical residency at Temple University Hospital and a senior medical residency and fellowship in medical oncology at Yale New Haven Hospital.

Dr. Vlock’s qualifications to serve on the board include his (i) familiarity with the Company and its business; (ii) experience in the industry, and (iii) his academic experience in medicine, immunotherapy and clinical studies.

Thomas T. Thomas – Chief Financial Officer

Thomas T. Thomas, our CFO, has over 35 years of experience as a financial executive, consultant and entrepreneur in biotechnology, packaged goods, wine production, financial services and non-profit organizations. Since 2016, Thomas served as an Independent Director on the Board of Opiant Pharmaceuticals (NASDAQ: OPNT) as Chairman of the Audit Committee and as a member of the Compensation Committee and served on its Nomination and Governance Committee until March 2023. He is the former Interim Chief Executive Officer of the Stupski Foundation (2009 to 2010). He joined the foundation in 2009 as its Chief Financial Officer and in 2010 was promoted to Chief Operating Officer and subsequently asked to serve as the Foundation’s interim CEO.

Prior to joining the Stupski Foundation, Thomas spent twelve years (1994 to 2006) at Genentech, Inc, a bio-pharmaceutical company, in various financial roles serving as the company's Corporate Treasurer from 2001 through 2006. His executive responsibilities included Treasury Operations and Investments, Corporate Finance, Global Procurement, Enterprise Risk Management and Insurance, Business Continuity and Real Estate. As Treasurer, he led Genentech's Corporate Investment Program, implemented and led an Enterprise Risk Management program to holistically assess and mitigate company risks, partnered with Business Development in the financing of Genentech's Drug Collaborations and also executed large corporate transactions in support of Genentech's growth, including a \$2 billion global public debt offering and the financing and construction of Genentech's 870,000 sq. ft. South Campus Research Center Expansion.

Earlier in his career, Thomas was a Manager of Financial Strategy with Del Monte Foods from 1990 to 1994, and he began his career at GE Capital Corporation from 1988 to 1989, as an Analyst in the Corporate Finance Group, which focused on leveraged buyouts and bankruptcy financing for public and private corporations.

From 2018 to 2021, Thomas served on the Board of Advisors for Symthera, LTD, a private preclinical biotechnology company. Thomas has also served on the boards of the Cancer Prevention Institute of California, San Francisco Security Analysts and Hospitality House. Since 2013, has served as a Mentor in the Ivy Exec Mentor Network.

Thomas is a Chartered Financial Analyst (CFA). He received his MBA from the University of Cincinnati College of Business, where he was a Graduate Fellow, and he has a Bachelor of Music in Voice Performance from the University of Cincinnati College-Conservatory of Music.

Christine de los Reyes, Pharm.D. – CBO/CCO

Christine de los Reyes has over 30 years of pharmaceutical experience and most recently was founder and Managing Director of Biotech Partnering Solutions (2007 to present), a business development consulting firm that advises life science companies on partnering strategy, search for potential partners, coordination of technical evaluation and due diligence, deal structure and transaction negotiation. In this capacity, she has had numerous clients and executed several licensing transactions. Christine also spent 12 years on the advisory board of the Neurotechnology Industry Organization, a non-profit trade association that represents companies involved in neuroscience, academic neuroscience research centers and brain-illness advocacy groups. Dr. Reyes has been the Chief Business Officer/Chief Commercial Officer for Alopecx since June 2021.

Prior to starting her own company, she was Executive Director of Licensing & Development at Pfizer (1995 to 2007), where she spent twelve years in its business development group with a focus on in-licensing in several therapeutic areas including neuroscience, infectious diseases, immunology, dermatology, and ophthalmology. Christine also held senior positions in Pfizer's US and International medical and marketing groups for six years.

Prior to working at Pfizer, she was an Associate Professor at The University of Texas, College of Pharmacy.

Ms. de los Reyes received her Doctorate in Clinical Pharmacy at the University of Texas, her MBA at St. Joseph's University and a Bachelor of Science at Wayne State University.

Director Nominees

Four additional individuals have agreed to serve on our board of directors as independent directors following the completion of this offering.

Gail H. Cassell, Ph.D., D.Sc. (Hon.) - Director Nominee

Dr. Cassell is Senior Lecturer, Department of Global Health and Social Medicine, Harvard Medical School. She is a member of the National Academy of Medicine (NAM) of the National Academy of Sciences, served two terms on the governing board and founded the Forum on Drug Discovery, Development and Translation. She is former Vice President for Scientific Affairs and Distinguished Lilly Research Scholar of Infectious Diseases and former Vice President for Infectious Diseases Drug Discovery and Development of Eli Lilly and Company. Prior to moving to Lilly in 1997, Dr. Cassell was the Charles H. McCauley Professor and Chair of the Department of Microbiology at the University of Alabama Schools of Medicine and Dentistry at Birmingham, a department which ranked first in research funding from the National Institutes of Health (NIH) during the decade of her leadership. She obtained her B.S. from the University of Alabama in Tuscaloosa and in 1993 was selected by that institution as one of the top 31 female graduates of the Centennial following the admission of the first female to the University in 1893. She obtained her Ph.D. in Microbiology from the University of Alabama at Birmingham and was selected as its 2003 Distinguished Alumnus. She is a past President of the American Society for Microbiology and is currently serving her second elected term on the Board of Governors of the American Academy of Microbiology.

Dr. Cassell is an elected lifetime member of the U.S. Council on Foreign Relations. She was named to the original Board of Scientific Councilors of the Center for Infectious Diseases, Centers for Disease Control (CDC) and served as Chair of the Board. She has served on the Advisory Board of the Director of NIH, Director of CDC, and the Secretary of Health and Human Services Advisory Council of Public Health Preparedness, the Food and Drug Administration's (FDA) Science Board, the Advisory Committee to the Commissioner. She was a member of the NIH Science Management Board and Advisory Councils of the National Institute of Allergy and Infectious Diseases and the Fogarty International Center of NIH. For two decades she was a member of the Steering Committee of the U.S.-Japan Cooperative Medical Sciences Program responsible for advising the respective governments on joint research agendas, (U.S. State Department/Japan Ministry of Foreign Affairs). She was instrumental in establishment of the U.S./Russia Cooperative Medical Sciences and Training Program under the Bilateral Presidential Commission in 2009 which was a collaboration involving NIH, the US National Academy of Sciences, the Russian Academy of Sciences, and the Russian Academy of Medical Sciences. In 2012, the American Society for Microbiology and the Federation of European Microbiology Societies established the Mäkelä-Cassell Exchange Program for pioneering international engagement for young scientists.

She has served on several editorial boards of scientific journals and has authored over 350 articles and book chapters. She has received national and international awards for her research in infectious diseases, including: two honorary degrees; the CDC Honor Award in Public Health for exceptional leadership and contributions in the development and implementation of CDC's Emerging Infectious Disease Plan 1997; a Citation from the FDA Commissioner for her role as Chair of the review of science and technology at the FDA and the Report FDA: Science and Mission at Risk 2008.

Dr. Cassell's qualifications to serve on the board include (i) her scientific expertise in microbiology and (ii) extensive industry and business experience in developing anti-infectives.

Richard Cohen – Director Nominee

Mr. Cohen has been the President of Richard M Cohen Consultants since 1996, a company providing financial consulting services to both public and private companies. From March 2012 to July 2015, he was the Founder and Managing Partner of Chord Advisors, a firm providing outsourced CFO services to both public and private companies. From May 2012 to August 2013, he was the Interim CEO and member of the Board of Directors of CorMedix Inc. (NYSE: CRMD) a biotech firm developing a catheter lock solution and its successful obtaining of a CE mark in Europe. From July 2008 to August 2012, Mr. Cohen was a member of the Board and Chair of the Audit Committee of Rodman and Renshaw, a publicly traded (NASDAQ: RODM) investment banking firm.

From 2006 to the present, he is a member of the Board and the Chair of the Audit Committee of privately held Helix BioMedix currently developing a topical cream to combat skin lesions and cancers in young children. Mr. Cohen is currently a member of the Boards and Audit Chair for Ondas, Great Elm Capital and Direct Digital Holdings. Mr. Cohen holds a BS with honors from the University of Pennsylvania (Wharton), an MBA from Stanford University and a CPA from New York State (inactive).

Mr. Cohen's qualifications to serve on the board include (i) his extensive CFO services experience and (ii) extensive experience serving as a director and Audit Chair of other publicly traded companies.

Ann MacDougall, JD – Director Nominee

Ms. MacDougall has more than 20 years of service with public and private boards as member, chair advisor and executive management.

Previously, she served as a PwC partner (1994 - 2007), including as US General Counsel and member of the 10-person US Management Committee. After a stint in Paris as PwC's Global Deputy General Counsel, she shifted her focus away from law, first as Chief Operating Officer of Acumen Fund (2007 - 2012), a global impact investment fund focused on goods and services for low-income consumers, then as President of Encore.org (2014 - 2017), a national non-profit that promotes second act careers.

Currently, she is Chair of the Board at Mazzetti, engineering company operating across the US, India and Africa, since February 2024. Additionally, she served as a board director of Opiant Pharmaceuticals, Inc. (NASDAQ: OPNT), a public company focused on addiction and overdose, where she chaired the Compensation Committee, served on the Governance and Nominations Committee and also served on the Audit Committee, from April 2016 to March 2023. In 2020, she completed her service as Interim Chair of the Board at Progenics Pharmaceuticals, Inc., a public company focused on cancer detection and diagnosis. She is an advisor to Nuvo Assets Inc, a rare earths and metals company and is on the Investment Committee of the Builders Fund.

In her volunteer capacity, she serves as a board member of Strong Minds, a non-profit tackling mental illness in Africa. She is on the Advisory Boards of Equality Now, a global women's rights non-organization, The Harvard Advanced Leadership Coalition, and the Global Leadership Council of the World Research Institute, a sustainability research group working with governments and large companies across the world.

Ms. MacDougall's qualifications to serve on the board include (i) her management, operational, governance, Environment, Social and Governance and legal experience and (ii) her prior experience on the boards as board chair and on governance, audit and compensation committees.

William Chin, MD –Director Nominee

Dr. Chin is the Bertarelli Professor of Translational Medical Science and Professor of Medicine Emeritus at Harvard Medical School. He is currently advising a number of startup biotech companies and serves on the Boards of Regenacy Pharmaceuticals and Deck Therapeutics. Dr. Chin has been a Director of Alopexx since June 2021. He has also acted as a strategic advisor in a non-executive capacity for the Company.

He was EVP, Science and Regulatory Advocacy, and CMO at the Pharmaceutical Research and Manufacturers of America (PhRMA) (2013 to 2018), where he led PhRMA's efforts in science and regulatory advocacy in the drug discovery and development ecosystem. Prior to PhRMA, he was the Executive Dean for Research at Harvard Medical School (2010 to 2013). Before that, he was at Eli Lilly and Company, last as Senior Vice President for Discovery Research and Clinical Investigation.

Dr. Chin is a Harvard-trained endocrinologist and longstanding faculty member with an extensive bibliography of over 300 papers, chapters and books. During his more than 25 years on the Harvard Medical School faculty, he was Chief of the Genetics Division in the Department of Medicine at the Brigham and Women's Hospital, a Howard Hughes Medical Institute investigator and Professor of Medicine.

As a pioneering molecular endocrinologist, Dr. Chin embraced the early use of emerging DNA technology to make important discoveries regarding the structure, function and regulation of hormone genes. He has been honored with numerous awards for research, mentorship and leadership. He received his A.B. in chemistry from Columbia University and his M.D. from Harvard Medical School.

Dr. Chin's qualifications to serve on the board include his (i) domain expertise and (ii) management experience in both industry and academics.

Advisors

Dr. Gerald B Pier is a scientific advisor to our Company in a non-executive position. His research interests focus on the definition of protective immune mechanisms relevant to microbial infections that can lead to the development of vaccines and passive immunotherapies, along with basic studies on mechanisms whereby bacterial pathogens cause infections. His laboratory was responsible for the development and pre-clinical assessment of both the vaccine targeting PNAG and monoclonal antibody F598, the antibody being developed by Alopexx.

He has over 330 peer-reviewed publications and more than 30 patents. He has had multiple successful partnerships with pharmaceutical companies that were an outgrowth of his research. His laboratory developed the synthetic PNAG-conjugate vaccine that Alopexx has brought to Phase 1 trials and has produced panels of fully human monoclonal antibodies derived originally from circulating B cells of vaccinated or infected individuals. These have been in phase 1 and 2 trials for use in passive therapy against *Pseudomonas aeruginosa* and the broad range of pathogens that express the PNAG antigen.

Dr. Pier received his B.S. from University of the Pacific and a Ph.D. in Microbiology from the University of California, Berkeley. After completing a post-doctoral Fellowship in Infectious Diseases at Walter Reed Army Institute of Research in 1978 he joined the faculty at Harvard Medical School, where he currently is a Professor of Medicine in the fields of Microbiology and Immunology.

Number and Terms of Office of Officers and Directors

Upon the effectiveness of the registration statement of which this prospectus forms a part, we expect that our board of directors will consist of five members. Our board of directors will be divided into three classes with only one class of directors being elected in each year and each class (except for those directors appointed prior to our first annual meeting of stockholders) serving a three-year term. The term of office of the first class of directors, consisting of William Chin, will expire at our first annual meeting of stockholders. The term of office of the second class of directors, consisting of Richard Cohen and Gail Cassell will expire at the second annual meeting of stockholders. The term of office of the third class of directors, consisting of Daniel Vlock and Ann MacDougall will expire at the third annual meeting of stockholders.

In accordance with 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 directors present or by a majority of the holders of our founder shares.

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 persons to the offices set forth in our bylaws as it deems appropriate. Our bylaws will provide that our officers may consist of a Chief Executive Officer, a President, a Chief Financial Officer, Vice Presidents, a Secretary, Assistant Secretaries, a Treasurer, Assistant Treasurers and such other offices as may be determined by the board of directors.

We expect that any additional directorships resulting from an increase in the number of directors will be distributed among the three classes. The division of our board of directors into multiple classes with staggered terms may delay or prevent a change of our management or a change in control.

Director Independence

Upon completion of this offering, our independent directors will be the following:

Name	Position
Gail H. Cassell, PhD	Director
Richard Cohen	Director, Audit Committee Chair
Ann MacDougall	Director, Compensation Committee Chair, Nominating and Corporate Governance Committee Chair

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 will be entirely composed of independent directors meeting the NYSE American’s additional requirements applicable to members of the audit committee. Our independent directors will have regularly scheduled meetings at which only independent directors are present.

Executive Officer and Director Compensation

After the completion of this offering, directors or members of our management team may be paid consulting or management fees or other compensation.

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 will have two standing committees: an audit committee and a compensation committee. Subject to phase-in rules and a limited exception, 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 NYSE American rules require that the compensation committee of a listed company be comprised solely of independent directors.

Audit Committee

Upon the effectiveness of the registration statement of which this prospectus forms a part, we will establish an audit committee of the board of directors. 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 will be chaired by Richard Cohen and its other members will be Ann MacDougall and Gail Cassell. Our board of directors will confirm that audit committee members are independent under the NYSE American listing standards and applicable SEC rules.

Each member of the audit committee will be financially literate. Mr. Cohen qualifies as an “audit committee financial expert” as defined in applicable SEC rules and has accounting or related financial management expertise. We will adopt an audit committee charter, which will detail 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

Upon the effectiveness of the registration statement of which this prospectus forms a part, we will establish a compensation committee of the board of directors. 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 will initially be Ann MacDougall, and the other members will be Richard Cohen and William Chin. Our board of directors will determine that all of our compensation committee members are independent under the NYSE American listing standards and applicable SEC rules.

We will adopt a compensation committee charter, which will detail 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 will also provide 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 nominating and corporate governance committee will consist of three members. The chair of our nominating and corporate governance committee will be Ann MacDougall, and the other members will be Richard Cohen and Gail Cassell. Our board of directors has determined that each member of the nominating and corporate governance committee is independent under the listing standards of the NYSE American.

Specific responsibilities of our nominating and corporate governance committee include:

- 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.

Our nominating and corporate governance committee will operate under a written charter, to be effective prior to the closing of this offering, that satisfies the applicable listing standards of the NYSE American.

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 <https://www.alopoexx.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.

Controlled Company Status

Following the completion of this offering, we will be a "controlled" company within the meaning of the corporate governance rules of the NYSE American. Although we do not intend to rely on the exemptions from these corporate governance requirements, if we do rely on such exemptions in the future, you will not have the same protections afforded to stockholders of companies that are subject to these corporate governance requirements. In the event that we cease to be a "controlled company" and our shares continue to be listed on the NYSE American, we will be required to comply with these provisions within the applicable transition periods.

EXECUTIVE COMPENSATION

The following table summarizes all compensation recorded by us in each of the fiscal years ended December 31, 2024, and 2023 for (i) our principal executive officers, and (ii) our two next most highly compensated executive officers other than our principal executive officer and whose total compensation exceeded \$100,000 during our last completed fiscal year (collectively our Named Executive Officers or "NEOs").

Summary Compensation Table

Name	Fiscal Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards (\$)(1)	All Other Compensation (\$)	Total (\$)
Daniel Vlock	2024	—	—	—	—	—	—
<i>President and Chief Executive Officer</i>	2023	—	—	—	189,660	—	189,660
Thomas T. Thomas	2024	366,667	—	—	—	—	366,667
<i>Chief Financial Officer</i>	2023	341,667	—	—	113,796	—	455,463
Christine de los Reyes	2024	137,500	—	—	—	—	137,500
<i>Chief Business Officer and Chief Marketing Officer</i>	2023	125,000	—	—	75,864	—	200,864

- (1) Represents the aggregate grant date fair values of awards granted during the fiscal years ended December 31, 2024 and 2023 under ASC Topic 718, which is calculated as of the grant date using a Black-Scholes option-pricing model. Accordingly, the dollar amounts listed do not necessarily reflect the dollar amount of compensation that may be realized by our executive officers. For information on the valuation assumptions with respect to option grants made during the fiscal year ended December 31, 2023, refer to Note 8 "Employee Incentive Plan" in our financial statements in this prospectus.

Following our initial public offering, the Compensation Committee will review and approve or ratify the compensation to our NEOs.

Corporate Incentive Bonus Plan

We will develop a Corporate Incentive Bonus Plan that provides for the opportunity to earn cash bonuses based on performance against corporate and department goals, subject to the approval of our Compensation Committee.

Employment Agreements

We have entered into agreements with our Chief Executive Officer, Chief Financial Officer and Chief Business Officer. In addition, each of our named executive officers has executed our standard proprietary information and invention assignment agreement.

Any potential payments and benefits due upon a termination of employment or change in control are described and quantified below in the subsection entitled “—Potential Payments upon Termination or Change in Control.”

Employment Agreement with Daniel R. Vlock

The Company entered into an employment agreement with Daniel R. Vlock on December 12, 2024 pursuant to which the Company engaged Mr. Vlock to serve as CEO. Pursuant to the terms of the employment agreement, Mr. Vlock will be paid an annual base salary of \$525,000 effective from when the Company consummates its initial public offering or obtains a private equity investment of more than \$10,000,000. Mr. Vlock’s employment is for an initial period of 3 years, which shall be automatically renewed annually unless terminated.

Mr. Vlock is also entitled to an annual bonus, as decided by the Compensation Committee and shall be entitled to participate in the Alopexx, Inc., 2021 Employee, Director and Consultant Equity Incentive Plan.

Mr. Vlock’s employment with the Company will continue in accordance with the terms of the employment agreement, unless it is terminated by one of the following events (and subject to the satisfaction of certain conditions outlined in the employment agreement): (i) by the Company for Cause (as defined in the employment agreement) or without Cause; (ii) by Mr. Vlock upon thirty (30) days’ prior written notice to the Company; (iii) immediately upon Mr. Vlock’s death or termination by the Company due to Disability (as defined in the employment agreement) or (iv) by the Company with written notice from the Company upon the failure to consummate an IPO.

Upon a termination of Mr. Vlock’s employment for any reason, Mr. Vlock will be paid (A) any unpaid base salary through the date of termination of employment (the “Termination Date”); (B) reimbursement for any unreimbursed reasonable and necessary business expenses incurred through the Termination Date; (C) any accrued but unused vacation time in accordance with Company policy; and (D) all other accrued payments, benefits or fringe benefits to which Mr. Vlock is entitled under the terms of any applicable compensation arrangement or benefit, equity or fringe benefit plan or program or grant or the employment agreement. In addition, upon a termination of Mr. Vlock’s employment for any reason, Mr. Vlock agrees to promptly resign from any position as an officer, director or fiduciary of the Company or any of its affiliates and to execute any documentation necessary to effectuate such resignations.

Further, if Mr. Vlock is terminated pursuant to a change in control of the Company (as defined in the employment agreement), Mr. Vlock shall be entitled to (i) 150% payment of his base salary; (ii) 150% payment of Mr. Vlock’s most recently paid (or earned if approved by the Compensation Committee but not yet paid) annual bonus; (iii) eighteen months (18) continuation of health benefits; and (iv) full vesting of all stock options, other equity-based awards and shares of the Company’s stock granted or awarded to Mr. Vlock pursuant to any Company compensation or benefit plan or arrangement that have not yet vested, effective upon Mr. Vlock’s execution of a release agreement.

Employment Agreement with Thomas T. Thomas

The Company entered into an employment agreement with Thomas T. Thomas on August 30, 2021 pursuant to which the Company engaged Mr. Thomas to serve as CFO, initially as a consultant and upon consummation of the Company’s initial public offering, as an executive. Pursuant to the terms of the employment agreement, for his services Mr. Thomas will receive a consulting fee of \$100,000 (“Consulting Fee”) over a three month period with pre-paid monthly installments of \$33,333.34, renewable on a month-to-month basis.

The agreement provides Mr. Thomas with the option to defer 50% of the Consulting Fee and to convert the remaining Consulting Fee into shares of the Company’s stock prior to the pricing of the Company’s initial public offering. Upon a capital raise of more than \$25,000,000, Mr. Thomas has the option to be paid the remaining Consulting Fee in cash, provided that any amounts payable to him would not be payable until the earlier of the five business days after the Company closed its bridge financing or October 31, 2021.

After the period indicated above, Mr. Thomas’s employment as CFO would come into effect with the completion of the Company’s initial public offering, for a period of three years, unless terminated earlier in accordance with the terms of the agreement. For such employment, Mr. Thomas would be paid a base salary of \$400,00 and would be entitled to an annual bonus, as determined by the Compensation Committee.

Mr. Thomas’ employment with the Company will continue in accordance with the terms of the employment agreement, unless it is terminated by one of the following events (and subject to the satisfaction of certain conditions outlined in the employment agreement): (i) by the Company for Cause (as defined in the employment agreement) or without Cause; (ii) by Mr. Thomas upon thirty (30) days’ prior written notice to the Company; (iii) immediately upon Mr. Thomas’ death or termination by the Company due to Disability (as defined in the employment agreement) or (iv) by the Company with written notice from the Company upon the failure to consummate an IPO.

Upon a termination of Mr. Thomas’ employment for any reason, Mr. Thomas will be paid (A) any unpaid base salary through the date of termination of employment (the “Termination Date”); (B) reimbursement for any unreimbursed reasonable and necessary business expenses incurred through the Termination Date; (C) any accrued but unused vacation time in accordance with Company policy; and (D) all other accrued payments, benefits or fringe benefits to which Mr. Thomas is entitled under the terms of any applicable compensation arrangement or benefit, equity or fringe benefit plan or program or grant or the employment agreement. In addition, upon a termination of Mr. Thomas’ employment for any reason, Mr. Thomas agrees to promptly resign from any position as an officer, director or fiduciary of the Company or any of its affiliates and to execute any documentation necessary to effectuate such resignations.

Consulting Agreement with BiotechPartnering Solutions, LLC

The Company entered into a consulting agreement with BiotechPartnering Solutions, LLC on July 1, 2021, which was amended and restated on December 11, 2024 pursuant to which the Company has engaged Christine de los Reyes as a consultant for the Company, pursuant to which Reyes would provide services including advising on business development and partnering strategy, tactics and presentation, identification of potential partners and corporate strategy.

For services rendered, BiotechPartnering Solutions, LLC would be provided a monthly retainer fee of \$25,000 and an option to purchase 100,000 shares of common stock at an exercise price of \$0.06. The term of this agreement is for 12 months from the effective date, and can be renewed or extended by mutual agreement, or terminated by either party with a written notice of 30 days.

Outstanding Equity Awards at Fiscal Year-End

The following table summarizes the aggregate number of stock options and stock awards held by our named executive officers at December 31, 2024:

Name	Option Awards					Stock Awards	
	Number of Securities Underlying Unexercised Options (#)	Number of Securities Underlying Unexercised Options (#)	Option Exercise Price (\$)	Option Expiration Date		Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)
	Exercisable	Unexercisable					
Daniel Vlock	25,778	32,222 (1)	4.04	8/31/2033		—	—
Thomas T. Thomas	15,467	19,333 (2)	4.04	8/31/2033		—	—
	228,375	65,250 (3)	4.04	8/31/2033		—	—
Christine de los Reyes	10,311	12,889 (4)	4.04	8/31/2033		—	—
	130,822	37,378 (5)	4.04	8/31/2033		—	—

- (1) Represents an option to purchase 58,000 shares of Common Stock with a grant date of August 31, 2023. The vesting period of the shares underlying the option commences upon the first anniversary of the grant with respect to 33.33% of the shares granted, with remaining shares becoming vested and exercisable on a pro rata monthly basis for the following twenty-four (24) months.
- (2) Represents an option to purchase 34,800 shares of Common Stock with a grant date of August 31, 2023. The vesting period of the shares underlying the option commences upon the first anniversary of the grant with respect to 33.33% of the shares granted, with remaining shares becoming vested and exercisable on a pro rata monthly basis for the following twenty-four (24) months.
- (3) Represents an option to purchase 293,625 shares of Common Stock with a grant date of August 31, 2023. The vesting period of the shares underlying the option commences immediately as of the grant date with respect to 33.33% of the shares granted, with remaining shares becoming vested and exercisable on a pro rata monthly basis for the following twenty-four (24) months.
- (4) Represents an option to purchase 23,200 shares of Common Stock with a grant date of August 31, 2023. The vesting period of the shares underlying the option commences upon the first anniversary of the grant with respect to 33.33% of the shares granted, with remaining shares becoming vested and exercisable on a pro rata monthly basis for the following twenty-four (24) months.
- (5) Represents an option to purchase 168,200 shares of Common Stock with a grant date of August 31, 2023. The vesting period of the shares underlying the option commences immediately as of the grant date with respect to 33.33% of the shares granted, with remaining shares becoming vested and exercisable on a pro rata monthly basis for the following twenty-four (24) months.

Executive Change in Control and Severance Agreements

In connection with the completion of this offering, we will enter into employment agreements including change in control and severance terms with our named executive officers. The agreements will provide for severance benefits upon a termination of employment by the Company without “cause” or by the executive for “good reason,” each as defined in the agreements, each of which we refer to as a qualifying termination. The severance benefits will vary depending on whether the qualifying termination occurs during the period three months prior to and twelve months after a “change in control,” as defined in the agreements, which we refer to as the change in control period, or at a time other than during the change in control period.

In the event of a qualifying termination other than during the change in control period, the executive will receive a lump sum severance payment equal to the sum of (a) a number of months of base salary and (b) any bonus earned but not yet paid with respect to the year preceding the qualifying termination. The executive will also receive payment of COBRA premiums for the number of months in the severance period. Receipt of severance benefits is contingent upon the executive entering into a release of claims and allowing it to become effective.

In the event of a qualifying termination during the change in control period, the executive will receive a lump sum severance payment equal to the sum of (a) a number of months of base salary, (b) a multiple of the executive’s target bonus for the year of termination and (c) any bonus earned but not yet paid with respect to the year preceding the qualifying termination. The executive will also receive payment of COBRA premiums for the number of months in the severance period and full vesting of all time-based equity awards. The vesting of performance-based equity awards will be based on the provisions of such awards, and we have not yet granted any performance-based equity awards. Receipt of severance benefits is contingent upon the executive entering into a release of claims and allowing it to become effective.

Other Compensation and Benefits

All of our current named executive officers will be eligible to participate in our employee benefit plans, including our medical, dental, vision, life, disability and accidental death and dismemberment insurance plans, in each case on the same basis as all of our other employees. We pay the premiums for the life, disability, accidental death and dismemberment insurance for all of our employees, including our named executive officers. We generally do not provide perquisites or personal benefits to our named executive officers. We may in the future adopt profit sharing and 401(k) plans.

Employee Benefit and Stock Plans

On August 31, 2023, our Board adopted and our stockholders approved the Alopetx, Inc. 2023 Equity Incentive Plan (the “Plan”). The Plan will provide for the grant of incentive stock options, or ISOs, within the meaning of Section 422 of the Internal Revenue Code, or the Code, to employees, including employees of any parent or subsidiary, and for the grant of non-statutory stock options, or NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of awards to employees, directors and consultants, including employees and consultants of our affiliates. The material terms of the Plan are summarized below:

Authorized Shares. Initially, the maximum number of shares of our common stock that may be issued under our Plan after it becomes effective will not exceed 2,500,000 shares of our common stock.

Plan Administration. Our board of directors, or a duly authorized committee of our board of directors, will administer our Plan and is referred to as the “plan administrator” herein. Our board of directors may also delegate to one or more of our officers the authority to (i) designate employees (other than officers) to receive specified stock awards and (ii) determine the number of shares subject to such stock awards. Under our Plan, our board of directors has the authority to determine award recipients, grant dates, the numbers and types of stock awards to be granted, the applicable fair market value, and the provisions of each stock award, including the period of exercisability and the vesting schedule applicable to a stock award.

Stock Options. ISOs and NSOs are granted under stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for stock options, within the terms and conditions of the Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the Plan vest at the rate specified in the stock option agreement as determined by the plan administrator.

The plan administrator determines the term of stock options granted under the Plan, up to a maximum of 10 years. Unless the terms of an option holder’s stock option agreement, or other written agreement between us and the recipient approved by the plan administrator, provide otherwise, if an option holder’s service relationship with us or any of our affiliates ceases for any reason other than disability, death or cause, the option holder may generally exercise any vested options for a period of three months following the cessation of service. This period may be extended in the event that exercise of the option is prohibited by applicable securities laws. If an option holder’s service relationship with us or any of our affiliates ceases due to death, or an option holder dies within a certain period following cessation of service, the option holder or a beneficiary may generally exercise any vested options for a period of 18 months following the date of death. If an option holder’s service relationship with us or any of our affiliates ceases due to disability, the option holder may generally exercise any vested options for a period of 12 months following the cessation of service. In the event of a termination for cause, options generally terminate upon the termination date. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include (i) cash, check, bank draft or money order, (ii) a broker-assisted cashless exercise, (iii) the tender of shares of our common stock previously owned by the option holder, (iv) a net exercise of the option if it is an NSO or (v) other legal consideration approved by the plan administrator.

Unless the plan administrator provides otherwise, options or stock appreciation rights generally are not transferable except by will or the laws of descent and distribution. Subject to approval of the plan administrator or a duly authorized officer, an option may be transferred pursuant to a domestic relations order, official marital settlement agreement or other divorce or separation instrument.

Tax Limitations on ISOs. The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an award holder during any calendar year under all of our stock plans may not exceed \$100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our parent or subsidiary corporations unless (i) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant and (ii) the term of the ISO does not exceed five years from the date of grant.

Restricted Stock Unit Awards. Restricted stock unit awards are granted under restricted stock unit award agreements adopted by the plan administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the plan administrator or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Except as otherwise provided in the applicable award agreement, or other written agreement between us and the recipient approved by the plan administrator, restricted stock unit awards that have not vested will be forfeited once the participant's continuous service ends for any reason.

Restricted Stock Awards. Restricted stock awards are granted under restricted stock award agreements adopted by the plan administrator. A restricted stock award may be awarded in consideration for cash, check, bank draft or money order, past or future services to us or any other form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. The plan administrator determines the terms and conditions of restricted stock awards, including vesting and forfeiture terms. If a participant's service relationship with us ends for any reason, we may receive any or all of the shares of common stock held by the participant that have not vested as of the date the participant terminates service with us through a forfeiture condition or a repurchase right.

Stock Appreciation Rights. Stock appreciation rights are granted under stock appreciation right agreements adopted by the plan administrator. The plan administrator determines the purchase price or strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of our common stock on the date of grant. A stock appreciation right granted under the Plan vests at the rate specified in the stock appreciation right agreement as determined by the plan administrator. Stock appreciation rights may be settled in cash or shares of common stock or in any other form of payment as determined by the Board and specified in the stock appreciation right agreement.

The plan administrator determines the term of stock appreciation rights granted under the Plan, up to a maximum of 10 years. If a participant's service relationship with us or any of our affiliates ceases for any reason other than cause, disability or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service. This period may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws. If a participant's service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, stock appreciation rights generally terminate immediately upon the occurrence of the event giving rise to the termination of the individual for cause. In no event may a stock appreciation right be exercised beyond the expiration of its term.

Performance Awards. The Plan permits the grant of performance awards that may be settled in stock, cash or other property. Performance awards may be structured so that the stock or cash will be issued or paid only following the achievement of certain pre-established performance goals during a designated performance period. Performance awards that are settled in cash or other property are not required to be valued in whole or in part by reference to, or otherwise based on, the common stock.

The performance goals may be based on any measure of performance selected by the board of directors. The performance goals may be based on company-wide performance or performance of one or more business units, divisions, affiliates or business segments, and may be either absolute or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise by the board of directors at the time the performance award is granted, the board will appropriately make adjustments in the method of calculating the attainment of performance goals as follows: (i) to exclude restructuring and/or other nonrecurring charges; (ii) to exclude exchange rate effects; (iii) to exclude the effects of changes to generally accepted accounting principles; (iv) to exclude the effects of any statutory adjustments to corporate tax rates; (v) to exclude the effects of items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (vi) to exclude the dilutive effects of acquisitions or joint ventures; (vii) to assume that any portion of our business which is divested achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (viii) to exclude the effect of any change in the outstanding shares of our common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change or any distributions to common stockholders other than regular cash dividends; (ix) to exclude the effects of stock based compensation and the award of bonuses under our bonus plans; (x) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; and (xi) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles.

Other Stock Awards. The plan administrator may grant other awards based in whole or in part by reference to our common stock. The plan administrator will set the number of shares under the stock award (or cash equivalent) and all other terms and conditions of such awards.

Non-Employee Director Compensation Limit. The aggregate value of all compensation granted or paid to any non-employee director with respect to any calendar year, including awards granted and cash fees paid by us to such non-employee director, will not exceed \$1,000,000 in total value; provided that such amount will be \$750,000 for the first year for newly appointed or elected non-employee directors.

Changes to Capital Structure. In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split or recapitalization, appropriate adjustments will be made to (i) the class and maximum number of shares reserved for issuance under the Plan, (ii) the class and maximum number of shares by which the share reserve may increase automatically each year, (iii) the class and maximum number of shares that may be issued on the exercise of ISOs and (iv) the class and number of shares and exercise price, strike price or purchase price, if applicable, of all outstanding stock awards.

Corporate Transactions. The following applies to stock awards under the Plan in the event of a corporate transaction (as defined in the Plan), unless otherwise provided in a participant's stock award agreement or other written agreement with us or one of our affiliates or unless otherwise expressly provided by the plan administrator at the time of grant.

In the event of a corporate transaction, any stock awards outstanding under the Plan may be assumed, continued or substituted for by any surviving or acquiring corporation (or its parent company), and any reacquisition or repurchase rights held by us with respect to the stock award may be assigned to the successor (or its parent company). If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such stock awards, then (i) with respect to any such stock awards that are held by participants whose continuous service has not terminated prior to the effective time of the corporate transaction, or current participants, the vesting (and exercisability, if applicable) of such stock awards will be accelerated in full to a date prior to the effective time of the corporate transaction (contingent upon the effectiveness of the corporate transaction), and such stock awards will terminate if not exercised (if applicable) at or prior to the effective time of the corporate transaction, and any reacquisition or repurchase rights held by us with respect to such stock awards will lapse (contingent upon the effectiveness of the corporate transaction), and (ii) any such stock awards that are held by persons other than current participants will terminate if not exercised (if applicable) prior to the effective time of the corporate transaction, except that any reacquisition or repurchase rights held by us with respect to such stock awards will not terminate and may continue to be exercised notwithstanding the corporate transaction.

In the event a stock award will terminate if not exercised prior to the effective time of a corporate transaction, the plan administrator may provide, in its sole discretion, that the holder of such stock award may not exercise such stock award but instead will receive a payment equal in value to the excess (if any) of (i) the per share amount payable to holders of common stock in connection with the corporate transaction over (ii) any per share exercise price payable by such holder, if applicable. In addition, any escrow, holdback, earn out or similar provisions in the definitive agreement for the corporate transaction may apply to such payment to the same extent and in the same manner as such provisions apply to the holders of common stock.

Change in Control. Awards granted under the Plan may be subject to acceleration of vesting and exercisability upon or after a change in control (as defined in the Plan) as may be provided in the applicable stock award agreement or in any other written agreement between us or any affiliate and the participant, but in the absence of such provision, no such acceleration will automatically occur.

Plan Amendment or Termination. Our board of directors has the authority to amend, suspend or terminate our Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our stockholders. No ISOs may be granted after the tenth anniversary of the date our board of directors adopts our Plan. No stock awards may be granted under our Plan while it is suspended or after it is terminated.

Non-Employee Director Compensation

The table below sets forth the compensation our director nominees have received for the twelve months ended December 31, 2024, and 2023:

Name	Fiscal Year	Fees Earned or Paid in Cash (\$)	Stock Awards (\$)	Option Awards (\$)	Non-Equity Incentive Plan Compensation (\$)	Change in Pension Value and Nonqualified Deferred Compensation Earnings	All Other Compensation (\$)	Total (\$)
Gaill Cassell	(1) 2024	15,000	—	—	—	—	—	15,000
Board Member Nominee	2023	15,000	—	9,483	—	—	—	24,483
Richard Cohen	2024	25,000	—	—	—	—	—	25,000
Board Member Nominee and Chair of Audit Committee	(2) 2023	25,000	—	9,483	—	—	—	34,483
Nominee	2024	25,000	—	—	—	—	—	25,000
Ann MacDougall	(3) 2023	25,000	—	9,483	—	—	—	34,483
Board Member Nominee and Chair of Audit Committee	2024	25,000	—	—	—	—	—	25,000
Nominee	(4) 2023	25,000	—	9,483	—	—	—	34,483
William Chin	(4,5) 2024	60,000	—	—	—	—	—	60,000
Board Member Nominee and Advisor to the Company	2023	60,000	—	9,483	—	—	—	69,483

- (1) The aggregate number of shares of Common Stock underlying option awards outstanding as of December 31, 2024 held by Gaill Cassell was 11,600.
- (2) The aggregate number of shares of Common Stock underlying option awards outstanding as of December 31, 2024 held by Richard Cohen was 11,600.
- (3) The aggregate number of shares of Common Stock underlying option awards outstanding as of December 31, 2024 held by Ann MacDougall was 11,600.
- (4) The aggregate number of shares of Common Stock underlying option awards outstanding as of December 31, 2024 held by William Chin was 281,213, 11,600 of which were granted as compensation for board member nominee services. Mr. Chin was awarded a total of 0 option awards during the twelve months ended December 31, 2024 and 2023 as compensation for advisory services.
- (5) William Chin is an advisor to the Company as well as a board member nominee. Mr. Chin's fees earned for the twelve months ended December 31, 2024 and 2023 are inclusive of his compensation as an advisor.

The table below sets forth the planned compensation to be paid to our directors following completion of the offering. The dollar amount of the stock options will be determined at the offering by the compensation committee.

Director Compensation

Position	Fees
Director	\$ 30,000
Audit Committee Chair	\$ 15,000
Compensation Committee Chair	\$ 10,000
Nominating & Governance Committee Chair	\$ 8,000
Audit Committee Membership	\$ 7,500
Compensation Committee Membership	\$ 5,000
Nominating & Governance Committee Membership	\$ 4,000

Expenses

We will reimburse each eligible non-employee director for ordinary, necessary and reasonable out-of-pocket travel expenses to cover in-person attendance at and participation in meetings of our board of directors and any committee of the board.

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, 2021 and each currently proposed transaction in which:

- we have been or are to be a participant;
- the amounts involved exceeded or will exceed \$120,000; 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.

In three congruent installments during the year ended December 31, 2020, on August 4, 2020, October 5, 2020 and November 11, 2020, KLP loaned the Company \$100,000, \$25,000 and \$75,000, respectively, for an aggregate of \$200,000. All three loans bore interest at a rate of 5% per annum. At December 31, 2020, there was accrued interest of \$2,842. As of December 31, 2020, the outstanding principal balance on the notes was \$200,000. On December 23, 2021, the Company and KLP entered into a contribution agreement and effectively forgave the principal and interest related to these loans for no consideration. As a result, the Company recognized a capital contribution to additional paid-in capital on the statements of equity in the amount of \$212,541.

On October 25, 2021, the Company and shareholder, Werth Family Investment Associates, LLC, entered into a convertible loan agreement, in which the Company received \$200,000. The note bears interest at a rate of 8% per annum and is payable in full on October 20, 2024, as amended. As of September 30, 2024 and December 31, 2023, the outstanding principal balance was \$200,000. The note is convertible into shares of common stock at a conversion price of 75% of the per share offering price of a next equity financing event which the agreement defines as “a sale by the Company of its shares in an initial public offering from which the Company receives gross proceeds of not less than \$25 million and in the event such initial public offering does not occur before the first anniversary, the next equity financing means the sale by the Company of its Shares in a public or private offering from which the Company receives gross proceeds of not less and \$5 million.” We expect this note to be converted into shares of our common stock upon completion of the offering.

On January 5, 2022, the Company entered into two convertible note agreements, including with a related party (Sandra Vlock, sister of the CEO), in which the Company received \$150,000 in cash proceeds. The notes bear interest at a rate of 8% per annum and are set to mature in January 2025, as amended. The notes are automatically converted into the Company’s voting common stock at 75% of the purchase price of a future financing of \$25 million prior to the first-year anniversary of the agreement or \$5 million after the first year of the agreement. As of September 30, 2024 and December 31, 2023, the outstanding principal balance was \$150,000. We expect this note to be converted into shares of our common stock upon completion of the offering.

On February 17, 2022, the Company entered into a convertible note agreement with Daniel Vlock, CEO, in which the Company received \$200,000 in cash proceeds. The note bears interest at a rate of 8% per annum and is set to mature in February 2025, as amended. The note is automatically converted into the Company’s voting common stock at 75% of the purchase price of a future financing of \$25 million prior to the first-year anniversary of the agreement or \$5 million after the first year of the agreement. As of September 30, 2024 and December 31, 2023, the outstanding principal balance was \$200,000. We expect this note to be converted into shares of our common stock upon completion of the offering.

On March 24, 2022, the Company entered into a convertible note agreement with Daniel Vlock, CEO, in which the Company received \$200,000 in cash proceeds. The note bears interest at a rate of 8% per annum and is set to mature in March 2025, as amended. The note is automatically converted into the Company’s voting common stock at 75% of the purchase price of a future financing of \$10 million prior to the first-year anniversary of the agreement or \$5 million after the first year of the agreement. As of September 30, 2024 and December 31, 2023, the outstanding principal balance was \$200,000. We expect this note to be converted into shares of our common stock upon completion of the offering.

On June 27, 2022, the Company entered into a note agreement with Daniel Vlock, CEO, in which the Company received \$400,000 in cash proceeds. The note bears interest at a rate of 9% per annum and is set to mature on June 27, 2025, as amended. As of September 30, 2024 and December 31, 2023, the outstanding principal balance was \$400,000.

On October 24, 2022, the Company entered into a note agreement with Gerald Pier, shareholder, in which the Company received \$50,000 in cash proceeds. The note bears interest at a rate of 9% per annum and is set to mature the earlier of October 24, 2024, as amended, or a future financing of \$10 million prior to December 31, 2022 or \$5 million thereafter. As of September 30, 2024 and December 31, 2023, the outstanding principal balance was \$50,000.

On October 26, 2022, the Company entered into a note agreement with Werth Family Investments Associates, LLC, in which the Company received \$300,000 in cash proceeds. The note bears interest at a rate of 15% per annum and is set to mature the earlier of October 26, 2024, as amended, or a future financing of \$10 million prior to December 31, 2022 or \$5 million thereafter. As of September 30, 2024 and December 31, 2023, the outstanding principal balance was \$300,000.

On December 12, 2022, the Company entered into a promissory note with Daniel Vlock, CEO, in which the Company received \$250,000 in cash proceeds. The note bears interest at 12% per annum and is set to mature the earlier of December 12, 2024, as amended, or a future financing of \$10 million prior to January 31, 2023 or \$5 million thereafter. As of September 30, 2024 and December 31, 2023, the outstanding principal balance was \$250,000.

On February 28, 2023, the Company entered into a promissory note with Daniel Vlock, CEO, in which the Company received \$200,000 in cash proceeds. The note bears interest at 12% per annum and is set to mature the earlier of February 28, 2025, as amended, or a future financing of \$10 million prior to February 24, 2024 or \$5 million thereafter. As of September 30, 2024 and December 31, 2023, the outstanding principal balance was \$200,000.

On May 12, 2023, the Company entered into a promissory note with Daniel Vlock, CEO, in which the Company received \$50,000 in cash proceeds. The note bears interest at 12% per annum and is set to mature the earlier of May 12, 2025, as amended, or a future financing of \$10 million prior to May 12, 2024 or \$5 million thereafter. As of September 30, 2024 and December 31, 2023, the outstanding principal balance was \$50,000.

On November 28, 2023, the Company entered into a promissory note with Daniel Vlock, CEO, in which the Company received \$200,000 in cash proceeds. The note bears interest at 15% per annum and is set to mature the earlier of November 28, 2025, as amended, or a future financing of \$10 million prior to January 31, 2024 or \$5 million thereafter. As of September 30, 2024 and December 31, 2024 the outstanding principal balance was \$200,000.

On August 6, 2024, the Company entered into a convertible note agreement with Daniel Vlock, CEO in which the Company received \$200,000 in cash proceeds. The note bears interest at a rate of 12% per annum and is set to mature two years from its commencement date. The conversion terms are similar to the existing outstanding convertible notes.

Accrued interest – related parties on the above notes payable totaled \$457,760 and \$280,360 at September 30, 2024 and December 31, 2023, respectively.

On July 21, 2023, the Company issued 75,902 shares of common stock to Daniel Vlock, CEO, for \$400,000.

On October 18, 2023, the Company issued 67,377 shares of common stock to Daniel Vlock, CEO, for approximately \$355,000.

On November 28, 2023, the Company issued 21,063 shares of common stock for approximately \$111,000 to Daniel Vlock, CEO. The per share price of the common stock was \$5.27 per share.

On February 26, 2024, the Company issued 37,951 shares of common stock for approximately \$200,000 to Daniel Vlock, CEO. The per share price of the common stock was \$5.27 per share.

On May 3, 2024, the Company issued 47,438 shares of common stock for approximately \$250,000 to Daniel Vlock, CEO. The per share price of the common stock was \$5.27 per share.

On May 6, 2024, the Company issued 9,487 shares of common stock for approximately \$50,000 to Daniel Vlock, CEO. The per share price of the common stock was \$5.27 per share.

PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our capital stock as of January 8, 2025, as adjusted to reflect the sale of our common stock offered by us in this offering assuming no exercise of the underwriters' option to purchase additional shares, for:

- 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. Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares that they beneficially own, subject to applicable community property laws.

The beneficial ownership of our common stock prior to the offering is based on 4,899,218 shares of common stock issued and outstanding as well as 919,219 stock options vested as of December 30, 2024. Applicable percentage ownership after the offering is based on 7,596,769 shares of common stock outstanding immediately after the closing of this offering, assuming no exercise by the underwriters of their option to purchase additional shares. 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 notes upon the completion of the offering and options held by the person that are currently exercisable, or exercisable within 60 days of December 30, 2024. 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.

Name and Address of Beneficial Owners ⁽¹⁾	Shares Beneficially Owned Before Offering		Shares Beneficially Owned After Offering	
	Number of Shares	Percentage	Number of Shares	Percentage
<u>5% Stockholders:</u>				
Daniel Vlock ⁽²⁾	4,254,039	72.9%	4,444,989(3)	58.5%
Peter Werth	535,623	9.2%	601,523(3)	7.9%
Dr. Gerald Pier	471,532	8.1%	540,608(3)	7.1%
<u>Director, Executive Officers and Director Nominees:</u>				
Daniel Vlock ⁽²⁾	4,254,039	72.9%	4,444,989(3)	58.5%
Gail H. Cassell	7,089	0.1%	8,700(3)	0.1%
Richard Cohen	7,089	0.1%	8,700(3)	0.1%
Ann MacDougall	7,089	0.1%	8,700(3)	0.1%
Christine de los Reyes	125,183	2.1%	151,767(3)	2.0%
William W. Chin	194,320	3.3%	233,378(3)	3.1%
Thomas T. Thomas	216,473	3.7%	262,088(3)	3.4%
All Directors, Executive Officers and Director Nominees as a group (7 persons)	4,811,283	82.5%	5,118,321(4)	67.4%

- (1) Unless otherwise noted, the business address of each of the following entities or individuals is 186 Alewife Brook Pkwy #1068, Cambridge, Massachusetts 02138.
- (2) Consists of (i) 439,662 shares and vested unexercised stock options owned directly by Dr. Vlock and (ii) 3,814,377 shares owned through KLP OBP LLC owned by Dr. Vlock and three family members in which Dr. Vlock has dispositive power.
- (3) The number of shares owned includes (i) 6,011,658 shares and vested unexercised options, and (ii) 248,793 shares underlying convertible notes which automatically convert upon the closing of the offering.
- (4) We issued a total of 1,419,388 stock options, of which, 1,010,529 options are exercisable into shares of common stock to our management (including directors and director nominees) resulting in approximately 5,118,321 shares owned by our executive officers, directors and director nominees.

DESCRIPTION OF CAPITAL STOCK

General

The following description of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws, which will each become effective prior to the closing of this offering, are summaries. You should also refer to our amended and restated certificate of incorporation and our amended and restated bylaws, each of which are filed as exhibits to the registration statement of which this prospectus is a part.

Upon the closing of this offering, our authorized capital stock will consist of 110,000,000 shares, all with a par value of \$0.0001 per share, of which:

- 100,000,000 shares are designated as common stock; and
- 10,000,000 shares are designated as preferred stock.

Common Stock

As of September 30, 2024, there were 4,899,218 shares of our common stock outstanding and held of record by four (4) stockholders.

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders, including the election of directors, and do not have cumulative voting rights. Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared by the board of directors out of legally available funds. In the event of our liquidation, dissolution or winding up, the holders of common stock will be entitled to share ratably in the assets legally available for distribution to stockholders after the payment of or provision for all of our debts and other liabilities, subject to the prior rights of any preferred stock then outstanding. Holders of common stock have no preemptive or conversion rights or other subscription rights and there are no redemption or sinking funds provisions applicable to the common stock. All outstanding shares of common stock are, and the common stock to be outstanding upon the closing of this offering will be, duly authorized, validly issued, fully paid and nonassessable. All authorized but unissued shares of our common stock will be available for issuance by our board of directors without any further stockholder action, except as required by the listing standards of the NYSE American. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Some provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws contain or will contain provisions that could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Stockholder Meetings

Our amended and restated bylaws will provide that a special meeting of stockholders may be called only by our chairman of the board, chief executive officer or president, or by a resolution adopted by a majority of our board of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our amended and restated bylaws will establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent

Our amended and restated certificate of incorporation and amended and restated bylaws will eliminate the right of stockholders to act by written consent without a meeting.

Staggered Board

Our board of directors will be divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders. For more information on the classified board, see the section entitled “Management—Composition of Our Board of Directors.” This system of electing and removing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Removal of Directors

Our amended and restated certificate of incorporation will provide that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two thirds of the total voting power of all of our outstanding voting stock then entitled to vote in the election of directors.

Stockholders Not Entitled to Cumulative Voting

Our amended and restated certificate of incorporation will not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock, if any, may be entitled to elect.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the DGCL, which prohibits persons deemed to be “interested stockholders” from engaging in a “business combination” with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an “interested stockholder” is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation’s voting stock. Generally, a “business combination” includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

Choice of Forum

Our amended and restated certificate of incorporation will provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers, or employees to us or our stockholders; (iii) any action or proceeding asserting a claim against us or any of our current or former directors, officers or employees arising pursuant to any provision of the DGCL or our certificate of incorporation or bylaws; (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; (v) any action or proceeding as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; or (vi) any action asserting a claim against us or any of our current or former directors, officers or employees governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Securities Act, Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction. Our amended and restated certificate of incorporation further provides that the federal district court for the District of Delaware will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act or the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction.

Our amended and restated certificate of incorporation will also provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to these choice of forum provisions. While the Delaware courts have determined that such choice of forum provisions are facially valid, it is possible that a court of law in another jurisdiction could rule that the choice of forum provisions to be contained in our amended and restated certificate of incorporation are inapplicable or unenforceable if they are challenged in a proceeding or otherwise. If a court were to find the choice of forum provision that will be contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

Amendment of Charter Provisions

The amendment of any of the above provisions would require approval by holders of at least two-thirds of the total voting power of all of our outstanding voting stock.

The provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

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 is 18 Lafayette Place, Woodmere, New York 11598.

Exchange Listing

Our common stock is currently not listed on any securities exchange. We have applied to have our common stock listed on the NYSE American under the symbol "ALPX".

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been 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 we have applied to have our common stock listed 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 September 30, 2024 and assuming (i) the issuance of 2,400,000 shares of common stock in this offering, (ii) no exercise of the underwriters' option to purchase additional shares, (iii) the conversion of the convertible notes currently outstanding into 297,551 shares of our common stock upon the closing of this offering, we will have an aggregate of approximately 7,596,769 shares of common stock outstanding.

Of these shares, all shares of common stock sold in this offering 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 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 either a 180-day or 365-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 stockholders and option holders, have agreed with the underwriters that for a period of 365 days with respect to us, our directors and executive officers and 180 days with respect to all of our other stockholders and option holders, 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 ThinkEquity 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 stockholders 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 75,968 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 our 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 the resale provisions of Rule 144.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK

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, subject to the proposed Treasury Regulations discussed below, 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, subject to the proposed Treasury Regulations discussed below, 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.

The U.S. Treasury Department recently released proposed regulations which, if finalized in their present form, would eliminate the federal withholding tax of 30% applicable to the gross proceeds of a disposition of our common stock. In its preamble to such proposed regulations, the U.S. Treasury Department stated that taxpayers may generally rely on the proposed regulations until final regulations are issued. 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

We have entered into an underwriting agreement, dated _____, 2025, with ThinkEquity LLC, acting as the sole book-running manager (sometimes referred to as the “Representative”). Subject to the terms and conditions of the underwriting agreement, each of the underwriters named below have agreed to purchase, and we have agreed to sell to it, the number of shares of common stock listed next to its name at the public offering price, less the underwriting discounts and commissions, as set forth on the cover page of this prospectus and as indicated below:

Underwriters	Number of Shares
ThinkEquity LLC	
Total	

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 its 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 the underwriters. 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 are taken.

We have agreed to indemnify the underwriters and certain of their affiliates and controlling persons (within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act), among others, against specified liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect thereof.

Discounts and Commissions

The underwriters propose to offer the shares of common stock directly to the public at the public offering price set forth on the cover page of this prospectus. After the offering to the public, the offering price and other selling terms may be changed by the underwriters without changing the proceeds we will receive from the underwriters.

The following table summarizes the public offering price, underwriting commissions and proceeds before expenses to us. The underwriting commissions are 7.0% of the public offering price. We have paid a \$50,000 advance to the Representative, which shall be applied against actual out-of-pocket-accountable expenses, and which will be returned to us to the extent such out-of-pocket accountable expenses are not actually incurred in accordance with FINRA Rule 5110(g)(4)(A).

	Per Share	Total Without Over-Allotment Option	Total With Full Over-Allotment Option
Public offering price	\$	\$	\$
Underwriting discount (7.0%)	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

We have agreed to pay a non-accountable expense allowance to the underwriters equal to 1% of the public offering price. Our total estimated expenses of the offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding underwriting discounts and commissions, are approximately \$1.9 million. We have also agreed to reimburse the underwriters for certain expenses incurred in connection with this offering pursuant to the underwriting agreement, including certain legal fees, up to an aggregate of \$212,500.

Over-Allotment Option

We have granted a 45-day option to the Representative to purchase up to 360,000 additional shares of common stock from us solely to cover over-allotments, if any, at the public offering price less underwriting discounts and commissions.

Representative's Warrants

Upon closing of this offering, we have agreed to issue to the Representative, or its designees, as compensation warrants to purchase a number of shares of common stock equal to 5% of the aggregate number of shares of common stock sold in this offering (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 in this offering. The Representative's Warrants are exercisable at any time and from time to time, in whole or in part, during the four and one-half year period commencing 180 days from the effective date of the registration statement of which this prospectus is a part.

The Representative's Warrants have been deemed compensation by FINRA and are therefore subject to a 180-day lock-up pursuant to FINRA Rule 5110(e)(1). The Representative (or permitted assignees under Rule 5110(e)(2)) 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. In addition, the warrants provide for registration rights upon request, in certain cases. The one-time 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 unlimited piggyback registration right 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.

Discretionary Accounts

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

Lock-Up Agreements

We, along with our directors, executive officers and all of our other stockholders and option holders, have agreed pursuant to "lock-up" agreements not to, or are subject to other restrictions so that they may not, without the prior written consent of the Representative, 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 shares of common stock or any other of our securities or publicly disclose the intention to do any of the foregoing, subject to customary exceptions, for, with respect to the Company, executive officers and directors a period of 365 days from the date of this prospectus, and with respect to our other stockholders, a period of 180 days from the date of this prospectus.

Right of First Refusal

We have granted the Representative a right of first refusal, for a period of twenty-four (24) months from the closing of the offering, to act as sole and exclusive investment banker, book-runner, financial advisor, underwriter and/or placement agent, at the Representative's sole and exclusive discretion, for each and every future public and private equity and debt offering, including all of our equity linked financings (each, a "Subject Transaction"), or any successor (or any of our subsidiaries), on terms and conditions customary to the Representative for such Subject Transactions.

NYSE American

We have applied to have our shares of common stock listed on the NYSE American under the symbol "ALPX". Our application might not be approved and the consummation of this offering is contingent upon such approval.

Price Stabilization, Short Positions and Penalty Bids

In order to facilitate the offering of our securities, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of our securities. In connection with the offering, the underwriters may purchase and sell our securities in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares of securities than they are required to purchase in the offering. "Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares of securities in the offering. The underwriters may close out any covered short position by either exercising the over-allotment option to purchase shares or purchasing shares in the open market. In determining the source of shares of securities to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option to purchase shares. "Naked" short sales are sales in excess of the over-allotment option to purchase shares. The underwriters must close out any naked short position by purchasing securities in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our securities in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of securities made by the underwriters in the open market before the completion of the offering.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our securities or preventing or retarding a decline in the market price of our securities. As result, the price of our securities may be higher than the price that might otherwise exist in the open market.

The underwriters make no representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our securities. In addition, neither we nor the underwriters make any representation that the underwriters will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Offer, Sale and Distribution of Securities

A prospectus in electronic format may be made available on the websites maintained by the underwriters or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares of securities to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriter and selling group members that may make internet distributions on the same basis as other allocations. Other than the 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.

Other Relationships

From time to time, the underwriters and/or their affiliates may provide in the future, various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which they will receive customary fees and commissions. However, except as disclosed in this prospectus, we have no present arrangements with the underwriters or any of their affiliates for any further services.

Pricing of the Offering

The public offering price was determined by negotiations between us and the Representative. Among the factors considered in determining the public offering price were our future prospects and those of our industry in general, our sales, earnings and certain other financial and operating information in recent periods, and the price-earnings ratios, price-sales ratios, market prices of securities, and certain financial and operating information of companies engaged in activities similar to ours. Neither we nor the underwriters can assure investors that an active trading market for the shares will develop or that, after the offering, the shares will trade in the public market at or above the public offering price.

Offer Restrictions Outside the United States

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

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.

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.

Hong Kong

Neither the information in this document nor any other document relating to the offer has been delivered for registration to the Registrar of Companies in Hong Kong, and its contents have not been reviewed or approved by any regulatory authority in Hong Kong, nor have we been authorized by the Securities and Futures Commission in Hong Kong. This document does not constitute an offer or invitation to the public in Hong Kong to acquire shares. Accordingly, unless permitted by the securities laws of Hong Kong, no person may issue or have in its possession for the purpose of issue, this document or any advertisement, invitation or document relating to the shares, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong other than in relation to shares which are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” (as such term is defined in the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong) (“SFO”) and the subsidiary legislation made thereunder) or in circumstances which do not result in this document being a “prospectus” as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance of Hong Kong (Cap. 32 of the Laws of Hong Kong) (the “CO”) or which do not constitute an offer or an invitation to the public for the purposes of the SFO or the CO. The offer of the shares is personal to the person to whom this document has been delivered by or on behalf of our company, and a subscription for shares will only be accepted from such person. No person to whom a copy of this document is issued may issue, circulate or distribute this document in Hong Kong or make or give a copy of this document to any other person. You are advised to exercise caution in relation to the offer. If you are in any doubt about any of the contents of this document, you should obtain independent professional advice. No document may be distributed, published or reproduced (in whole or in part), disclosed by or to any other person in Hong Kong or to any person to whom the offer of sale of the shares would be a breach of the CO or SFO.

Israel

The securities offered by this prospectus have not been approved or disapproved by the Israeli Securities Authority (the “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.

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 our 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.

LEGAL MATTERS

The validity of the shares of common stock being offered by this prospectus will be passed upon for us by Sichenzia Ross Ference Carmel LLP, New York, New York. Nelson Mullins Riley & Scarborough LLP, Raleigh, North Carolina, is acting as counsel to the underwriters.

EXPERTS

The financial statements of Alopexx, Inc. as of December 31, 2023 and 2022 and for the years then ended included in this prospectus have been audited by Marcum LLP, an independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph relating to substantial doubt about the ability of Alopexx, Inc. to continue as a going concern as described in Note 1 to the financial statements) appearing elsewhere in this prospectus, and are included in reliance on such report given on the authority of such firm 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, including exhibits and schedules, under the Securities Act, with respect to the shares of common stock being offered by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to 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. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the Internet at the SEC’s website at www.sec.gov.

Upon the closing of this offering, we will be subject to the information reporting requirements of the Securities Exchange Act and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection at the web site of the SEC referred to above. We also maintain a website at <https://www.alopexx.com>, at which, following the closing of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

ALOPEXX, INC. FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2023 AND 2022
INDEX TO AUDITED FINANCIAL STATEMENTS

<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Balance Sheet as of December 31, 2023 and December 31, 2022</u>	F-3
<u>Statement of Operations for the years ended December 31, 2023 and 2022</u>	F-4
<u>Statement of Stockholders' Deficit for the years ended December 31, 2023 and 2022</u>	F-5
<u>Statement of Cash Flows for the years ended December 31, 2023 and 2022</u>	F-6
<u>Notes to Financial Statements</u>	F-7 – F-15
<u>Condensed Balance Sheets as of September 30, 2024 (unaudited) and December 31, 2023</u>	F-16
<u>Condensed Statements of Operations for the three and nine months ended September 30, 2024 and 2023 (unaudited)</u>	F-17
<u>Condensed Statements of Stockholders' Deficit for the three and nine months ended September 30, 2024 and 2023 (unaudited)</u>	F-18
<u>Condensed Statements of Cash Flows for the nine months ended September 30, 2024 and 2023 (unaudited)</u>	F-19
<u>Notes to Unaudited Condensed Financial Statements</u>	F-20

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of

Alopexx, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Alopexx, Inc. (the “Company”) as of December 31, 2023 and 2022, the related statements of operations, stockholders’ deficit and cash flows for each of the two years in the period ended December 31, 2023 and 2022, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, the Company has a significant working capital deficiency, has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company’s ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1. 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 Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

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

/s/ Marcum llp

Marcum llp

We have served as the Company’s auditor since 2021.

Hartford, CT
March 14, 2024

**ALOPEXX, INC.
BALANCE SHEET**

	For the Years Ended,	
	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash	\$ 49,831	\$ 39,387
Deferred offering costs	859,822	650,016
Total current assets	<u>909,653</u>	<u>689,403</u>
Total Assets	<u><u>\$ 909,653</u></u>	<u><u>\$ 689,403</u></u>
Liabilities and Stockholders' Deficit		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 2,472,965	\$ 1,910,545
Accrued interest	7,944	3,945
Accrued interest – related parties	280,361	85,404
Notes payable – related parties	1,050,000	1,000,000
Convertible notes payable	50,000	—
Convertible notes payable - related parties	700,000	—
Total current liabilities	<u>4,561,270</u>	<u>2,999,894</u>
Long-Term Liabilities:		
Notes payable – long term – related parties	400,000	—
Convertible notes payable – long-term	—	50,000
Convertible notes payable – long-term - related parties	—	700,000
Total long-term liabilities	<u>400,000</u>	<u>750,000</u>
Total Liabilities	<u>4,961,270</u>	<u>3,749,894</u>
Stockholders' Deficit:		
Preferred Stock, \$.0001 par value – 10,000,000 shares authorized, no shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	—	—
Common Stock, \$.0001 par value – 100,000,000 shares authorized, 4,804,342 and 4,640,000 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	481	464
Additional paid-in capital	6,991,837	4,202,791
Accumulated deficit	(11,043,935)	(7,263,746)
Total Stockholders' Deficit	<u>(4,051,617)</u>	<u>(3,060,491)</u>
Total Liabilities and Stockholders' Deficit	<u><u>\$ 909,653</u></u>	<u><u>\$ 689,403</u></u>

The accompanying notes are an integral part of these financial statements

ALOPEXX, INC.
STATEMENT OF OPERATIONS

	For the Years Ended	
	December 31, 2023	December 31, 2022
OPERATING COSTS AND EXPENSES:		
Research and development	\$ 357,234	\$ 471,326
General and administrative	3,223,999	1,760,501
TOTAL OPERATING EXPENSES	<u>3,581,233</u>	<u>2,231,827</u>
LOSS FROM OPERATIONS	(3,581,233)	(2,231,827)
OTHER INCOME (EXPENSE):		
Interest expense	(198,956)	(86,237)
NET INCOME LOSS BEFORE INCOME TAX	<u>(3,780,189)</u>	<u>(2,318,064)</u>
Provision for income taxes	—	—
NET LOSS	<u>\$ (3,780,189)</u>	<u>\$ (2,318,064)</u>
Loss per common share – basic and diluted	<u>\$ (0.81)</u>	<u>\$ (0.50)</u>
Weighted-average common shares outstanding - basic and diluted	<u>4,689,460</u>	<u>4,640,000</u>

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

ALOPEXX, INC.
STATEMENT OF STOCKHOLDERS' DEFICIT
FOR THE YEARS ENDED DECEMBER 31, 2023 AND 2022

	<u>Common Stock</u>		<u>Additional Paid-In Capital</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Deficit</u>
	<u>Shares</u>	<u>Amount</u>			
Balance as of December 31, 2021	4,640,000	\$ 464	4,202,791	\$ (4,945,682)	(742,427)
Net loss	—	—	—	(2,318,064)	(2,318,064)
Balance as of December 31, 2022	<u>4,640,000</u>	<u>\$ 464</u>	<u>4,202,791</u>	<u>\$ (7,263,746)</u>	<u>(3,060,491)</u>
Balance as of December 31, 2022	4,640,000	\$ 464	4,202,791	\$ (7,263,746)	(3,060,491)
Stock-based compensation	—	—	1,922,988	—	1,922,988
Issuance of common stock to Daniel Vlock, CEO	164,342	17	866,058	—	866,075
Net loss	—	—	—	(3,780,189)	(3,780,189)
Balance as of December 31, 2023	<u>4,804,342</u>	<u>\$ 481</u>	<u>6,991,837</u>	<u>\$ (11,043,935)</u>	<u>(4,051,617)</u>

The accompanying notes are an integral part of these financial statements

ALOPEXX, INC.
STATEMENT OF CASH FLOWS

	For the Years Ended,	
	December 31, 2023	December 31, 2022
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net Loss	\$ (3,780,189)	\$ (2,318,064)
Reconciliation of net loss to net cash used in operating activities		
Stock-based compensation	1,922,988	—
Non-cash interest expense – related party	194,957	82,292
Non-cash interest expense	3,999	3,945
Changes in operating assets and liabilities:		
Deferred offering costs	(209,806)	(542,507)
Other current assets	—	1,099
Accounts payable and accrued expenses	562,420	1,222,414
NET CASH USED IN OPERATING ACTIVITIES	<u>(1,305,631)</u>	<u>(1,550,821)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock to a related party	866,075	—
Proceeds from notes payable – related party	450,000	1,000,000
Proceeds from convertible notes payable	—	50,000
Proceeds from convertible notes payable – related parties	—	500,000
NET CASH PROVIDED BY FINANCING ACTIVITIES:	<u>1,316,075</u>	<u>1,550,000</u>
Net change in cash	10,444	(821)
Cash, beginning	<u>\$ 39,387</u>	<u>\$ 40,208</u>
Cash, end	<u>\$ 49,831</u>	<u>\$ 39,387</u>
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for taxes	<u>\$ —</u>	<u>\$ —</u>
Cash paid for interest	<u>\$ —</u>	<u>\$ —</u>

The accompanying notes are an integral part of these financial statements

ALOPEXX, INC.
NOTES TO FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2023 AND 2022

Note 1 – Nature of Operations and Going Concern

Alopxx, Inc., (formerly OBP Acquisition, Inc.) (the “Company” or “Alopxx”), headquartered in Cambridge, Massachusetts, was incorporated in the state of Delaware in May 2021. On May 25, 2021, the Company entered into a Merger Agreement (the “Merger”) with Alopxx, Inc. (formerly One Biopharma Inc.) (“OBP”), a related party under common control, and pursuant to the Merger, the shareholders of OBP’s common stock received \$2.01 for every 1,000 common shares. These shares were repurchased by Alopxx and retired. Additionally, on a one-to-one share basis, OBP’s Preferred Stock was converted into one share of Alopxx’s non-voting common stock. Additionally, on August 15, 2022, the Company had a stock split of 1.45 to 1.00 of the common stock and converted the common non-voting stock to common voting stock. The Company has retroactively reflected the recapitalization in the balance sheets, statements of operations, stockholders’ deficit and footnotes.

The Company was formed as a clinical stage biotechnology company for the purpose of developing novel, broad-spectrum immune-mediated therapeutics for the prevention and treatment of a wide range of bacterial, fungal, and parasitic microbial infections. The Vaccine AV0328 (the “Vaccine”) and MAF598 Antibody (the “Antibody”) was therapeutics developed to target Poly B-acetyl glucosamine (“PNAG”) found in a wide range of pathogens. As a result of the Merger, the acquisition transaction was accounted for as a common control transaction in accordance with the Financial Accounting Standards Board (“FASB”) (Accounting Standard Codification (“ASC”) 805-50, Business Combinations – Common control transactions). The Company evaluated the guidance contained in ASC 805-50 with respect to the combinations among entities or businesses under common control and concluded that since the majority shareholders of the Company and OBP are the same, this was a common control transaction and did not result in a change in control at the ultimate parent or the controlling shareholder level.

Going Concern and Management’s Plan

Since inception, the Company has incurred significant losses from operations and has not generated positive cash flows from operations. In addition, as of December 31, 2023, the Company does not have any revenue streams to support its cost structure. The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”), which contemplates continuation of the Company as a going concern. The Company has an accumulated deficit of approximately \$11.0 million and \$7.3 million as of December 31, 2023 and December 31, 2022, respectively. As of December 31, 2023 and 2022, the Company had a working capital deficiency of approximately \$3.7 million and \$2.3 million, respectively.

The Company’s losses from operations have been funded with the proceeds of equity financing and notes payables from related parties. We expect to operate at a loss for the foreseeable future while we execute our business plan to obtain regulatory approval and commercially launch the product in the United States and foreign jurisdictions. We will require additional financing to implement our business plan. We believe that we have access to capital resources through the sale of equity securities, however, we have not secured any commitments for new financing at this time. These factors, among others, raise substantial doubt about the Company’s ability to continue as a going concern over the next 12 months from the issuance date of these financial statements. The financial statements do not include any adjustments that might result from this uncertainty.

Risks and Uncertainties

As a result of the military action commenced in February 2022 by the Russian Federation and Belarus in the country of Ukraine and related economic sanctions, the Company’s ability to consummate a Business Combination, or the operations of a target business with which the Company ultimately consummates a Business Combination, may be materially and adversely affected. In addition, the Company’s ability to consummate a transaction may be dependent on the ability to raise equity and debt financing which may be impacted by these events, including as a result of increased market volatility, or decreased market liquidity in third-party financing being unavailable on terms acceptable to the Company or at all. The impact of this action and related sanctions on the world economy and the specific impact on the Company’s financial position, results of operations and/or ability to consummate a Business Combination are not yet determinable. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Note 2 – Significant Accounting Policies

Use of Estimates

The preparation of these financial statements in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) and applicable rules and regulations of the Securities and Exchange Commission (“SEC”), involves the use of estimates and assumptions that affect the recorded amounts of assets and liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Significant estimates include the accounts payable and accrued expenses, equity related transactions and deferred taxes. Actual results may differ substantially from these estimates.

Cash and Cash Equivalents

The Company considers liquid investments with an original maturity of three months or less to be cash equivalents. As of December 31, 2023 and 2022, the Company held all of its cash with one financial institution. Such funds are insured by the Federal Deposit Insurance Corporation (“FDIC”) up to \$250,000. Cash balances could exceed insured amounts at any given time; however, the Company has not experienced any such losses. At December 31, 2023 and December 31, 2022, there were no cash equivalents.

Deferred Offering Costs

Deferred offering costs consist of underwriting, legal, accounting and other expenses incurred through the balance sheet date that are directly related to a future offering and that will be charged to shareholders’ deficit upon the completion of such offering. Should the offering prove to be unsuccessful, these deferred costs, as well as additional expenses incurred, will be charged to operations. As of December 31, 2023 and December 31, 2022 the Company had capitalized deferred offering costs of \$859,822 and \$650,016, respectively.

Fair Value Measurements

The carrying amount of the Company’s financial instruments classified as current assets and current liabilities approximate fair values based on the short-term nature of the accounts.

Convertible Debt and Derivative Financial Instruments

The Company accounts for convertible debt in accordance with the accounting standards and assesses whether embedded conversion options are required to be bifurcated under ASC 815.

The Company evaluates its financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives in accordance with ASC Topic 815, “Derivatives and Hedging”. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value on the grant date and is then re-valued at each reporting date, with changes in the fair value reported in the statements of operations. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period. Derivative liabilities are classified in the balance sheet as current or non-current based on whether net-cash settlement or conversion of the instrument could be required within 12 months of the balance sheet date.

Stock-Based Compensation

Stock-based compensation expense is recorded for all option grants and awards of non-vested stock and recognized in the financial statements based on the grant date fair value of the awards granted. Stock-based compensation is recognized as expense over the requisite service period, which generally represents the vesting period. The Company calculates the fair value of stock options using the Black-Scholes option-pricing model at grant date.

Emerging Growth Company

The Company is an “emerging growth company,” as defined in Section 2(a) of the Securities Act of 1933, as amended (the “Securities Act”), as modified by the Jumpstart Our Business Startups Act of 2012, as amended (the “JOBS Act”), and it may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the independent registered public accounting firm attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in its periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. The Company has elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, the Company, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of the Company’s financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

Research and Development Costs and Clinical Trial Expenses

The Company expenses the cost of research and development as incurred. Research and development expenses comprise costs incurred in performing research and development activities, including clinical trial costs, manufacturing costs for both clinical and pre-clinical materials as well as other contracted services, license fees, and other external costs. Research and development costs include costs directly attributable to the conduct of research and development programs, including the cost of services provided by outside contractors, the cost of manufacturing drugs for use in research, preclinical development costs, consulting costs, and costs related to FDA submissions and clinical trials. All costs associated with research and development are expensed as incurred.

Earnings per Share

The computation of basic earnings per common share is based on the weighted average number of shares outstanding during the period. The computation of diluted earnings per common share is based on the weighted average number of shares outstanding during the period plus the weighted average common stock equivalents which would arise from the exercise of stock options, warrants, convertible notes and other rights during the period. For the years ended December 31, 2023 and 2022, due to the net loss during the period, the inclusion of any common stock equivalents would be anti-dilutive and therefore, basic and dilutive weighted average shares were equivalent.

Income Taxes

Deferred tax assets and liabilities are computed based upon the difference between the financial statement and income tax basis of assets and liabilities using the enacted marginal tax rate applicable when the related asset or liability is expected to be realized or settled. Deferred income tax expenses or benefits are based on the changes in the asset or liability each period. If available evidence suggests that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is required to reduce the deferred tax assets to the amount that is more likely than not to be realized. Future changes in the valuation allowance are included in the provision for deferred income taxes in the period of change.

Deferred income taxes may arise from temporary differences resulting from income and expense items reported for financial accounting and tax purposes in different periods. Deferred taxes are classified as current or non-current, depending on the classification of assets and liabilities to which they relate. Deferred taxes arising from temporary differences that are not related to an asset or liability are classified as current or non-current depending on the periods in which the temporary differences are expected to reverse.

The Company applies a more-likely-than-not recognition threshold for all tax uncertainties, which allows the recognition of those tax benefits that have a greater than fifty percent likelihood of being sustained upon examination by the taxing authorities. The Company has not incurred any interest or penalties, however when incurred in potential future period, the Company will include in income tax expense in the accompanying statements of operations in the period they become determinable.

Segment Information

The Company has a single operating and reportable segment. The Company's chief operating decision maker is its Chief Executive Officer, who reviews financial information presented on a consolidated basis for purposes of making operating decisions, assessing financial performance, and allocating resources. The Company does not have significant long-lived assets, does not generate revenue and does not have any operations outside of the United States.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that the Company adopts as of the specified effective date. Unless otherwise discussed, the Company does not believe that the impact of recently issued standards that are not yet effective will have a material impact on its financial position or results of operations upon adoption.

Note 3 – License Agreements

In May 2019, the Company entered into assignment agreements for two exclusive patent license agreements (AV0238 Vaccine and F598 Antibody) with Brigham and Women's Hospital (BWH). Pursuant to the assignment, the Company obtained an exclusive, royalty-bearing, sublicensable (with approval from BWH) license to certain U.S. and foreign patents related to the vaccine and methods of use thereof, the F598 monoclonal antibody and variants thereof and the methods of use of the vaccine and/or the anti-PNAG antibody. The Company may sublicense the patent rights licensed under the agreement subject to certain conditions, including obtaining the review and approval by BWH of such sublicense and any such sublicense must be consistent with and subject to the terms of the agreement.

In consideration for the licenses granted under the agreement, the Company must pay BWH annual license fees prior to the first commercial sale of a licensed product that range in the mid-five-digit figures to low six-digit figures, and a low single digit royalty on net sales of licensed products beginning with the first commercial sale of a licensed product in any country during the term of the agreement. In the event the Company commercializes a product in the therapeutic space, the Company is also required to make certain drug-approval regulatory and commercialization milestone payments to BWH of up to a low seven-digit figure in the aggregate for licensed products. In the event the Company sublicenses any of the licensed intellectual property, the Company must pay BWH a percentage of any sublicense income received by the Company, which on a going-forward basis will be in the low double digits.

Under the terms of the agreement, the Company is required to use commercially reasonable efforts to develop and commercialize the licensed products, including in accordance with certain developmental, funding, regulatory and commercialization milestones. BWH controls the prosecution, maintenance and enforcement of all licensed patents and patent applications under the agreement. Subject to an applicable cure period, BWH may terminate the agreements if we fail to comply with applicable payments or diligence obligations or upon a breach of our obligations under the agreement, or for certain insolvency-related events.

Unless earlier terminated, the agreement continues until the expiration of the last to expire patent right licensed under the agreement which ranges from 2025 to 2033. Subject to an applicable cure period, BWH may terminate the agreement if the Company fails to comply with applicable payments or diligence obligations or upon a breach of our obligation under the agreement, or for certain insolvency-related events.

Note 4 – Accounts Payable and Accrued Expenses

Accrued expenses consist of the following:

	As of	
	December 31, 2023	December 31, 2022
Research and Development Consultants	\$ 93,037	\$ 101,315
Executives Consultant Fees	347,167	150,000
Business Development Consultants	750,000	450,000
Accounting and Legal Fees	454,016	685,520
Board of Director Fees	333,745	193,710
Accrued License Fees – Alopexx Pharmaceuticals	300,000	200,000
Accrued License Fees – Alopexx Vaccine	195,000	130,000
Total	\$ 2,472,965	\$ 1,910,545

Note 5 – Debt

Convertible Notes Payable – Related Parties

On October 25, 2021, the Company and shareholder, Werth Family Investment Associates, LLC, entered into a convertible loan agreement, in which the Company received \$200,000. The note bears interest at a rate of 8% per annum and is payable in full on October 20, 2024. At December 31, 2023 and December 31, 2022, there was accrued interest related to this loan of \$35,112 and \$19,112, respectively. As of December 31, 2023 and December 31, 2022, the outstanding principal balance was \$200,000. The note is convertible into shares of common stock at a conversion price of 75% of the per share offering price of a next equity financing event which the agreement defines as “a sale by the Company of its shares in an initial public offering from which the Company receives gross proceeds of not less than \$25 million and in the event such initial public offering does not occur before the first anniversary, the next equity financing means the sale by the Company of its Shares in a public or private offering from which the Company receives gross proceeds of not less and \$5 million.” Management evaluated the accounting guidance for embedded conversion features and ultimately determined that the embedded conversion feature did not require to be bifurcated under ASC Topic 815 Derivatives and Hedging and therefore, the convertible debt instrument is accounted for as a single liability measured at amortized cost.

On January 5, 2022, the Company entered into two convertible note agreements, including with a related party, in which the Company received \$150,000 in cash proceeds. The notes bear interest at a rate of 8% per annum and are set to mature in January 2024. The notes are automatically converted into the Company’s voting common stock at 75% of the purchase price of a future financing of \$25 million prior to the first-year anniversary of the agreement or \$5 million after the first year of the agreement. At December 31, 2023 and December 31, 2022, there was accrued interest of \$23,835 and \$11,836, respectively. As of December 31, 2023 and December 31, 2022, the outstanding principal balance was \$150,000.

On February 17, 2022, the Company entered into a convertible note agreement with a related party, in which the Company received \$200,000 in cash proceeds. The note bears interest at a rate of 8% per annum and is set to mature in February 2025. The note is automatically converted into the Company’s voting common stock at 75% of the purchase price of a future financing of \$25 million prior to the first-year anniversary of the agreement or \$5 million after the first year of the agreement. At December 31, 2023 and December 31, 2022, there was accrued interest of \$29,852 and \$13,852, respectively. As of December 31, 2023 and December 31, 2022, the outstanding principal balance was \$200,000.

In February 2022, the Company amended the four outstanding convertible notes payable agreements with a total principal balance of \$550,000 to decrease the automatic conversion threshold. Subsequent to this amendment, the notes are automatically converted into the Company’s voting common stock at 75% of the purchase price of a future financing of \$10 million prior to the first-year anniversary of the agreement or \$5 million after the first year of the original agreement and treated as a modification.

On March 24, 2022, the Company entered into a convertible note agreement with a related party, in which the Company received \$200,000 in cash proceeds. The note bears interest at a rate of 8% per annum and is set to mature in March 2024. The note is automatically converted into the Company's voting common stock at 75% of the purchase price of a future financing of \$10 million prior to the first-year anniversary of the agreement or \$5 million after the first year of the agreement. At December 31, 2023 and December 31, 2022, there was accrued interest of \$28,362 and \$12,362, respectively. As of December 31, 2023 and December 31, 2022, the outstanding principal balance was \$200,000.

Notes Payable – Related Parties

On June 27, 2022, the Company entered into a note agreement with a related party, in which the Company received \$400,000 in cash proceeds. The note bears interest at a rate of 9% per annum and is set to mature one year from its commencement date. At December 31, 2023 and December 31, 2022, there was accrued interest of \$54,444 and \$18,444, respectively. As of December 31, 2023 and December 31, 2022, the outstanding principal balance was \$400,000.

On October 24, 2022, the Company entered into a note agreement with a related party, in which the Company received \$50,000 in cash proceeds. The note bears interest at a rate of 9% per annum and is set to mature the earlier of one year from its commencement date or a future financing of \$10 million prior to December 31, 2022 or \$5 million thereafter. At December 31, 2023 and December 31, 2022, there was accrued interest of \$5,338 and \$838, respectively. As of December 31, 2023 and December 31, 2022, the outstanding principal balance was \$50,000.

On October 26, 2022, the Company entered into a note agreement with a related party, in which the Company received \$300,000 in cash proceeds. The note bears interest at a rate of 15% per annum and is set to mature the earlier of one year from its commencement date or a future financing of \$10 million prior to December 31, 2022 or \$5 million thereafter. At December 31, 2023 and December 31, 2022, there was accrued interest of \$53,137 and \$11,343, respectively. As of December 31, 2023 and December 31, 2022, the outstanding principal balance was \$300,000.

Notes Payable – Related Parties, continued

On December 12, 2022, the Company entered into a promissory note with a related party, in which the Company received \$250,000 in cash proceeds. The note bears interest at 12% per annum and is set to mature the earlier of one year from its commencement date or a future financing of \$10 million prior to January 31, 2023 or \$5 million thereafter. At December 31, 2023 and December 31, 2022, there was accrued interest of \$31,562 and \$1,562, respectively. As of December 31, 2023 and December 31, 2022, the outstanding principal balance was \$250,000.

On February 28, 2023, the Company entered into a promissory note with a related party, in which the Company received \$200,000 in cash proceeds. The note bears interest at 12% per annum and is set to mature the earlier of two years from its commencement date or a future financing of \$10 million prior to February 24, 2024 or \$5 million thereafter. At December 31, 2023 and December 31, 2022, there was accrued interest of \$20,121 and \$0, respectively. As of December 31, 2023 and December 31, 2022, the outstanding principal balance was \$200,000 and \$0, respectively.

On May 12, 2023, the Company entered into a promissory note with a related party, in which the Company received \$50,000 in cash proceeds. The note bears interest at 12% per annum and is set to mature the earlier of one year from its commencement date or a future financing of \$10 million prior to May 12, 2024 or \$5 million thereafter. At December 31, 2023 and December 31, 2022, there was accrued interest of \$3,830 and \$0, respectively. As of December 31, 2023 and December 31, 2022, the outstanding principal balance was \$50,000 and \$0, respectively.

On November 28, 2023, the Company entered into a promissory note with a related party, in which the Company received \$200,000 in cash proceeds. The note bears interest at 15% per annum and is set to mature the earlier of two years from its commencement date or a future financing of \$10 million prior to January 31, 2024 or \$5 million thereafter. At December 31 2023, there was accrued interest of \$2,712 and the outstanding principal balance was \$200,000.

Note 6 – Contractual Obligations, 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.

On June 8, 2022, the Company was sued in the Commercial Court of Nantes, France by Xenothera. The litigation is seeking, among other things, to compel the Company to enter into a license agreement with Xenothera or provide 120,000,000 euros (\$132,432,000 at December 31, 2023) in damages. No liability has been recorded related to this matter as the Company intends to vigorously defend this claim and believes the claim is without merit.

Note 7 – Stockholders’ Deficit

Recapitalization in 2022

As disclosed in Note 1, on August 15, 2022, the Company had a stock split of 1.45 to 1.00 of the common stock and converted the common non-voting stock to common voting stock. Additionally, the Company increased the authorized number of common stock to 100,000,000 shares and preferred stock to 10,000,000. The Company has retroactively reflected the recapitalization in the balance sheets, statements of operations, stockholders’ deficit and footnotes.

Preferred Stock

As of December 31, 2023 and December 31, 2022, there was no Preferred Stock issued or outstanding.

Note 7 – Stockholders’ Deficit (continued)

Common Stock

As discussed above, in conjunction with the Merger, the 4,970,467 OBP common shares were purchased for total consideration of \$10,009. These shares were retired after the purchase.

On July 21, 2023, the Company issued 75,902 shares of common stock for \$400,000 to a related party. The per share price of the common stock was \$5.27 per share.

On October 18, 2023, the Company issued 67,377 shares of common stock for approximately \$355,000 to a related party. The per share price of the common stock was \$5.27 per share.

On November 28, 2023, the Company issued 21,063 shares of common stock for \$111,000 to a related party. The per share price of the common stock was \$5.27 per share.

As of December 31, 2023 and December 31, 2022, respectively, there were 4,804,342 and 4,640,000 shares issued and outstanding.

Note 8 – Employee Incentive Plan

On August 31, 2023, the Company entered into the 2023 Employee Incentive Plan to attract and retain the type of Employees, Consultants and Directors who will contribute to the Company’s long-term success. The options under the plan are service-based grants that vest over three years and are exercisable over periods not exceeding ten years.

The aggregate number of shares that may be issued under the plan as of December 31, 2023 is 1,419,388. The options granted generally vest either 33% upfront then ratably over the remaining two years or ratably over three years.

Stock options are granted at a price not less than the market price of the common stock on the date of grant. The fair value of each stock option awarded in 2023 was estimated using a Black-Scholes model and is recognized as compensation expense ratably over the vesting term, where applicable. Valuation assumptions used to value stock options granted during the year ended December 31, 2023 were as follows:

Common stock value	\$	4.04
Expected term (in years)		6.0 - 6.5
Expected volatility		93%
Risk-free interest rate		4.19%
Dividend yield		0%

The Company is a private company and lacks company-specific historical and implied volatility information for its shares. Therefore, it estimates its volatility based on the historical volatility of publicly traded peer companies and expects to continue to do so until it has adequate historical data regarding the volatility of its own traded share price. The expected dividend yield is based on historical yields on the date of grant. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant.

The following represents of a summary of options:

	Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term
Issued and outstanding, December 31, 2022	—	—	—
Granted	1,419,388	\$ 4.04	—
Issued	—	—	—
Forfeited/Expired	—	—	—
Issued and outstanding, December 31, 2023	1,419,388	\$ 4.04	9.67
Exercisable, December 31, 2023	422,646	\$ 4.04	9.67

For the year ended December 31, 2023, the Company had \$1,922,988 of stock compensation. As of December 31, 2023, the remaining unamortized expense of \$2,642,335 will be recognized over the next 1.80 years.

Note 9 – Related Parties

Convertible Notes Payable – Related Parties

On October 25, 2021, the Company and shareholder, Werth Family Investment Associates, LLC, entered into a convertible loan agreement, in which the Company received \$200,000. The note bears interest at a rate of 8% per annum and is payable in full on October 20, 2023. At December 31, 2023 and December 31, 2022, there was accrued interest related to this loan of \$35,112 and \$19,112, respectively. As of December 31, 2023 and December 31, 2022, the outstanding principal balance was \$200,000. The note is convertible into shares of common stock at a conversion price of 75% of the per share offering price of a next equity financing event which the agreement defines as “a sale by the Company of its shares in an initial public offering from which the Company receives gross proceeds of not less than \$25 million and in the event such initial public offering does not occur before the first anniversary, the next equity financing means the sale by the Company of its Shares in a public or private offering from which the Company receives gross proceeds of not less than \$5 million.” Management evaluated the accounting guidance for embedded conversion features and ultimately determined that the embedded conversion feature did not require to be bifurcated under ASC Topic 815 Derivatives and Hedging and therefore, the convertible debt instrument is accounted for as a single liability measured at amortized cost.

On January 5, 2022, the Company entered into two convertible note agreements, including with a related party, in which the Company received \$150,000 in cash proceeds. The notes bear interest at a rate of 8% per annum and are set to mature in January 2024. The notes are automatically converted into the Company’s voting common stock at 75% of the purchase price of a future financing of \$25 million prior to the first-year anniversary of the agreement or \$5 million after the first year of the agreement. At December 31, 2023 and December 31, 2022, there was accrued interest of \$23,835 and \$11,836, respectively. As of December 31, 2023 and December 31, 2022, the outstanding principal balance was \$150,000.

On February 17, 2022, the Company entered into a convertible note agreement with a related party, in which the Company received \$200,000 in cash proceeds. The note bears interest at a rate of 8% per annum and is set to mature in February 2024. The note is automatically converted into the Company’s voting common stock at 75% of the purchase price of a future financing of \$25 million prior to the first-year anniversary of the agreement or \$5 million after the first year of the agreement. At December 31, 2023, 2023 and December 31, 2022, there was accrued interest of \$29,852 and \$13,852, respectively. As of December 31, 2023 and December 31, 2022, the outstanding principal balance was \$200,000.

In February 2022, the Company amended the four outstanding convertible notes payable agreements with a total principal balance of \$550,000 to decrease the automatic conversion threshold. Subsequent to this amendment, the notes are automatically converted into the Company's voting common stock at 75% of the purchase price of a future financing of \$10 million prior to the first-year anniversary of the agreement or \$5 million after the first year of the original agreement and treated as a modification.

On March 24, 2022, the Company entered into a convertible note agreement with a related party, in which the Company received \$200,000 in cash proceeds. The note bears interest at a rate of 8% per annum and is set to mature in March 2024. The note is automatically converted into the Company's voting common stock at 75% of the purchase price of a future financing of \$10 million prior to the first-year anniversary of the agreement or \$5 million after the first year of the agreement. At December 31, 2023 and December 31, 2022, there was accrued interest of \$28,362 and \$12,362, respectively. As of December 31, 2023 and 2022, the outstanding principal balance was \$200,000.

Note 9 – Related Parties (continued)

Notes Payable – Related Parties

On June 27, 2022, the Company entered into a note agreement with a related party, in which the Company received \$400,000 in cash proceeds. The note bears interest at a rate of 9% per annum and is set to mature one year from its commencement date. At December 31, 2023 and December 31, 2022, there was accrued interest of \$54,444 and \$18,444, respectively. As of December 31, 2023 and December 31, 2022, the outstanding principal balance was \$400,000.

On October 24, 2022, the Company entered into a note agreement with a related party, in which the Company received \$50,000 in cash proceeds. The note bears interest at a rate of 9% per annum and is set to mature the earlier of one year from its commencement date or a future financing of \$10 million prior to December 31, 2022 or \$5 million thereafter. At December 31, 2023 and December 31, 2022, there was accrued interest of \$5,338 and \$838, respectively. As of December 31, 2023 and December 31, 2022, the outstanding principal balance was \$50,000.

On October 26, 2022, the Company entered into a note agreement with a related party, in which the Company received \$300,000 in cash proceeds. The note bears interest at a rate of 15% per annum and is set to mature the earlier of one year from its commencement date or a future financing of \$10 million prior to December 31, 2022 or \$5 million thereafter. At December 31, 2023 and December 31, 2022, there was accrued interest of \$53,137 and \$11,343, respectively. As of December 31, 2023 and December 31, 2022, the outstanding principal balance was \$300,000.

On December 12, 2022, the Company entered into a promissory note with a related party, in which the Company received \$250,000 in cash proceeds. The note bears interest at 12% per annum and is set to mature the earlier of one year from its commencement date or a future financing of \$10 million prior to January 31, 2023 or \$5 million thereafter. At December 31, 2023 and December 31, 2022, there was accrued interest of \$31,562 and \$1,562, respectively. As of December 31, 2023 and December 31, 2022, the outstanding principal balance was \$250,000.

On February 28, 2023, the Company entered into a promissory note with a related party, in which the Company received \$200,000 in cash proceeds. The note bears interest at 12% per annum and is set to mature the earlier of two years from its commencement date or a future financing of \$10 million prior to February 24, 2024 or \$5 million thereafter. At December 31, 2023 and 2022, there was accrued interest of \$20,121 and \$0, respectively. As of December 31, 2023 and 2022, the outstanding principal balance was \$200,000 and \$0, respectively.

On May 12, 2023, the Company entered into a promissory note with a related party, in which the Company received \$50,000 in cash proceeds. The note bears interest at 12% per annum and is set to mature the earlier of one year from its commencement date or a future financing of \$10 million prior to May 12, 2024 or \$5 million thereafter. At December 31, 2023 and 2022, there was accrued interest of \$3,830 and \$0, respectively. As of December 31, 2023 and 2022, the outstanding principal balance was \$50,000 and \$0, respectively.

On November 28, 2023, the Company entered into a promissory note with a related party, in which the Company received \$200,000 in cash proceeds. The note bears interest at 15% per annum and is set to mature the earlier of two years from its commencement date or a future financing of \$10 million prior to January 31, 2024 or \$5 million thereafter. At December 31, 2023 and December 31, 2022, there was accrued interest of \$2,712 and \$0, respectively. As of December 31, 2023 and December 31, 2022, the outstanding principal balance was \$200,000 and \$0, respectively.

Note 10 – Income Taxes

At December 31, 2023, the Company has approximately \$6,360,000 of operating loss carryforwards for federal and \$6,400,000 of operating loss carryforwards for Massachusetts state tax purposes that may be applied against future taxable income. None of the federal net operating losses will expire, and are subject to 80% of taxable income, and the Massachusetts net operating losses will begin to expire in the year 2038 if not utilized prior to that date. There is no provision for income taxes because the Company has historically incurred operating losses and maintains a full valuation allowance against its net deferred tax assets. The valuation allowance increased by approximately \$1,023,000 and \$616,000 during the years 2023 and 2022, respectively. The deferred tax assets are approximately \$3,187,000 and \$2,164,000 at December 31, 2023 and 2022, respectively.

A reconciliation of the statutory U.S. Federal rate to the Company's effective tax rate is as follows:

	December 31,	
	2023	2022
Federal income tax benefit at statutory rate	21.00%	21.00%
State income tax, net of federal benefits	6.05%	6.32%
Permanent items and other	0.02%	(0.75)%
Change in valuation allowance	(27.07)%	(26.57)%
Provision from income taxes	—	—

Note 10 – Income Taxes (continued)

The tax effect of temporary differences that gave rise to significant portion of the deferred tax assets / (liabilities) were as follows:

	December 31,	
	2023	2022
Net Operating loss carryforwards - Federal	1,335,550	1,117,553
Net Operating loss carryforwards - State	404,456	338,878
Stock based compensation	525,360	—
Research and development	324,852	324,711
Accrued Liabilities	525,798	223,115
Depreciation and Amortization	71,556	159,820
Valuation allowance	(3,187,572)	(2,164,076)
Net deferred tax assets	—	—

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax asset will not be realized. The Company's ability to realize its deferred tax assets depends upon the generation of sufficient future taxable income to allow for the utilization of the deductible temporary difference carryforwards. At this time, based on current facts and circumstances, management believes that is not likely that the Company will realize the benefits for its deferred tax assets, and a valuation allowance has been recorded on the same.

The Company does not have any recorded unrecognized tax benefit for uncertain tax positions as of December 31, 2023 and 2022.

Note 11 – Subsequent Events

The Company has completed an evaluation of all subsequent events through March 14, 2024, the date the financial statements were issued. Except as described below, the Company has concluded that no subsequent event has occurred that requires disclosure.

On February 26, 2024, the Company issued 37,951 shares of common stock for approximately \$200,000 to a related party. The per share price of the common stock was \$5.27 per share.

ALOPEXX, INC.
CONDENSED BALANCE SHEETS

	September 30, 2024	December 31, 2023
	(unaudited)	
Assets		
Current assets:		
Cash	\$ 638,522	\$ 49,831
Deferred offering costs	883,417	859,822
Total current assets	1,521,939	909,653
Total Assets	\$ 1,521,939	\$ 909,653
Liabilities and Stockholders' Deficit		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 2,588,291	\$ 2,472,965
Deferred revenue	666,667	—
Accrued interest	10,946	7,944
Accrued interest – related parties	457,760	280,361
Notes payable – related parties	1,050,000	1,050,000
Convertible notes payable	50,000	50,000
Convertible notes payable - related parties	900,000	700,000
Total current liabilities	5,723,664	4,561,270
Long-Term Liabilities:		
Notes payable – long term – related parties	400,000	400,000
Total long-term liabilities	400,000	400,000
Total Liabilities	6,123,664	4,961,270
Commitments and Contingencies (Note 6)		
Stockholders' Deficit:		
Preferred Stock, \$.0001 par value – 10,000,000 shares authorized, no shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	—	—
Common Stock, \$.0001 par value – 100,000,000 shares authorized, 4,899,218 and 4,804,342 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	490	481
Additional paid-in capital	8,606,289	6,991,837
Accumulated deficit	(13,208,504)	(11,043,935)
Total Stockholders' Deficit	(4,601,725)	(4,051,617)
Total Liabilities and Stockholders' Deficit	\$ 1,521,939	\$ 909,653

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

ALOPEXX, INC.
CONDENSED STATEMENT OF OPERATIONS
(unaudited)

	For the Three Months Ended,		For the Nine Months Ended,	
	September 30,	September 30,	September 30,	September 30,
	2024	2023	2024	2023
OPERATING COSTS AND EXPENSES:				
Research and development	\$ 48,459	\$ 104,643	\$ 177,605	\$ 290,000
General and administrative	392,024	1,796,286	1,806,561	2,557,685
TOTAL OPERATING EXPENSES	440,483	1,900,929	1,984,166	2,847,685
LOSS FROM OPERATIONS	(440,483)	(1,900,929)	(1,984,166)	(2,847,685)
OTHER EXPENSE:				
Interest expense	(62,975)	(51,797)	(180,403)	(147,653)
NET LOSS BEFORE INCOME TAX	(503,458)	(1,952,726)	(2,164,569)	(2,995,338)
Provision for income taxes	—	—	—	—
NET LOSS	\$ (503,458)	\$ (1,952,726)	\$ (2,164,569)	\$ (2,995,338)
Loss per common share — basic and diluted	<u>(0.10)</u>	<u>(0.42)</u>	<u>(0.44)</u>	<u>(0.64)</u>
Weighted-average common shares outstanding - basic and diluted	<u>4,899,218</u>	<u>4,699,878</u>	<u>4,865,557</u>	<u>4,659,812</u>

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

ALOPEXX, INC.

CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2024 AND 2023
(unaudited)

	Common Stock		Additional Paid- In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Balance as of December 31, 2023	4,804,342	\$ 481	6,991,837	\$ (11,043,935)	\$ (4,051,617)
Stock-based compensation	—	—	371,485	—	371,485
Issuance of common stock to a related party	37,951	4	199,996	—	200,000
Net loss	—	—	—	(891,395)	(891,395)
Balance as of March 31, 2024	4,842,293	485	7,563,318	(11,935,330)	(4,371,527)
Stock-based compensation	—	—	371,488	—	371,488
Issuance of common stock to a related party	56,925	5	299,995	—	300,000
Net loss	—	—	—	(769,716)	(769,716)
Balance as of June 30, 2024	4,899,218	\$ 490	8,234,801	\$ (12,705,046)	\$ (4,469,755)
Stock-based compensation	—	—	371,488	—	371,488
Net loss	—	—	—	(503,458)	(503,458)
Balance as of September 30, 2024	4,899,218	490	8,606,289	(13,208,504)	(4,601,725)
Balance as of December 31, 2022	4,640,000	\$ 464	4,202,791	\$ (7,263,746)	\$ (3,060,491)
Net loss	—	—	—	(500,256)	(500,256)
Balance as of March 31, 2023	4,640,000	464	4,202,791	(7,764,002)	(3,560,747)
Net loss	—	—	—	(542,356)	(542,356)
Balance as of June 30, 2023	4,640,000	464	4,202,791	(8,306,358)	(4,103,103)
Stock-based compensation	—	—	1,551,501	—	1,551,501
Issuance of common stock to a related party	75,902	8	399,992	—	400,000
Net loss	—	—	—	(1,952,726)	(1,952,726)
Balance as of September 30, 2023	4,715,902	\$ 472	6,154,284	(10,259,084)	(4,104,328)

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

ALOPEXX, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(unaudited)

	For the Nine Months Ended,	
	September 30,	September 30,
	2024	2023
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net Loss	\$ (2,164,569)	\$ (2,995,338)
Reconciliation of net loss to net cash used in operating activities		
Accrued interest – related party	177,399	144,662
Accrued interest	3,002	2,991
Stock-based compensation	1,114,461	1,551,501
Changes in operating assets and liabilities:		
Deferred offering costs	(23,595)	(59,265)
Accounts payable and accrued expenses	115,326	710,293
Deferred revenue	666,667	—
NET CASH USED IN OPERATING ACTIVITIES	(111,309)	(645,157)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from notes payable – related party	—	250,000
Proceeds from notes payable – long term – related party	200,000	—
Proceeds from issuance of common stock to related party	500,000	400,000
NET CASH PROVIDED BY FINANCING ACTIVITIES:	700,000	650,000
Net change in cash	588,691	4,843
Cash, beginning of period	\$ 49,831	\$ 39,387
Cash, end of period	\$ 638,522	\$ 44,230
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for taxes	\$ —	\$ —
Cash paid for interest	\$ —	\$ —

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

ALOPEXX, INC.
NOTES TO THE UNAUDITED CONDENSED FINANCIAL STATEMENTS
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2024 AND 2023

Note 1 – Nature of Operations and Going Concern

Alopxx, Inc., (the “Company” or “Alopxx”), headquartered in Cambridge, Massachusetts, was incorporated in the state of Delaware in May 2021.

The Company was formed as a clinical stage biotechnology company for the purpose of developing novel, broad-spectrum immune-mediated therapeutics for the prevention and treatment of a wide range of bacterial, fungal, and parasitic microbial infections. The Vaccine AV0328 (the “Vaccine”) and MAF598 Antibody (the “Antibody”) was therapeutics developed to target Poly B-acetyl glucosamine (“PNAG”) found in a wide range of pathogens.

Going Concern and Management’s Plan

Since inception, the Company has incurred significant losses from operations and has not generated positive cash flows from operations. In addition, as of September 30, 2024, the Company does not have any revenue streams to support its cost structure. The accompanying unaudited condensed financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”), which contemplates continuation of the Company as a going concern. The Company has an accumulated deficit of approximately \$13.2 million and \$11.0 million as of September 30, 2024 and December 31, 2023, respectively. As of September 30, 2024 and December 31, 2023, the Company had a working capital deficiency of approximately \$4.2 million and \$3.7 million, respectively.

The Company’s losses from operations have been funded with the proceeds of equity financing and notes payables from related parties. We expect to operate at a loss for the foreseeable future while we execute our business plan to obtain regulatory approval and commercially launch the product in the United States and foreign jurisdictions. We will require additional financing to implement our business plan. We believe that we have access to capital resources through the sale of equity securities, however, we have not secured any commitments for new financing at this time. These factors, among others, raise substantial doubt about the Company’s ability to continue as a going concern over the next 12 months from the issuance date of these unaudited condensed financial statements. The financial statements do not include any adjustments that might result from this uncertainty.

Risks and Uncertainties

As a result of the military action commenced in February 2022 by the Russian Federation and Belarus in the country of Ukraine and related economic sanctions, as well as recent wars in Israel/Gaza, the Company’s ability to raise equity and debt financing may be impacted by these events, including as a result of increased market volatility, or decreased market liquidity in third-party financing being unavailable on terms acceptable to the Company or at all. The impact of this action and related sanctions on the world economy and the specific impact on the Company’s financial position and results of operations are not yet determinable. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Note 2 – Significant Accounting Policies

Interim Financial Statements

The accompanying unaudited condensed financial statements and notes are representations of the Company's management, who are responsible for their integrity and objectivity. These statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP") for interim financial information pursuant to Regulation S-X. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for annual financial statements. These condensed financial statements should be read in conjunction with the audited financial statements and related disclosures of the Company as of December 31, 2023 and 2022 and for the years then ended, included in the Company's Form S-1 Registration No. 333-263328.

Use of Estimates

The preparation of these unaudited condensed financial statements in accordance with the U.S. GAAP and applicable rules and regulations of the Securities and Exchange Commission ("SEC"), involves the use of estimates and assumptions that affect the recorded amounts of assets and liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Significant estimates include the accounts payable and accrued expenses and equity related transactions. Actual results may differ substantially from these estimates.

Cash and Cash Equivalents

The Company considers liquid investments with an original maturity of three months or less to be cash equivalents. As of September 30, 2024 and December 31, 2023, the Company held all of its cash with one financial institution. Such funds are insured by the Federal Deposit Insurance Corporation ("FDIC") up to \$250,000. Cash balances could exceed insured amounts at any given time; however, the Company has not experienced any such losses. At September 30, 2024 and December 31, 2023, there were no cash equivalents.

Deferred Offering Costs

Deferred offering costs consist of underwriting, legal, accounting and other expenses incurred through the balance sheet date that are directly related to a future offering and that will be charged to shareholders' deficit upon the completion of such offering. Should the offering prove to be unsuccessful, these deferred costs, as well as additional expenses incurred, will be charged to operations. As of September 30, 2024 and December 31, 2023 the Company had capitalized deferred offering costs of \$883,417 and \$859,822, respectively.

Fair Value Measurements

The carrying amount of the Company's financial instruments classified as current assets and current liabilities approximate fair values based on the short-term nature of the accounts.

Convertible Debt and Derivative Financial Instruments

The Company accounts for convertible debt in accordance with the accounting standards and assesses whether embedded conversion options are required to be bifurcated under ASC Topic 815, "*Derivatives and Hedging*".

The Company evaluates its financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives in accordance with ASC Topic 815, "*Derivatives and Hedging*". For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value on the grant date and is then re-valued at each reporting date, with changes in the fair value reported in the statements of operations. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period. Derivative liabilities are classified in the balance sheet as current or non-current based on whether net-cash settlement or conversion of the instrument could be required within 12 months of the balance sheet date.

Collaboration and License Revenue

At contract inception, the Company analyzes its collaboration and license arrangement to assess whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities and therefore within the scope of ASC Topic 808, Collaborative Arrangements (ASC 808). This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of ASC 808 and which elements of the collaboration are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606.

For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, either by analogy to authoritative accounting literature or by applying a reasonable and rational policy election. The Company evaluates the income statement classification for presentation of amounts due from or owed to other participants associated with multiple activities in a collaboration arrangement based on the nature of each separate activity.

For elements accounted within scope of ASC 606, to determine the appropriate amount of revenue to be recognized for the arrangements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. As part of the accounting for these arrangements, the Company must use significant judgment to determine: (a) the performance obligations based on the determination under step (ii) above; (b) the transaction price under step (iii) above; and (c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above. The Company uses judgment to determine whether milestones or other variable consideration, except for royalties and sales-based milestones, should be included in the transaction price as described further below. The transaction price is allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied.

For the revenue from non-refundable, upfront fees allocated to the license the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. The measure of progress, and thereby periods over which revenue should be recognized, are subject to estimates by management and may change over the course of the research and development and licensing agreement. Such a change could have a material impact on the amount of revenue the Company records in future periods.

Stock-Based Compensation

Stock-based compensation expense is recorded for all option grants and awards of non-vested stock and recognized in the financial statements based on the grant date fair value of the awards granted. Stock-based compensation is recognized as expense over the requisite service period, which generally represents the vesting period. The Company calculates the fair value of stock options using the Black-Scholes option-pricing model at grant date.

Emerging Growth Company

The Company is an “emerging growth company,” as defined in Section 2(a) of the Securities Act of 1933, as amended (the “Securities Act”), as modified by the Jumpstart Our Business Startups Act of 2012, as amended (the “JOBS Act”), and it may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the independent registered public accounting firm attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in its periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. The Company has elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, the Company, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of the Company’s financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

Research and Development Costs and Clinical Trial Expenses

The Company expenses the cost of research and development as incurred. Research and development expenses comprise costs incurred in performing research and development activities, including clinical trial costs, manufacturing costs for both clinical and pre-clinical materials as well as other contracted services, license fees, and other external costs. Research and development costs include costs directly attributable to the conduct of research and development programs, including the cost of services provided by outside contractors, the cost of manufacturing drugs for use in research, preclinical development costs, consulting costs, and costs related to FDA submissions and clinical trials. All costs associated with research and development are expensed as incurred.

Earnings per Share

The computation of basic earnings per common share is based on the weighted average number of shares outstanding during the period. The computation of diluted earnings per common share is based on the weighted average number of shares outstanding during the period plus the weighted average common stock equivalents which would arise from the exercise of stock options, warrants, convertible notes and other rights during the period. For the three and nine months ended September 30, 2024 and 2023, due to the net loss during the period, the inclusion of any common stock equivalents would be anti-dilutive and therefore, basic and dilutive weighted average shares were equivalent.

Income Taxes

Deferred tax assets and liabilities are computed based upon the difference between the financial statement and income tax basis of assets and liabilities using the enacted marginal tax rate applicable when the related asset or liability is expected to be realized or settled. Deferred income tax expenses or benefits are based on the changes in the asset or liability each period. If available evidence suggests that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is required to reduce the deferred tax assets to the amount that is more likely than not to be realized. Future changes in the valuation allowance are included in the provision for deferred income taxes in the period of change.

Deferred income taxes may arise from temporary differences resulting from income and expense items reported for financial accounting and tax purposes in different periods. Deferred taxes are classified as current or non-current, depending on the classification of assets and liabilities to which they relate. Deferred taxes arising from temporary differences that are not related to an asset or liability are classified as current or non-current depending on the periods in which the temporary differences are expected to reverse.

The Company applies a more-likely-than-not recognition threshold for all tax uncertainties, which allows the recognition of those tax benefits that have a greater than fifty percent likelihood of being sustained upon examination by the taxing authorities. The Company has not incurred any interest or penalties, however when incurred in potential future period, the Company will include in income tax expense in the accompanying statements of operations in the period they become determinable.

Segment Information

The Company has a single operating and reportable segment. The Company's chief operating decision maker is its Chief Executive Officer, who reviews financial information presented for purposes of making operating decisions, assessing financial performance, and allocating resources. The Company does not have significant long-lived assets, does not generate revenue and does not have any operations outside of the United States.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that the Company adopts as of the specified effective date. Unless otherwise discussed, the Company does not believe that the impact of recently issued standards that are not yet effective will have a material impact on its financial position or results of operations upon adoption.

Note 3 – License Agreements

Brigham Women's Hospital

In May 2019, the Company entered into assignment agreements for two exclusive patent license agreements (AV0238 Vaccine and F598 Antibody) with Brigham and Women's Hospital (BWH). Pursuant to the assignment, the Company obtained an exclusive, royalty-bearing, sublicensable (with approval from BWH) license to certain U.S. and foreign patents related to the vaccine and methods of use thereof, the F598 monoclonal antibody and variants thereof and the methods of use of the vaccine and/or the anti-PNAG antibody. The Company may sublicense the patent rights licensed under the agreement subject to certain conditions, including obtaining the review and approval by BWH of such sublicense and any such sublicense must be consistent with and subject to the terms of the agreement.

In consideration for the licenses granted under the agreement, the Company must pay BWH annual license fees prior to the first commercial sale of a licensed product that range in the mid-five-digit figures to low six-digit figures, and a low single digit royalty on net sales of licensed products beginning with the first commercial sale of a licensed product in any country during the term of the agreement. In the event the Company commercializes a product in the therapeutic space, the Company is also required to make certain drug-approval regulatory and commercialization milestone payments to BWH of up to a low seven-digit figure in the aggregate for licensed products. In the event the Company sublicenses any of the licensed intellectual property, the Company must pay BWH a percentage of any sublicense income received by the Company, which on a going-forward basis will be in the low double digits.

Under the terms of the agreement, the Company is required to use commercially reasonable efforts to develop and commercialize the licensed products, including in accordance with certain developmental, funding, regulatory and commercialization milestones. BWH controls the prosecution, maintenance and enforcement of all licensed patents and patent applications under the agreement. Subject to an applicable cure period, BWH may terminate the agreements if we fail to comply with applicable payments or diligence obligations or upon a breach of our obligations under the agreement, or for certain insolvency-related events.

Unless earlier terminated, the agreement continues until the expiration of the last to expire patent right licensed under the agreement which ranges from 2025 to 2033. Subject to an applicable cure period, BWH may terminate the agreement if the Company fails to comply with applicable payments or diligence obligations or upon a breach of our obligation under the agreement, or for certain insolvency-related events.

Bharat License Agreement

On September 5, 2024, the Company and Biotech Consortia, Inc ("BCI"), an affiliate of Bharat Biotech International Limited ("BBIL"), entered into a Collaboration and License Agreement (the "License Agreement"), which was subsequently amended effective December 27, 2024.

Pursuant to the License Agreement, the Company agreed to grant an exclusive royalty-bearing license to BCI to certain intellectual property rights controlled by the Company related to its proprietary broad-spectrum anti-microbial vaccine, AV0328, for the prevention of infections caused by *Streptococcus pneumoniae*; and two additional target indications in India and other countries classified as "low income" and "lower middle income" countries by the World Bank, subject to certain retained rights by Alopexx. In addition, the License Agreement provides for the grant to the Company of a limited non-exclusive, non-royalty bearing, non-sublicensable license to certain patent and technology rights of BCI, as set forth in the License Agreement, to conduct certain development activities as part of the collaboration contemplated by the License Agreement.

Under the terms of the License Agreement, BCI will co-develop and commercialize AV0328, a synthetic vaccine targeting poly N-acetyl glucosamine (PNAG) (the "Licensed Product"), in India and other licensed territories. In addition, Alopexx will be entitled to upfront, development and milestone payments, including royalties on sales of AV0328 in the licensed territories.

Pursuant to the terms of the License Agreement, the Company has received an initial upfront payment of \$666,666 and will receive additional upfront payments in the aggregate amount of approximately \$1.3 million upon the occurrence of certain events. In addition, pursuant to the terms of the License Agreement, the Company may receive an aggregate of up to \$3 million in consideration of the Company's preclinical work and upon achievement of certain milestones. In addition, the Company may receive royalty payments in the single digits on net sales of each product (as defined in the License Agreement) in the public market and in the low teens on net sales in the private market. Public market includes sales of the vaccine to individuals or groups with limited financial resources as would be encountered in "low income" and "lower middle income" countries (as classified by the World Bank). The private market includes sales to individuals and groups better able to afford the full cost of the vaccine. The royalty obligations under the License Agreement will commence upon the first commercial sale of such product through the expiration or termination of the License Agreement.

Unless earlier terminated, the License Agreement continues from the date of the License Agreement through the commercial life of the last Licensed Product under the License Agreement. Either party may terminate the License Agreement by providing notice in writing to the other party (i) if the other party is in material breach of the License Agreement, and in the case of a breach that is curable within 60 days, that is not cured in such time period upon notice from the other party, (ii) in the event the other party challenges or assist in a third party in challenging any technology controlled by such party, or (iii) the other party makes a general assignment for the benefit of creditors, files a voluntary petition in bankruptcy, an involuntary petition in bankruptcy is undismissed for a period of more than 60 days. In addition, the Company may terminate the License Agreement in the event BCI ceases development of the Licensed Product (subject to certain exceptions for normal pauses or gaps between clinical studies).

Upon termination of the License Agreement, BCI shall have the right to sell, use or dispose of any unsold or unused product for a period of 18 months after termination, provided it remains in compliance with all other provisions of the License Agreement.

If the License Agreement is terminated by the Company upon the expiration of a 60 days' notice of default, the licenses granted to BCI under the License Agreement will terminate and be of no further effect and BCI shall assign to the Company all regulatory filings, as such term is defined in the License Agreement. Further, within 45 days after termination, BCI will provide a summary of the status and results of its development, manufacturing and commercialization activities for the product prior to the effective date of the termination. In addition, BCI shall use commercially reasonable efforts to transition to the Company all development, manufacturing and commercialization activities and responsibilities for the product as in existence as of the date of termination and upon the request of the Company grant to the Company a fully paid-up, non-royalty bearing, perpetual license under BCI's right in the joint program technology and joint program patent rights.

If the License Agreement is terminated by BCI upon the expiration of a 60 days' notice of default then the licenses granted to BCI shall continue to be valid in accordance with the License Agreement, provided that BCI continues to pay amounts due to the Company for the balance of the term.

The last patent subject to the License Agreement is set to expire in 2040.

Note 4 – Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	As of	
	September 30, 2024	December 31, 2023
	(unaudited)	
Research and Development Consultants	\$ 93,042	\$ 93,037
Executives Consultant Fees	316,667	347,167
Business Development Consultants	637,500	750,000
Accounting and Legal Fees	494,837	454,016
Board of Director Fees	427,495	333,745
Accrued License Fees – Alopexx Pharmaceuticals	375,000	300,000
Accrued License Fees – Alopexx Vaccine	243,750	195,000
Total	\$ 2,588,291	\$ 2,472,965

Note 5 – Debt

Convertible Notes Payable

On January 5, 2022, the Company entered into a convertible note agreement in which the Company received \$50,000 in cash proceeds. The note bears interest at a rate of 8% per annum and is set to mature in January 2025, as amended. The note is automatically converted into the Company's voting common stock at 75% of the purchase price of a future financing of \$25 million prior to the first-year anniversary of the agreement or \$5 million after the first year of the agreement. At September 30, 2024 and December 31, 2023, there was accrued interest of \$10,948 and \$7,944, respectively. As of September 30, 2024 and December 31, 2023, the outstanding principal balance was \$50,000.

Convertible Notes Payable – Related Parties

On October 25, 2021, the Company and shareholder, Werth Family Investment Associates, LLC, entered into a convertible loan agreement, in which the Company received \$200,000. The note bears interest at a rate of 8% per annum and is payable in full on October 20, 2024, as amended. As of September 30, 2024 and December 31, 2023, the outstanding principal balance was \$200,000. The note is convertible into shares of common stock at a conversion price of 75% of the per share offering price of a next equity financing event which the agreement defines as "a sale by the Company of its shares in an initial public offering from which the Company receives gross proceeds of not less than \$25 million and in the event such initial public offering does not occur before the first anniversary, the next equity financing means the sale by the Company of its Shares in a public or private offering from which the Company receives gross proceeds of not less and \$5 million." Management evaluated the accounting guidance for embedded conversion features and ultimately determined that the embedded conversion feature did not require to be bifurcated under ASC Topic 815 "Derivatives and Hedging" and therefore, the convertible debt instrument is accounted for as a single liability measured at amortized cost.

On January 5, 2022, the Company entered into a convertible note agreement with a related party in which the Company received \$100,000 in cash proceeds. The note bears interest at a rate of 8% per annum and is set to mature in January 2025, as amended. The notes are automatically converted into the Company's voting common stock at 75% of the purchase price of a future financing of \$25 million prior to the first-year anniversary of the agreement or \$5 million after the first year of the agreement. As of September 30, 2024 and December 31, 2023, the outstanding principal balance was \$100,000.

On February 17, 2022, the Company entered into a convertible note agreement with a related party, in which the Company received \$200,000 in cash proceeds. The note bears interest at a rate of 8% per annum and is set to mature in February 2025, as amended. The note is automatically converted into the Company's voting common stock at 75% of the purchase price of a future financing of \$25 million prior to the first-year anniversary of the agreement or \$5 million after the first year of the agreement. As of September 30, 2024 and December 31, 2023, the outstanding principal balance was \$200,000.

In February 2022, the Company amended the four outstanding convertible notes payable agreements with a total principal balance of \$550,000 to decrease the automatic conversion threshold. Subsequent to this amendment, the notes are automatically converted into the Company's voting common stock at 75% of the purchase price of a future financing of \$10 million prior to the first-year anniversary of the agreement or \$5 million after the first year of the original agreement and treated as a modification.

On March 24, 2022, the Company entered into a convertible note agreement with a related party, in which the Company received \$200,000 in cash proceeds. The note bears interest at a rate of 8% per annum and is set to mature in March 2025, as amended. The note is automatically converted into the Company's voting common stock at 75% of the purchase price of a future financing of \$10 million prior to the first-year anniversary of the agreement or \$5 million after the first year of the agreement. As of September 30, 2024 and December 31, 2023, the outstanding principal balance was \$200,000.

On August 6, 2024, the Company entered into a convertible note agreement with Daniel Vlock, CEO in which the Company received \$200,000 in cash proceeds. The note bears interest at a rate of 12% per annum and is set to mature two years from its commencement date. The conversion terms are similar to the existing outstanding convertible notes.

Accrued interest – related parties on the above convertible notes payable totaled \$154,871 and \$109,216 at September 30, 2024 and December 31, 2023, respectively.

Notes Payable – Related Parties

On June 27, 2022, the Company entered into a note agreement with a related party, in which the Company received \$400,000 in cash proceeds. The note bears interest at a rate of 9% per annum and is set to mature on June 27, 2025, as amended. As of September 30, 2024 and December 31, 2023, the outstanding principal balance was \$400,000.

On October 24, 2022, the Company entered into a note agreement with a related party, in which the Company received \$50,000 in cash proceeds. The note bears interest at a rate of 9% per annum and is set to mature the earlier of October 24, 2024, as amended, or a future financing of \$10 million prior to December 31, 2022 or \$5 million thereafter. As of September 30, 2024 and December 31, 2023, the outstanding principal balance was \$50,000.

On October 26, 2022, the Company entered into a note agreement with a related party, in which the Company received \$300,000 in cash proceeds. The note bears interest at a rate of 15% per annum and is set to mature the earlier of October 26, 2024, as amended, or a future financing of \$10 million prior to December 31, 2022 or \$5 million thereafter. As of September 30, 2024 and December 31, 2023, the outstanding principal balance was \$300,000.

On December 12, 2022, the Company entered into a promissory note with a related party, in which the Company received \$250,000 in cash proceeds. The note bears interest at 12% per annum and is set to mature the earlier of December 12, 2024, as amended, or a future financing of \$10 million prior to January 31, 2023 or \$5 million thereafter. As of September 30, 2024 and December 31, 2023, the outstanding principal balance was \$250,000.

On February 28, 2023, the Company entered into a promissory note with a related party, in which the Company received \$200,000 in cash proceeds. The note bears interest at 12% per annum and is set to mature the earlier of February 28, 2025, as amended, or a future financing of \$10 million prior to February 24, 2024 or \$5 million thereafter. As of September 30, 2024 and December 31, 2023, the outstanding principal balance was \$200,00.

On May 12, 2023, the Company entered into a promissory note with a related party, in which the Company received \$50,000 in cash proceeds. The note bears interest at 12% per annum and is set to mature the earlier of May 12, 2025, as amended, or a future financing of \$10 million prior to May 12, 2024 or \$5 million thereafter. As of September 30, 2024 and December 31, 2023, the outstanding principal balance was \$50,000.

On November 28, 2023, the Company entered into a promissory note with a related party, in which the Company received \$200,000 in cash proceeds. The note bears interest at 15% per annum and is set to mature the earlier of November 28, 2025, as amended, or a future financing of \$10 million prior to January 31, 2024 or \$5 million thereafter. As of September 30, 2024 and December 31, 2023, the outstanding principal balance was \$200,000.

Accrued interest – related parties on the above notes payable totaled \$302,889 and \$171,145 at September 30, 2024 and December 31, 2023, respectively.

Note 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.

On June 8, 2022, the Company was sued in the Commercial Court of Nantes, France by Xenothera. The litigation is seeking, among other things, to compel the Company to enter into a license agreement with Xenothera or provide 120,000,000 euros (\$133,714,891 at September 30, 2024) in damages. No liability has been recorded related to this matter as the Company intends to vigorously defend this claim and believes the claim is without merit.

Note 7 – Stockholders’ Deficit

Preferred Stock

As of September 30, 2024 and December 31, 2023, there was no Preferred Stock issued or outstanding.

Common Stock

On May 6, 2024, the Company issued 9,487 shares of common stock for approximately \$50,000 to a related party. The per share price of the common stock was \$5.27 per share.

On May 3, 2024, the Company issued 47,438 shares of common stock for approximately \$250,000 to a related party. The per share price of the common stock was \$5.27 per share.

On February 26, 2024, the Company issued 37,951 shares of common stock for approximately \$200,000 to a related party. The per share price of the common stock was \$5.27 per share.

On November 28, 2023, the Company issued 21,063 shares of common stock for \$111,000 to a related party. The per share price of the common stock was \$5.27 per share.

On October 18, 2023, the Company issued 67,377 shares of common stock for approximately \$355,000 to a related party. The per share price of the common stock was \$5.27 per share.

On July 21, 2023, the Company issued 75,902 shares of common stock for \$400,000 to a related party. The per share price of the common stock was \$5.27 per share.

As of September 30, 2024 and December 31, 2023, respectively, there were 4,899,218 and 4,804,342 shares issued and outstanding.

Note 8 – Employee Incentive Plan

On August 31, 2023, the Company entered into the 2023 Employee Incentive Plan to attract and retain the type of Employees, Consultants and Directors who will contribute to the Company's long-term success. The options under the plan are service-based grants that vest over three years and are exercisable over periods not exceeding ten years.

The aggregate number of shares reserved to be issued under the plan is 2,500,000. The options granted generally vest either 33% upfront then ratably over the remaining two years or ratably over three years.

There were 0 and 1,419,388 stock options granted for the three months ended September 30, 2024 and 2023. There were 0 and 1,419,388 stock options granted for the nine months ended September 30, 2024 and 2023.

The following represents of a summary of options:

	Stock Options	Weighted-Average Exercise Price	Weighted- Average Remaining Contractual Term
Issued and outstanding, December 31, 2023	1,419,388	\$ 4.04	9.67
Granted	—	—	—
Issued	—	—	—
Forfeited/Expired	—	—	—
Issued and outstanding, September 30, 2024	1,419,388	\$ 4.04	9.01
Exercisable, September 30, 2024	935,203	\$ 4.04	9.01

For the three and nine months ended September 30, 2024, the Company had \$371,488 and \$1,114,460 of stock compensation, respectively, included in general and administrative expenses on the accompanying unaudited condensed statements of operations for the period ended. For the three and nine months ended September 30, 2023, the Company had \$1,551,501 of stock compensation, included in general and administrative expenses on the accompanying unaudited condensed statements of operations for the period ended. As of September 30, 2024, the remaining unamortized expense of \$1,527,875 will be recognized over the next 1.05 years.

Note 9 – Related Parties

See Note 5, *Convertible Notes Payable – Related Parties*.

See Note 5, *Notes Payable – Related Parties*.

Shares Issued – Related Parties

On May 6, 2024, the Company issued 9,487 shares of common stock for approximately \$50,000 to a related party. The per share price of the common stock was \$5.27 per share.

On May 3, 2024, the Company issued 47,438 shares of common stock for approximately \$250,000 to a related party. The per share price of the common stock was \$5.27 per share.

On February 26, 2024, the Company issued 37,951 shares of common stock for approximately \$200,000 to a related party. The per share price of the common stock was \$5.27 per share.

On July 21, 2023, the Company issued 75,902 shares of common stock for \$400,000 to a related party. The per share price of the common stock was \$5.27 per share.

On October 18, 2023, the Company issued 67,377 shares of common stock for approximately \$355,000 to a related party. The per share price of the common stock was \$5.27 per share.

On November 28, 2023, the Company issued 21,063 shares of common stock for \$111,000 to a related party. The per share price of the common stock was \$5.27 per share.

Note 10 – Subsequent Events

The Company has completed an evaluation of all subsequent events through January 8, 2025, the date these unaudited condensed financial statements were issued. The Company has concluded that no subsequent event has occurred that requires disclosure.

2,400,000 Shares of Common Stock

ALOPEXX, Inc.

Alopexx, Inc.

PRELIMINARY PROSPECTUS

ThinkEquity

, 2025

Through and including , 2025 (25 days after the date of this prospectus), all dealers that effect transactions in our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to unsold allotments or subscriptions.

The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED JANUARY [*], 2025

PRELIMINARY PROSPECTUS

ALOPEXX, INC

Up to 300,000 Selling Stockholder Shares to be sold by the Selling Stockholder.

This prospectus relates to the resale of up to 300,000 shares of common stock, par value \$0.0001 per share (the “Selling Stockholder Shares”) of Alopexx, Inc, a Delaware corporation, by the stockholder named in this prospectus (the “Selling Stockholder”). We will not receive any of the proceeds from the sale of the Selling Stockholder Shares by the Selling Stockholder. Furthermore, the underwriters will neither underwrite the sale of the Company Shares in the underwritten primary offering nor receive any compensation from the sale of the Selling Stockholder Shares by the Selling Stockholder.

The resale of the Selling Stockholder Shares is conditioned upon the successful completion of the sale of the Shares by the Company in the underwritten primary offering and the listing of the Shares on NYSE American. Following listing of our Shares on the NYSE American, the per share public offering price of the Selling Stockholder Shares to be sold by the Selling Stockholder will be at market prices prevailing at the time of sale, at prices related to prevailing market prices, or at negotiated prices. The registration of the Selling Stockholder Shares does not mean that the Selling Stockholder will offer or sell any of the Selling Stockholder Shares. In addition, we will pay all fees and expenses incident to the registration of the Selling Stockholder Shares. The Selling Stockholder may offer their shares from time to time directly or through one or more broker-dealers or agents at market prices prevailing at the time of sale. For additional information on the possible methods of sale that may be used by the Selling Stockholder, you should refer to the section of this prospectus entitled “Selling Stockholder Plan of Distribution”.

Prior to this Offering, there has been no public market for the Company’s shares of Common Stock. The Company expects that the initial public offering price will be US\$5.00 per share. It intends to list the Shares of the Company on NYSE American under the symbol “ALPX”. However, there is no assurance that the initial public offering will be closed and that the Company Shares will trade on the NYSE American.

Alopexx, Inc is an “emerging growth company” under applicable U.S. federal securities laws and is eligible for reduced public company reporting requirements.

Investing in our securities involves a high degree of risk. See “Risk Factors” beginning on page __ of the primary offering prospectus.

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

TABLE OF CONTENTS

PROSPECTUS SUMMARY	1
THE OFFERING	Alt-1
RISK FACTORS	5
CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS	20
SELLING STOCKHOLDER	Alt-2
SELLING STOCKHOLDER PLAN OF DISTRIBUTION	Alt-3
USE OF PROCEEDS	Alt-5
DIVIDEND POLICY	22
MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	25
BUSINESS	28
MANAGEMENT	68
EXECUTIVE COMPENSATION	74
SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT	75
CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS	77
DESCRIPTION OF SECURITIES	78
SHARES ELIGIBLE FOR FUTURE SALE	82
LEGAL MATTERS	Alt-5
EXPERTS	89
WHERE YOU CAN FIND ADDITIONAL INFORMATION	89
INDEX TO FINANCIAL STATEMENTS	F-1

You should rely only on the information contained in this prospectus or in any related free-writing prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus or in any related free-writing prospectus. We are offering to sell, and seeking offers to buy, the Shares only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is current only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of the Selling Stockholder Shares.

We have not taken any action to permit a public offering of the Shares outside the United States or to permit the possession or distribution of this prospectus or any filed free writing prospectus outside the United States. Persons outside the United States who come into possession of this prospectus or any filed free writing prospectus must inform themselves about and observe any restrictions relating to the offering of the Shares and the distribution of this prospectus or any filed free writing prospectus outside the United States.

THE OFFERING

Issuer	Alopexx, Inc
Securities Being Offered by the Selling Stockholder	Up to 300,000 Selling Stockholder Shares
Voting Rights	Each Share is entitled to one vote.
Use of Proceeds	We will not receive any proceeds from the sale of the Selling Stockholder Shares.
Risk Factors	See “ <i>Risk Factors</i> ” and other information included in the Public Offering Prospectus for a discussion of factors you should carefully consider before deciding to invest in the Selling Stockholder Shares.
Listing	The Company plans to have the Shares listed on NYSE American under the symbol “ALPX.” The Shares will not be listed on any other stock exchange or on any automated quotation system.

[RESALE PROSPECTUS ALTERNATE PAGE]

Alt-1

SELLING STOCKHOLDER

The table below presents information regarding the Selling Stockholder and the Selling Stockholder Shares that they may offer from time to time under this prospectus. This table is prepared based on information supplied to us by the Selling Stockholder and reflects holdings as of the date of this prospectus.

The number of shares in the column “Total Number of Shares to be Offered for Selling Stockholder Account” represents all of the Shares that the Selling Stockholder may offer under this Resale Prospectus. The Selling Stockholder may sell some, all, or none of their shares offered by this prospectus. We do not know how long the Selling Stockholder will hold the shares before selling them, and we currently have no agreements, arrangements, or understandings with the Selling Stockholder regarding the sale of any of the shares. Other than as set forth below, no selling stockholder is a broker-dealer or an affiliate of a broker-dealer. Except for the certain Collaboration and License Agreement dated September 5, 2024, as amended, between the Company and the Selling Stockholder, as amended, the selling stockholder has not had a material relationship with the Company or any predecessor of the Company within the past 3 years.

Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the Commission under the Exchange Act and includes shares of the Common Stock of the Company with respect to which the Selling Stockholder has the voting and investment power. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days after the date of this table. We had an aggregate of 4,899,218 Shares of Common Stock outstanding as of the date of this prospectus.

Name of Selling Stockholder	Shares Owned Prior to this Offering	Total Number of Shares to be Offered for Selling Stockholder Account	Total Shares to be Owned Upon Completion of the Offering	Percentage to be Owned Upon Completion of the Offering
Biotech Consortia, Inc	300,000 ⁽¹⁾	300,000	0	* *

* Less than 1%.

(1) We have entered into a Stock Purchase Agreement dated as of December 26, 2024 for the purchase by the Selling Stockholder of 300,000 shares of our common stock. The closing of the Stock Purchase Agreement will occur immediately prior to the effective date of this registration statement of which this prospectus forms a part.

Alt-2

SELLING STOCKHOLDER PLAN OF DISTRIBUTION

We are registering the Selling Stockholder Shares to permit the resale of the Selling Stockholder Shares by the Selling Stockholder from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale of the Selling Stockholder Shares. We will bear all fees and expenses incident to the registration of the Selling Stockholder Shares in the registration statement of which this prospectus forms a part. The Selling Stockholder Shares will not be sold through the Underwriter in the initial public offering, nor will it receive any compensation from the sale of the Selling Stockholder Shares.

The Selling Stockholder may sell all or a portion of the Selling Stockholder Shares beneficially owned by them and offered hereby from time to time directly or through one or more broker-dealers or agents or in the over-the-counter market at market prices prevailing at the time of sale. If the Selling Stockholder Shares are sold through broker-dealers, the Selling Stockholder will be responsible for any commissions or agent’s commissions. The Selling Stockholder Shares may be sold in one or more transactions at prevailing market prices at the time of the sale. However, the Selling Stockholder will not sell any Selling Stockholder Shares until after the closing of the underwritten primary offering. These sales may be effected in transactions, which may involve crosses or block transactions:

- on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale;
- in the over-the-counter market;
- in transactions otherwise than on these exchanges or systems or in the over-the-counter market;
- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- short sales;
- in transactions through broker-dealers that agree with the Selling Stockholder to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;

- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The Selling Stockholder may also sell securities under Rule 144 or any other exemption from registration under the Securities Act, if available, rather than under this prospectus. However, the Selling Stockholder will not sell any Selling Stockholder Shares until after the closing of the primary underwritten initial public offering.

Under applicable rules and regulations under the Securities Exchange Act, as amended (the “Exchange Act”), any person engaged in the distribution of the Shares may not simultaneously engage in market making activities with respect to the Shares for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the Selling Stockholder will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of the Selling Stockholder Shares by the Selling Stockholder or any other person. We will make copies of this prospectus available to the Selling Stockholder and have informed them of the need to deliver a copy of this prospectus at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act, as amended).

If the Selling Stockholder effects such transactions by Selling Stockholder Shares to or through broker-dealers or agents, such broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the Selling Stockholder or commissions from purchasers of the Selling Stockholder Shares for whom they may act as agent or to whom they may sell as principal (which discounts, concessions or commissions as to particular broker-dealers or agents may be in excess of those customary in the types of transactions involved). In connection with sales of the Selling Stockholder Shares or otherwise, the Selling Stockholder may enter into hedging transactions with broker-dealers, which may, in turn, engage in short sales of the Selling Stockholder Shares in the course of hedging in positions they assume. The Selling Stockholder may also sell Selling Stockholder Shares short and deliver Selling Stockholder Shares covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The Selling Stockholder may also loan or pledge Selling Stockholder Shares to broker-dealers that in turn may sell such shares.

The Selling Stockholder may pledge or grant a security interest in some or all of the warrants or Selling Stockholder Shares owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the Selling Stockholder Shares from time to time pursuant to an amendment to this prospectus under applicable provision of the Securities Act, amending, if necessary, the list of Selling Stockholder to include the pledgee, transferee or other successors in interest as Selling Stockholder under this prospectus.

Alt-3

The Selling Stockholder and any broker-dealer participating in the distribution of the Selling Stockholder Shares may be deemed to be “underwriters” within the meaning of the Securities Act, and any commission paid, or any discounts or concessions allowed to, any such broker-dealer may be deemed to be underwriting commissions or discounts under the Securities Act. At the time a particular offering of the Selling Stockholder Shares is made, a prospectus supplement, if required, will be distributed which will set forth the aggregate amount of Selling Stockholder Shares being offered and the terms of the offering, including the name or names of any broker-dealers or agents, any discounts, commissions and other terms constituting compensation from the Selling Stockholder and any discounts, commissions or concessions allowed or reallocated or paid to broker-dealers.

Under the securities laws of some states, the Selling Stockholder Shares may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the Selling Stockholder Shares may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

There can be no assurance that the Selling Stockholder will sell any or all of the Selling Stockholder Shares registered pursuant to the registration statement, of which this prospectus forms a part. We have no agreements, arrangements or understandings with the Selling Stockholder regarding the sale of any of the Selling Stockholder Shares. The selling stockholder is not a broker-dealer or an affiliate of a broker-dealer. Except for the certain Collaboration and License Agreement dated September 5, 2024 between the Company and the Selling Stockholder, the Selling Stockholder does not have a material relationship with the Company or any predecessor of the Company within the past 3 years. The Selling Stockholder is not acting as a conduit for the Company

The Selling Stockholder and any other person participating in such distribution will be subject to applicable provisions of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder, including, without limitation, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the Selling Stockholder Shares by the Selling Stockholder and any other participating person. Regulation M may also restrict the ability of any person engaged in the distribution of the Selling Stockholder Shares to engage in market-making activities with respect to the Selling Stockholder Shares. All of the foregoing may affect the marketability of the Selling Stockholder Shares and the ability of any person or entity to engage in market-making activities with respect to the Selling Stockholder Shares.

Once sold under the registration statement, of which this prospectus forms a part, the Selling Stockholder Shares will be freely tradeable in the hands of persons other than our affiliates.

Alt-4

[RESALE PROSPECTUS ALTERNATE PAGE]

USE OF PROCEEDS

We will not receive any of the proceeds from the sale of our Selling Stockholder Shares by the Selling Stockholder. In addition, the Underwriter will not receive any compensation from the sale of the Shares by the Selling Stockholder. The Selling Stockholder will receive all of the net proceeds from the sales of the Selling Stockholder Shares offered by it under this prospectus. We have agreed to bear the expenses relating to the registration of the Selling Stockholder Shares for the Selling Stockholder.

LEGAL MATTERS

The validity of the Selling Stockholder Shares to be offered by the Selling Stockholder will be passed upon for us by Sichenzia Ross Ference Carmel LLP, New York, New York.

Alt-5

PRELIMINARY RESALE PROSPECTUS

Up to 300,000 Selling Stockholder Shares to be Offered by the Selling Stockholder.

, 2025

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution

The following table sets forth the costs and expenses, other than the underwriting discounts and commissions, payable by the registrant in connection with the sale of common stock being registered. All amounts are estimates except for the SEC registration fee, the Financial Industry Regulatory Authority, or FINRA, filing fee and NYSE American listing fee.

Item	Amount to be paid
SEC registration fee	\$ 3,101
FINRA filing fee	6,540
NYSE American Listing fee	5,000
Printing fees and expenses	65,000
Legal fees and expenses	693,000
Accounting fees and expenses	571,500
Underwriter's expenses	215,000
Transfer agent's fees and expenses	25,000
Miscellaneous fees and expenses	100,000
Total	\$ 1,684,141

Item 14. Indemnification of Directors and Officers

Section 145 of the DGCL, or Section 145, provides that a Delaware corporation may indemnify any person who was, is or is threatened to be made, party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person is or was an officer, director, employee or agent of such corporation or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the corporation's best interests and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was illegal. A Delaware corporation may indemnify any persons who are, were or are a party to any threatened, pending or completed action or suit by or in the right of the corporation by reason of the fact that such person is or was a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit, provided such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the corporation's best interests, provided that no indemnification is permitted without judicial approval if the officer, director, employee or agent is adjudged to be liable to the corporation. Where an officer or director is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him against the expenses which such officer or director has actually and reasonably incurred.

Section 145 further authorizes a corporation to purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation or enterprise, against any liability asserted against him and incurred by him in any such capacity, or arising out of his or her status as such, whether or not the corporation would otherwise have the power to indemnify him under Section 145.

Our bylaws provide that we must indemnify our directors and officers to the fullest extent permitted by the DGCL and must indemnify against all expenses, liability, and loss incurred in investigating, defending or participating in such proceedings.

As of the date of the effectiveness of this registration statement, we have entered into separate indemnification agreements with each of our directors and executive officers. Each indemnification agreement provides, among other things, for indemnification to the fullest extent permitted by law and our bylaws against any and all expenses, judgments, fines, penalties and amounts paid in settlement of any claim. The indemnification agreements provide for the advancement or payment of all expenses to the indemnitee.

Item 15. Recent Sales of Unregistered Securities

On October 25, 2021, the Company entered into a convertible note agreement with a related party in which the Company received \$200,000 in cash proceeds. The note bears interest at a rate of 8% per annum and is payable in full on October 20, 2024, as amended. The note is automatically converted into the Company's voting common stock at 75% of the purchase price of a future financing of \$10 million prior to the first-year anniversary of the agreement or \$5 million after the first-year anniversary of the agreement.

On January 5, 2022, the Company entered into two convertible note agreements, including with a related party, for which the Company received \$150,000 in cash proceeds. The notes bear interest at a rate of 8% per annum and are set to mature in January 2025, as amended. The notes are automatically converted into the Company's voting common stock at 75% of the purchase price of a future financing of \$10 million prior to the first-year anniversary of the agreement or \$5 million after the first year anniversary of the agreement.

On February 17, 2022, the Company entered into a convertible note agreement with a related party, in which the Company received \$200,000 in cash proceeds. The note bears interest at a rate of 8% per annum and is set to mature in February 2025, as amended. The note is automatically converted into the Company's voting common stock at 75% of the purchase price of a future financing of \$10 million prior to the first-year anniversary of the agreement or \$5 million after the first year of the agreement.

On March 24, 2022, the Company entered into a convertible note agreement with a related party, in which the Company received \$200,000 in cash proceeds. The note bears interest at a rate of 8% per annum and is set to mature in March 2025, as amended. The note is automatically converted into the Company's voting common stock at 75% of the purchase price of a future financing of \$10 million prior to the first-year anniversary of the agreement or \$5 million after the first year of the agreement.

These issuances were made in reliance upon Section 4(a)(2) of the Securities Act of 1933, as amended, and Regulation D, Rule 506(d), and did not involve any underwriters, underwriting discounts or commissions, or any public offering. The persons and entities who received such securities have represented their intention to acquire these securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends are be affixed to all share certificates issued. All recipients have adequate access through their relationship with us to information about us.

On June 27, 2022, the Company entered into a promissory note with a related party, in which the Company received \$400,000 in cash proceeds. The note bears interest at a rate of 9% per annum and is set to mature on June 27, 2025, as amended, or a future financing of \$10 million prior to December 31, 2022 or \$5 million thereafter.

On October 24, 2022, the Company entered into a note agreement with a related party, in which the Company received \$50,000 in cash proceeds. The note bears interest at a rate of 9% per annum and is set to mature the earlier of October 24, 2024, as amended, or a future financing of \$10 million prior to December 31, 2022 or \$5 million thereafter.

On October 26, 2022, the Company entered into a note agreement with a related party, in which the Company received \$300,000 in cash proceeds. The note bears interest at a rate of 15% per annum and is set to mature the earlier of October 26, 2024, as amended, or a future financing of \$10 million prior to December 31, 2022 or \$5 million thereafter.

On December 12, 2022, the Company entered into a promissory note with a related party, in which the Company received \$250,000 in cash proceeds. The note bears interest at 12% per annum and is set to mature the earlier of December 12, 2024, as amended, or a future financing of \$10 million prior to January 31, 2023 or \$5 million thereafter.

On February 28, 2023, the Company entered into a promissory note with a related party, in which the Company received \$200,000 in cash proceeds. The note bears interest at 12% per annum and is set to mature the earlier of February 28, 2025, as amended, or a future financing of \$10 million prior to February 24, 2024 or \$5 million thereafter.

On May 12, 2023, the Company entered into a promissory note with a related party, in which the Company received \$50,000 in cash proceeds. The note bears interest at 12% per annum and is set to mature the earlier of May 12, 2025, as amended, or a future financing of \$10 million prior to May 12, 2024 or \$5 million thereafter.

On July 21, 2023, the Company issued 75,902 shares of common stock to a related party for \$400,000.

On October 18, 2023, the Company issued 67,377 shares of common stock to a related party for approximately \$355,000.

On October 31, 2023, the Company entered into a number of agreements with certain related party note holders to extend the maturity dates of the notes entered into on October 21, 2021; October 24, 2022; October 26, 2022; December 12, 2022; and February 28, 2023 by one year each.

On November 28, 2023, the Company issued 21,063 shares of common stock to a related party for \$111,000.

On November 28, 2023, the Company entered into a promissory note with a related party, in which the Company received \$200,000 in cash proceeds. The note bears interest at 15% per annum and is set to mature the earlier of November 28, 2025, as amended, or a future financing of \$10 million prior to January 31, 2024 or \$5 million thereafter.

On January 29, 2024, the Company entered into a number of agreements with certain related party note holders to extend the maturity dates of the notes entered into on January 5, 2022 by one year each.

On February 26, 2024, the Company issued 37,951 shares of common stock to a related party for \$200,000.

On May 3, 2024, the Company issued 47,438 shares of common stock for approximately \$250,000 to a related party.

On May 6, 2024, the Company issued 9,487 shares of common stock for approximately \$50,000 to a related party.

During May and June 2024, the Company entered into agreements with Daniel Vlock, CEO, to extend the maturity dates of notes entered into on June 27, 2022 and May 12, 2023 by one year each.

On August 6, 2024, the Company entered into a convertible note agreement with Daniel Vlock, CEO in which the Company received \$200,000 in cash proceeds. The note bears interest at a rate of 12% per annum and is set to mature two years from its commencement date. The conversion terms are similar to the existing outstanding convertible notes.

On December 26, 2024, the Company entered into a Stock Purchase Agreement with BCI (the "Purchase Agreement") for the sale by the Company of 300,000 shares of its common stock at a purchase price of \$5 per share for gross proceeds of \$1,500,000. Pursuant to the terms of the Purchase Agreement, the Company granted BCI "piggy-back" registration rights. In addition, BCI will enter into a lock-up agreement with the underwriters for approximately 180 days after the date of this prospectus, which will impose certain restrictions on the resale of the shares purchased under the Purchase Agreement. The transactions contemplated by the Purchase Agreement have not yet closed. However, the parties intend to close the transactions prior to the effective date of this Registration Statement of which this prospectus forms a part.

Item 16. Exhibits and Financial Statement Schedules)

(a) Exhibits

- [1.1**](#) [Form of Underwriting Agreement.](#)
- [3.1**](#) [Certificate of Incorporation of the Registrant as currently in effect.](#)
- [3.2**](#) [Form of Amended and Restated Certificate of Incorporation of Registrant, to be in effect prior to the completion of this offering.](#)
- [3.3**](#) [Bylaws of the Registrant, as currently in effect.](#)
- [3.4**](#) [Form of Amended and Restated Bylaws of the Registrant, to be in effect prior to the completion of this offering.](#)
- [4.1**](#) [Specimen Common Stock Certificate.](#)
- [5.1*](#) [Opinion of Sichenzia Ross Ference Carmel LLP](#)
- [10.1**](#) [2023 Equity Plan and form of award agreements thereunder.](#)
- [10.2**](#) [Form of Indemnification Agreement between the Registrant and each of its directors.](#)
- [10.3**#](#) [Exclusive Patent License Agreement dated as of December 4, 2007, by and between Alopexx Pharmaceuticals, LLC and The Brigham and Women's Hospital, Inc., as amended on November 30, 2009, January 27, 2010, and March 6, 2015.](#)
- [10.4**#](#) [Amendment No. 5 to Exclusive Patent License Agreement dated as of February 2, 2022, by and between Alopexx, Inc. and The Brigham and Women's Hospital, Inc.](#)
- [10.5**#](#) [Exclusive Patent License Agreement dated as of March 2, 2012, by and between Alopexx Vaccine, LLC and The Brigham and Women's Hospital, Inc. as amended on April 9, 2019.](#)
- [10.6**#](#) [Amendment No. 2 to the Exclusive Patent License Agreement by and between Alopexx, Inc. and Brigham and Women's Hospital, Inc. dated as of February 2, 2022.](#)
- [10.7*#](#) [Collaboration and License Agreement by and between Alopexx, Inc and Biotech Consortia, Inc](#)
- [10.8*](#) [Amendment to Collaboration and License Agreement by and between Alopexx, Inc and Biotech Consortia, Inc](#)
- [10.9*](#) [Stock Purchase Agreement dated December 26, 2024 by and between Alopexx, Inc and Biotech Consortia, Inc](#)
- [10.10*](#) [Employment Agreement with Daniel R Vlock](#)
- [10.11*](#) [Employment Agreement with Thomas T. Thomas](#)
- [10.12*](#) [Amended and Restated Consulting Agreement with BiotechPartnering Solutions, LLC](#)
- [23.1*](#) [Consent of Marcum LLP](#)
- [23.2*](#) [Consent of Sichenzia Ross Ference Carmel LLP \(included in Exhibit 5.1\)](#)
- [99.1**](#) [Consents of Director Nominees](#)
- [107.1*](#) [Filing Fee Table](#)

Certain sections, schedules, exhibits and similar attachments have been omitted pursuant to Item 601(a)(5) and Item 601(b)(10) of Regulation S-K. The Company hereby undertakes to furnish copies of such omitted materials supplementally upon request by the Securities and Exchange Commission.

*Filed herewith

** Previously filed.

Item 17. Undertakings

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933, as amended (the “Securities Act”);

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission (the “Commission”) pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the “Calculation of Registration Fee” table in the effective registration statement;

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

Provided, however, that Paragraphs (a)(1)(i), (ii), and (iii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), that are incorporated by reference in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser: If the registrant is subject to Rule 430C (§230.430C of this chapter), each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A (§230.430A of this chapter), shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(5) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424 (§230.424 of this chapter);

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(c) The undersigned Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Signatures

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in Cambridge, Massachusetts, on January 8, 2025.

ALOPEXX, INC.

By: /s/ Daniel R. Vlock

Name: Daniel R. Vlock

Title: President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, as amended, the following persons in the capacities and on the dates indicated have signed this Registration Statement below.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Daniel R. Vlock</u> Daniel R. Vlock	President, Chief Executive Officer and Director (Principal Executive Officer)	January 8, 2025
<u>/s/ Thomas T. Thomas</u> Thomas T. Thomas	Chief Financial Officer (Principal Financial and Accounting Officer)	January 8, 2025



January 8, 2025

Alopexx, Inc.
186 Alewife Brook Pkwy #1068
Cambridge, Massachusetts 02138

Ladies and Gentlemen:

We have acted as counsel for Alopexx, Inc, a Delaware corporation (the “Company”), in connection with the preparation and filing of a Registration Statement on Form S-1 (the “Registration Statement”), including a related prospectus filed with the Registration Statement (the “Prospectus”), with the Securities and Exchange Commission (the “Commission”) pursuant to the Securities Act of 1933, as amended (the “Securities Act”), covering the public offer and sale of (A) up to 2,400,000 shares of common stock (the “Shares”) of the Company, par value \$0.0001 per share (“Common Stock”) and (B) 300,000 shares of Common Stock (the “Selling Stockholder Shares”) for resale by a certain selling stockholder. This opinion is being rendered in connection with the filing of the Registration Statement with the Commission.

In connection with this opinion, we have examined originals or copies (certified or otherwise identified to our satisfaction) of (i) the Company’s Amended and Restated certificate of Incorporation, as currently in effect, (ii) the Company’s Bylaws as currently in effect, (iii) the Registration Statement and related Prospectus and (vi) such corporate records, agreements, documents and other instruments, and such certificates or comparable documents of public officials or of officers and representatives of the Company, as we have deemed relevant and necessary as a basis for the opinion hereinafter set forth.

In such examination, we have assumed the genuineness of all signatures, the legal capacity of all natural persons, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted to us as certified, conformed or photostatic copies, and the authenticity of the originals of such latter documents. As to certain questions of fact material to this opinion, we have relied upon certificates or comparable documents of officers and representatives of the Company and have not sought to independently verify such facts.

Based on the foregoing, and in reliance thereon, and subject to the qualifications, limitations, exceptions and assumptions set forth herein, we are of the opinion that

- (A) the Shares have been duly authorized and will be duly and validly issued, fully paid and non-assessable shares of common stock of the Company;
- (B) the Selling Stockholder Shares have been duly authorized and will be duly and validly issued, fully paid and non-assessable shares of common stock of the Company;

We express no opinion herein as to the laws of any state or jurisdiction other than Delaware General Corporation Law (including the statutory provisions and all applicable judicial decisions interpreting those laws) and the federal laws of the United States of America.

This opinion speaks only as of the date hereof and we assume no obligation to update or supplement this opinion if any applicable laws change after the date of this opinion or if we become aware after the date of this opinion of any facts, whether existing before or arising after the date hereof, that might change the opinions expressed above.

This opinion is furnished in connection with the filing of the Registration Statement and may not be relied upon for any other purpose without our prior written consent in each instance.



We assume no obligation to update or supplement any of our opinions to reflect any changes of law or fact that may occur. We hereby consent to the filing of this letter as an exhibit to the Registration Statement and to the reference to our firm under the caption “Legal Matters” in the Prospectus which is a part of the Registration Statement. In giving such consents, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the Rules and Regulations of the Commission promulgated thereunder.

Very truly yours,

/s/ Sichenzia Ross Ference Carmel LLP
Sichenzia Ross Ference Carmel LLP

AMENDMENT No. 1 to

COLLABORATION AND LICENSE AGREEMENT

This Amendment No. 1 to the COLLABORATION AND LICENSE Agreement (“Amendment No. 1”) is effective as of December 27, 2024 (“Amendment No. 1 Effective Date”) by and between Alopexx, Inc, a Delaware company, having an address of 186 Alewife Brook Parkway #1068, Cambridge, MA 02138, USA (together with its Affiliates, subsidiaries, successors and permitted assigns, “Alopexx”), and Biotech Consortia, Inc., a Bahamas international business company, having a registered office address at Trident Trust Company (Bahamas) Ltd, 1st Floor, Building A, Caves Corporate Center, Blake Road and West Bay Street, PO Box N-3944, Nassau, Bahamas (together with its Affiliates, subsidiaries, successors and permitted assigns, “BCI”). BCI and Alopexx may be referred to each individually as a “PARTY” or together collectively as the “PARTIES.”

RECITALS

WHEREAS, the PARTIES have executed a COLLABORATION AND LICENSE AGREEMENT which has an effective date of September 05, 2024; and

WHEREAS, the PARTIES have executed a STOCK PURCHASE AGREEMENT which has an effective data of December 26, 2024; and

WHEREAS, the PARTIES now desire to further amend the Collaboration and License Agreement in order to be consistent with the STOCK PURCHASE AGREEMENT.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the PARTIES hereby agree as follows:

1. Section 8.2 of the COLLABORATION AND LICENSE AGREEMENT will be revised to read as follows:

Equity Investment. BCI shall invest in Alopexx US\$1.5 million. BCI shall make such investment in connection with an alternative Alopexx funding event, in such event to be made consistent with independent valuation criteria as and then generally applicable to investment in Alopexx.

[The remainder of this page is intentionally left blank.]

IN WITNESS WHEREOF, the PARTIES hereto have duly executed and delivered this Amendment No. 1 to be effective as of the Amendment No. 1 Effective Date as evidenced by the signatures of their authorized representatives below.

COMPANY:
ALOPEXX, INC.

By: Daniel R. Vlock

Name: Daniel R. Vlock, MD

Title: Chief Executive Officer

Address: 186 Alewife Brook Parkway #1068
Cambridge, Massachusetts 02138 USA

Email:

IN WITNESS WHEREOF, the parties have executed this Stock Purchase Agreement as of the date first written above.

PURCHASER:
BIOTECH CONSORTIA, INC.

By: Aria K Bhooma

Name: Aria K. Bhooma

Title:

Authorized Signatory

Address:

STOCK PURCHASE AGREEMENT

THIS STOCK PURCHASE AGREEMENT (this “**Agreement**”) is made as of December 26, 2024, by and between Alopexx, Inc., a Delaware corporation (the “**Company**”) and Biotech Consortia, Inc., a Bahamas international business company (the “**Purchaser**”).

The parties hereby agree as follows:

1. Purchase and Sale of Common Stock.

1.1 Sale and Issuance of Common Stock. Subject to the terms and conditions of this Agreement, at the Closing (as defined below), the Purchaser shall purchase from the Company, and the Company shall issue and sell to the Purchaser 300,000 shares (the “**Shares**”) of common stock, par value \$0.0001 per share, of the Company (the “**Common Stock**”), at a purchase price of \$5.00 per share of Common Stock, and an aggregate price of One Million and Five Hundred Thousand \$1,500,000 (the “**Purchase Price**”) free and clear of any encumbrance or lien.

1.2 Closing; Delivery. Subject to the satisfactory completion of all conditions listed in Section 5 and Section 6 below, the purchase and sale of the Shares, and payment of the Purchase Price by the Purchaser, shall take place remotely via the exchange of documents and signatures, and is intended to occur one (1) day prior to the effective date of the Registration Statement (which time and place are designated as the “**Closing**”). After the Closing, the Company shall deliver to the Purchaser a certificate (which may be in electronic form) representing the Shares against payment of the Purchase Price.

1.3 At the Closing, the Company shall deliver to the Purchaser:

(a) certificates dated as of a date not more than five (5) days prior to the Closing Date, as to the Company’s good standing, together with a copy, dated as of a date not more than ten (10) days prior to the Closing Date, of the Certificate of the Company certified by the Secretary or Assistant Secretary of the Company;

(b) by-laws of the Company, together with all amendments thereto or restatements thereof, certified by the Secretary or Assistant Secretary of the Company as of the Closing Date;

(c) resolutions of the Board of Directors of Company, certified by the Secretary or Assistant Secretary of Company, approving and authorizing the execution, delivery and performance of this Agreement by the Company, and the consummation of the transactions contemplated hereby, in form and substance reasonably satisfactory to Purchaser.

1.4 Defined Terms Used in this Agreement. In addition to the terms defined above, the following terms used in this Agreement shall be construed to have the meanings set forth or referenced below:

- (a) “**Certificate**” means the certificate of incorporation of the Company, as amended through the date hereof.
 - (b) “**Closing Date**” means the date prior to the effective date of the Registration Statement.
-

(c) “**Code**” means the Internal Revenue Code of 1986, as amended.

(d) “**Company Intellectual Property**” means all patents, patent applications, registered and unregistered trademarks, trademark applications, registered and unregistered service marks, service mark applications, tradenames, copyrights, trade secrets, trade dress, logos, slogans, taglines, corporate or business names, brand names, product names, copyrights and copyrightable works, moral rights, mask work rights, and design rights, in each case whether or not registered, and registrations and applications for registration thereof, domain names, information and proprietary rights and processes, rights in software, data and databases, technology, know-how, improvements, similar or other intellectual property rights, subject matter of any of the foregoing, tangible embodiments of any of the foregoing, licenses in, to and under any of the foregoing, and in any and all such cases that are owned, licensed or used by the Company in the conduct of the Company’s business as now conducted.

(e) “**Governmental Authority**” means any foreign, federal, state, local or other court, arbitration, administrative agency or commission, insurance or securities regulatory or self-regulatory body or securities or commodities exchange

(f) “**IPO**” means the initial public offering of the Company’s securities.

(g) “**Material Adverse Effect**” means a material adverse effect on the business, assets (including intangible assets), liabilities, financial condition, property, or results of operations of the Company or on the ability of either Party to perform their obligations under this Agreement.

(h) “**Person**” means any individual, corporation, partnership, trust, limited liability company, association or other entity.

(i) “**Registration Statement**” means that certain registration statement on Form S-1, as may be amended from time to time, filed by the Company in connection with the Company’s IPO.

(j) “**Securities Act**” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

2. Representations and Warranties of the Company. The Company hereby represents and warrants to the Purchaser that, except as set forth on the Disclosure Schedule attached as Exhibit A to this Agreement, which exceptions shall be deemed to be part of the representations and warranties made hereunder, the following representations are true and complete as of the date of this Agreement and shall be true and correct in all respects as of the Closing.

2.1 Organization, Authority, and Qualification. The Company is a corporation duly organized, validly existing and in good standing under the Laws of the state of Delaware and has all necessary corporate power and authority to own, operate or lease the properties and assets now owned, operated or leased by it and to carry on its business as it is currently conducted. The Company is duly licensed or qualified to do business and is in good standing in each jurisdiction in which the properties owned or leased by it or the operation of its business as currently conducted makes such licensing or qualification necessary, except where the failure to be so licensed, qualified or in good standing would not have a Material Adverse Effect. All corporate actions taken by the Company in connection with this Agreement have been duly authorized. The execution, delivery, and performance of this Agreement by the Company does not and will not conflict with, violate, or result in a default under any applicable law, rule, regulation, judgment, decree, or contract to which the Company is a party or by which its properties are bound.

2.2 Capitalization. The authorized capital stock of the Company consists of 100,000,000 shares of common stock, \$0.0001 par value and 10,000,000 shares of preferred stock, \$0.0001 per share of which 4,899,218 of common stock are issued and outstanding and no shares of Preferred Stock are designated or issued and outstanding. Except as set out in Section 2.2 of the Disclosure Schedule, there are no outstanding or authorized options, warrants, convertible securities, stock appreciation, phantom stock, profit participation or other rights, agreements or commitments relating to the shares of the Company or other commitments (other than this Agreement) pursuant to which the Company is or may be obligated to issue, sell, purchase, return or redeem any shares of capital stock or other securities of the Company, and there are no equity securities of the Company reserved for issuance for any purpose.

2.3 Subsidiaries. Except as set forth in Section 2.3 of the Disclosure Schedule, the Company does not currently own or control, directly or indirectly, any interest in any other corporation, partnership, trust, joint venture, limited liability company, association, or other business entity.

2.4 Authorization. All corporate action required to be taken by the Company's Board and stockholders in order to authorize the Company to enter into this Agreement, and to issue the Shares at the Closing, has been taken. All action on the part of the officers of the Company necessary for the execution and delivery of the Agreement, the performance of all obligations of the Company under the Agreement to be performed as of the Closing, and the issuance and delivery of the Shares has been taken. The Agreement, when executed and delivered by the Company, shall constitute valid and legally binding obligations of the Company, enforceable against the Company in accordance with its terms except (i) as limited by applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance, or other laws of general application relating to or affecting the enforcement of creditors' rights generally, or (ii) as limited by laws relating to the availability of specific performance, injunctive relief, or other equitable remedies.

2.5 Valid Issuance of Shares. The Shares, when issued, sold and delivered in accordance with the terms and for the consideration set forth in this Agreement, will be validly issued, fully paid and nonassessable and free of restrictions on transfer other than restrictions on transfer under the Agreement, applicable state and federal securities laws and liens or encumbrances created by or imposed by a Purchaser. Assuming the accuracy of the representations of the Purchaser in Section 3 of this Agreement, the Shares will be issued in compliance with all applicable federal and state securities laws.

2.6 Governmental Consents and Filings. Assuming the accuracy of the representations made by the Purchaser in Section 3 of this Agreement, no consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any federal, state or local Governmental Authority is required on the part of the Company in connection with the consummation of the transactions contemplated by this Agreement, except for filings pursuant to applicable securities laws, which have been made or will be made in a timely manner. Neither the execution, delivery and performance by the Company of this Agreement nor the Company's consummation of the transactions contemplated hereby will, in of itself: (i) violate any provision of the Certificate, by-laws or other charter or organizational document of the Company or; (ii) violate, conflict with or result in the breach of any of the terms of, result in any modification of the effect of, otherwise give any other contracting party the right to terminate, or constitute (or with notice or lapse of time or both constitute) a default under, any material contract to which the Company is a party or by or to which it or its assets or properties may be bound or subject; (iii) violate any order, judgment, injunction, award or decree of any Governmental Authority against, or binding upon, or any contract with, or condition imposed by, any Governmental Authority binding upon, the Company or the business, properties or assets of the Company; (iv) violate any statute, law or regulation of any jurisdiction as such statute, law or regulation relates to the Company or to the business, properties or assets of the Company; or (v) result in the creation or imposition of any lien (other than permitted liens) on any of the properties or assets of the Company (including the Shares).

2.7 Litigation. There is no claim, action, suit, proceeding, arbitration, complaint, charge or investigation pending or threatened in writing (i) against the Company or any officer or director of the Company arising out of their employment or board relationship with the Company; (ii) to the Company's knowledge, that questions the validity of the Agreement or the right of the Company to enter into them, or to consummate the transactions contemplated by the Agreement; or (iii) to the Company's knowledge, that would reasonably be expected to have, either individually or in the aggregate, a Material Adverse Effect. Neither the Company nor, to the Company's knowledge, any of its officers or directors is a party or is named as subject to the provisions of any order, writ, injunction, judgment or decree of any court or government agency or instrumentality (in the case of officers or directors, such as would affect the Company) or settled. There is no action, suit, proceeding or investigation by the Company pending or which the Company intends to initiate. The foregoing includes, without limitation, actions, suits, proceedings or investigations pending or threatened in writing (or any basis therefor known to the Company) involving the prior employment of any of the Company's employees, their services provided in connection with the Company's business, any information or techniques allegedly proprietary to any of their former employers or their obligations under any agreements with prior employers.

2.8 Intellectual Property.

(a) The Company exclusively owns or possesses sufficient legal rights to all Company Intellectual Property free and clear of any lien without any known conflict with, or infringement of, the rights of others, including prior employees or consultants to conduct its current and presently contemplated future business and all of the registered Company Intellectual Property rights are valid and subsisting and enforceable and in full force and effect. To the Company's knowledge, the Company has not infringed, misappropriated or otherwise violated, or by conducting its business, would violate any of the patents, trademarks, service marks, tradenames, copyrights, trade secrets, mask works or other proprietary rights or processes of any other Person. Other than the Company Intellectual Property, the Company does not use any licensed intellectual property rights of any other Person for its business as currently carried on.

(b) To the Company's knowledge, with respect to third party patents and trademarks only, no product or service marketed or sold by the Company violates or will violate any license or infringes or will infringe any intellectual property rights of any other party.

(c) Other than with respect to commercially available software products under standard end-user license agreements, there are no outstanding options, licenses, agreements, claims, encumbrances or shared ownership interests of any kind relating to the Company Intellectual Property, nor is the Company bound by or a party to any options, licenses or agreements of any kind with respect to the patents, trademarks, service marks, trade names, copyrights, trade secrets, licenses, information, proprietary rights and processes of any other Person.

(d) The Company has obtained and possesses valid licenses to use all of the software programs present on the computers and other software-enabled electronic devices that it owns or leases or that it has otherwise provided to its employees for their use in connection with the Company's business.

(e) Section 2.8(e) of the Disclosure Schedule lists all patents, patent applications, registered trademarks, trademark applications, registered service marks, service mark applications, tradenames, registered copyrights, domains, and licenses to and under any of the foregoing, in each case owned by the Company.

(f) The Company has listed all of its owned Company Intellectual Property and all details relating thereto and all of its licensed Company Intellectual Property and all details thereto in the Disclosure Schedule. The Company represents and warrants that it owns all rights, title, and interest, whether legal, beneficial, or otherwise, in and to the Company Intellectual Property listed in the Disclosure Schedule. Furthermore, the Company affirms that it holds the sole and exclusive rights to use, license, and otherwise exploit any Company Intellectual Property listed in the Disclosure Schedule, subject to the terms of any underlying agreements governing such Company Intellectual Property.

(g) The Company represents and warrants that the Company Intellectual Property does not infringe upon or misappropriate any intellectual property rights, including but not limited to patents, trademarks, copyrights, trade secrets, or other proprietary rights, of any third party.

(h) The Company has provided copies of all the relevant documentation regarding such Company Intellectual Property to the Purchaser.

(i) Except as disclosed in Disclosure Schedule (i) the Company has not sent or received any written notice, charge, complaint, claim or other written assertion that (A) alleges infringement, misappropriation, dilution or other violation of any Company Intellectual Property or (B) challenges the validity or enforceability of any registered Company Intellectual Property rights (excluding non-final office actions from Governmental Authorities);

(j) At Closing, no employee, founder, officer, director, agent, consultant or contractor of Company or any of its affiliates will hold any right, title or interest, directly or indirectly, in whole or in part, in or to any Company Intellectual Property rights.

2.9 Property. The tangible property and assets that the Company owns are free and clear of all mortgages, deeds of trust, liens, loans and encumbrances, except for statutory liens for the payment of current taxes that are not yet delinquent and encumbrances and liens that arise in the ordinary course of business and do not materially impair the Company's ownership or use of such property or assets. With respect to the tangible or real property and assets it leases, the Company is in compliance in all material respects with such leases and, to the Company's knowledge, holds a valid leasehold interest free of any liens, claims or encumbrances other than those of the lessors of such property or assets, and encumbrances on real property which have not had or would not reasonably be expected to result in a Material Adverse Effect. The Company does not own any real property.

2.10 Financial Statements. The Company has made to the Purchaser, at its request, (a) the unaudited financial statements of the Company as of June 30, 2024, and September 30, 2024, which includes balance sheet, income statement; and (b) the audited financial statements consisting of the balance sheet of the Company as at December 31, in each of the years 2023, 2022 and 2021 and the related statements of income and retained earnings, stockholders' equity, and cash flow for the years then ended (collectively the “**Financial Statements**”). The Financial Statements fairly present in all material respects the financial condition and operating results of the Company, as of the dates, and for the periods indicated therein, subject to normal year-end audit adjustments. Since the date of the most recent Financial Statements, there has been no Material Adverse Effect on the financial condition or operating results of the Company.

2.11 No Undisclosed Liabilities. As of the date of this Agreement, the Company does not have any liabilities or obligations, whether accrued, contingent, or otherwise, that are not reflected or disclosed in the Financial Statements, except for liabilities incurred in the ordinary course of business since the date of the most recent Financial Statements, which would not, individually or in the aggregate, have a Material Adverse Effect on the Company.

2.12 Money Laundering. The operations of the Company and its Subsidiaries are and have been conducted at all times in compliance with applicable financial record-keeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, applicable money laundering statutes and applicable rules and regulations thereunder (collectively, the “**Money Laundering Laws**”), and no action or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any Subsidiary with respect to the Money Laundering Laws is pending or, to the knowledge of the Company or any Subsidiary, threatened.

2.13 Office of Foreign Assets Control. Neither the Company nor any Subsidiary nor, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company or any Subsidiary is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department.

2.14 Foreign Corrupt Practices. Neither the Company nor any Subsidiary, any agent or other person acting on behalf of the Company or any Subsidiary, has (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by the Company or any Subsidiary (or made by any person acting on its behalf of which the Company is aware) which is in violation of law or (iv) violated in any material respect any provision of the Foreign Corrupt Practices Act of 1977, as amended.

2.15 Taxes. The Company has filed all federal, state, local, and foreign tax returns required to be filed by it, and has paid all taxes due and payable, including any assessments, penalties, or interest, except for those taxes being contested in good faith and for which adequate reserves have been established in the Financial Statements. The Company has not received any notice of deficiency or assessment, nor is it currently under audit, investigation, or subject to any proceeding or claim in respect of taxes, except for those that, individually or in the aggregate, would not have a Material Adverse Effect on the Company. The Company has withheld and paid all taxes required to have been withheld and paid in connection with amounts paid to employees, contractors, shareholders, or other third parties, and has complied with all tax reporting requirements, except where the failure to do so would not have a Material Adverse Effect.

2.16 IPO related documents and filings. The Registration Statement on Form S-1 and the Prospectus filed by the Company with the Securities Exchange Commission ("SEC") covering the public offer and sale of up to 2,760,000 shares of common stock and all other filings made by the Company with the SEC in connection with such public offer disclose all information as required under the Securities Act and do not contain any misrepresentations, inaccuracy or false information and that the legal opinion dated September 9, 2024 issued by Sichenzia Ross Ference Carmel LLP to the Company in connection with such filings with the SEC can be relied upon by the Purchaser.

2.17 Certificate of Incorporation. The Company has delivered to Purchaser true, complete and correct copies of the Certificate and the by-laws of the Company and all amendments thereof. The minute books of the Company accurately reflect in all material respects all resolutions adopted at all meetings (and consents in lieu of meetings) of its shareholders and all resolutions adopted at all meetings (and consents in lieu of meetings) of its Board of Directors and all committees of its Board of Directors.

2.18 Compliance with Law. Except as set forth in Section 2.18 of Disclosure Schedule, the Company at all times has complied in all material respects with, and is now complying in all material respects with, all foreign, federal, state and local statutes, laws, regulations, ordinances, judgments, injunctions, orders, licenses, approvals, permits and other requirements (collectively, "Laws") applicable to the Company or its business, properties or assets.

2.19 Assets and Properties. Except as set forth on Disclosure Schedule, the Company has good and marketable title to all assets and properties that it purports to own, free of any liens.

2.20 Environmental Matters. (i) The Company is operating its business in compliance with all applicable environmental laws required thereunder; (ii) to the knowledge of Company, there are no events, conditions or circumstances that could result in any action, claim or allegation by any Person against the Company under applicable environmental laws nor has the Company received any notice from any Governmental Authority that any of the Company's business or real property that is owned, leased, used or operated (whether currently or formerly) by the Company is in violation of any environmental laws.

2.21 Regulatory Filings. Except as set forth on Disclosure Schedule, the Company has in all material respects timely filed, or caused to be timely filed, all reports, statements, documents, registrations, filings, applications or submissions required to be filed by or on behalf of the Company with any Governmental Authority in connection with the business conducted by the Company, the Company is acting in compliance in all material respects with all such reports, statements, documents, registrations, filings, applications and submissions, and all required regulatory approvals in respect thereof are in full force and effect. Except as set forth on Disclosure Schedule, all such reports, statements, documents, registrations, filings, applications and submissions were in compliance in all material respects with applicable Law when filed or as amended or supplemented and there were no material omissions therefrom, and no material deficiencies have been asserted by any Governmental Authority with respect to such reports, statements, documents, registrations, filings, applications or submissions that have not been satisfied.

2.22 Employee Benefits and Employees: The Company is and has been in compliance in all material respects with all applicable Laws relating to employment or the engagement of labor, including all applicable Laws relating to wages, hours, overtime, collective bargaining, employment discrimination, civil rights, safety and health, workers' compensation, pay equity, classification of employees and independent contractors, and the collection and payment of withholding and/or social security taxes.

2.23 Company Liabilities. As of the Closing Date, to the knowledge of the Company, the Company will have no liabilities, whether known, unknown or contingent, except for Liabilities for Taxes. As of the date of this Agreement, to the knowledge of the Company, there are no liabilities of the Company, that may have a Material Adverse Effect on the Purchaser's interests under this Agreement.

3. Representations and Warranties of the Purchaser. The Purchaser hereby represents and warrants to the Company, severally and not jointly, that:

3.1 Authorization. The Purchaser has full power and authority to enter into this Agreement. This Agreement when executed and delivered by the Purchaser, will constitute valid and legally binding obligations of the Purchaser, enforceable against the Purchaser in accordance with their terms, except as limited by applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance and any other laws of general application affecting enforcement of creditors' rights generally, and as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies.

3.2 Purchase Entirely for Own Account. This Agreement is made with the Purchaser in reliance upon the Purchaser's representation to the Company that the Shares will be acquired for investment for the Purchaser's own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and that the Purchaser has no present intention of selling, granting any participation in, or otherwise distributing the same. By executing this Agreement, the Purchaser further represents that the Purchaser does not presently have any contract, undertaking, agreement or arrangement with any Person to sell, transfer or grant participations to such Person or to any third Person, with respect to any of the Shares.

3.3 Disclosure of Information. The Purchaser has had an opportunity to discuss the Company's business, management, financial affairs and the terms and conditions of the offering of the Shares with the Company's management. The foregoing, however, does not limit or modify the representations and warranties of the Company in Section 2 of this Agreement or the right of the Purchaser to rely thereon.

3.4 Restricted Securities. The Purchaser understands that the Shares have not been, and will not be, registered under the Securities Act, by reason of a specific exemption from the registration provisions of the Securities Act which depends upon, among other things, the bona fide nature of the investment intent and the accuracy of the Purchaser's representations as expressed herein. The Purchaser understands that the Shares are "restricted securities" under applicable U.S. federal and state securities laws and that, pursuant to these laws, the Purchaser must hold the Shares indefinitely unless they are registered with the Securities and Exchange Commission and qualified by state authorities, or an exemption from such registration and qualification requirements is available. The Purchaser acknowledges that the Company has no obligation to register or qualify the Shares except as provided under this Agreement. The Purchaser further acknowledges that if an exemption from registration or qualification is available, it may be conditioned on various requirements including, but not limited to, the time and manner of sale, the holding period for the Shares, and on requirements relating to the Company which are outside of the Purchaser's control, and which the Company is under no obligation and may not be able to satisfy.

3.5 No Public Market. The Purchaser understands that no public market now exists for the Shares, and that the Company has made no assurances that a public market will ever exist for the Shares. However, the Company has disclosed that it plans to pursue an initial public offering (IPO) and, subject to the successful completion of the IPO, a public market for the Shares is expected to exist after the Closing. Even if the IPO is successful, the Company cannot provide any assurance that an active public market will develop.

3.6 Legends. The Purchaser understands that the Shares and any securities issued in respect of or exchange for the Shares, may be notated with the following or substantially similar legend:

“THE SHARES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933 AND HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A VIEW TO, OR IN CONNECTION WITH, THE SALE OR DISTRIBUTION THEREOF. NO SUCH TRANSFER MAY BE EFFECTED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT RELATED THERETO OR AN OPINION OF COUNSEL (WHICH MAY BE COMPANY COUNSEL) IN A FORM SATISFACTORY TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED UNDER THE SECURITIES ACT OF 1933.”

and any legend required by the securities laws of any state to the extent such laws are applicable to the Shares represented by the certificate, instrument, or book entry so legended.

3.7 Own Account. The Purchaser understands that the Shares are “restricted securities” and have not been registered under the Securities Act or any applicable state securities law and is acquiring the Shares as principal for its own account and not with a view to or for distributing or reselling such Shares or any part thereof in violation of the Securities Act or any applicable state securities law, has no present intention of distributing any of such Shares in violation of the Securities Act or any applicable state securities law and has no direct or indirect arrangement or understandings with any other persons to distribute or regarding the distribution of the Shares in violation of the Securities Act or any applicable state securities law (this representation and warranty not limiting such Purchaser’s right to sell the Shares pursuant to the Registration Statement or otherwise in compliance with applicable federal and state securities laws). Such Purchaser is acquiring the Shares hereunder in the ordinary course of its business.

3.8 Purchaser Status. At the time the Purchaser was offered the Shares, it was, and as of the date hereof it is: (i) an “accredited investor” as defined in Rule 501(a)(1), (a)(2), (a)(3), (a)(7), (a)(8), (a)(9), (a)(12) or (a)(13) under the Securities Act or (ii) a “qualified institutional buyer” as defined in Rule 144A(a) under the Securities Act. The Purchaser hereby represents that neither it nor any of its Rule 506(d) Related Parties (as defined below) is a “bad actor” within the meaning of Rule 506(d) promulgated under the Securities Act. For purposes of this Agreement, “Rule 506(d) Related Party” shall mean a person or entity covered by the “Bad Actor disqualification” provision of Rule 506(d) of the Securities Act.

3.9 Experience of Purchaser. The Purchaser, either alone or together with its representatives, has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the Shares, and has so evaluated the merits and risks of such investment. The Purchaser is able to bear the economic risk of an investment in the Shares and, at the present time, is able to afford a complete loss of such investment.

3.10 Foreign Investors. If the Purchaser is not a United States person (as defined by Section 7701(a)(30) of the Code), the Purchaser hereby represents that it has satisfied itself as to the full observance of the laws of its jurisdiction in connection with any invitation to subscribe for the Shares or any use of this Agreement, including (i) the legal requirements within its jurisdiction for the purchase of the Shares, (ii) any foreign exchange restrictions applicable to such purchase, (iii) any governmental or other consents that may need to be obtained, and (iv) the income tax and other tax consequences, if any, that may be relevant to the purchase, holding, redemption, sale, or transfer of the Shares. The Purchaser’s subscription and payment for and continued beneficial ownership of the Shares will not violate any applicable securities or other laws of the Purchaser’s jurisdiction.

3.11 No General Solicitation. To the knowledge of the Purchaser, neither the Company nor any of its officers, directors, employees, agents, stockholders or partners has either directly or indirectly, including, through a broker or finder (a) engaged in any general solicitation, or (b) published any advertisement in connection with the offer and sale of the Shares.

4. Other Agreements.

4.1 Lock-Up. The Purchaser hereby agrees that in connection with the initial public offering of the Company’s Common Stock that it will enter into a Lock-Up Agreement in the form attached hereto as Exhibit B, agreeing to certain restrictions on the sale, transfer or disposition of the Shares.

4.2 Registration Rights. The Purchaser shall have the right to include the Shares as part of any registration of securities filed by the Company (other than in connection with a transaction contemplated by Rule 145(a) promulgated under the Securities Act or pursuant to Form S-8 or any equivalent form); provided, however, that if, solely in connection with any primary underwritten public offering for the account of the Company, the managing underwriter(s) thereof shall, in its reasonable discretion, impose a limitation on the number of Shares which may be included in the Registration Statement because, in such underwriter(s)’ judgment, marketing or other factors dictate such limitation is necessary to facilitate public distribution, then the Company shall be obligated to include in such Registration Statement only such limited portion of the Shares with respect to which the Purchaser requested inclusion hereunder as the underwriter shall reasonably permit.

5. Conditions to the Purchaser's Obligations at Closing. The obligations of the Purchaser to purchase Shares at the Closing are subject to the fulfillment, on or before the Closing, of each of the following conditions, unless otherwise waived:

5.1 Representations and Warranties. The representations and warranties of the Company contained in Section 2 shall be true and correct in all respects as of the date of this Agreement and true and correct in all material respects as of the Closing.

5.2 Performance. The Company shall have performed and complied with all covenants, agreements, obligations and conditions contained in this Agreement that are required to be performed or complied with by the Company on or before the Closing.

5.3 Consents and Approvals. All consents, licenses, approvals, orders, authorizations, registrations, declarations and filings with, and notices to each Governmental Authority and each other Person required to be obtained prior to the execution of this Agreement in connection with the consummation of the transactions contemplated hereby shall have been duly obtained, made or given and shall be in full force and effect at the Closing, without the imposition of any conditions or limitations consents and approvals..

5.4 No Injunctions or Restraints. No temporary restraining order, preliminary or permanent injunction or other order issued by any Governmental Authority or other legal restraint or prohibition preventing the consummation of the Closing shall be in effect.

5.5 Litigation. No suit, action, investigation, inquiry or other proceeding by any Governmental Authority or arbitrator, asserted by any non-affiliate third party, shall be pending which (i) questions the validity or legality of, or seeks to restrain, enjoin, alter, delay or otherwise prohibit the consummation of the transactions contemplated by this Agreement, or (ii) which could reasonably be expected to have a Material Adverse Effect.

5.6 No Material Adverse Effect. During the period from the date of this Agreement until the Closing Date, there shall not have occurred a Material Adverse Effect.

6. Conditions of the Company's Obligations at Closing. The obligations of the Company to sell Shares to the Purchaser at the Closing are subject to the fulfillment, on or before the Closing, of each of the following conditions, unless otherwise waived:

6.1 Representations and Warranties. The representations and warranties of the Purchaser contained in Section 3 shall be true and correct in all respects as of the Closing.

6.1 Performance. The Purchaser shall have performed and complied with all covenants, agreements, obligations and conditions contained in this Agreement that are required to be performed or complied with by it on or before the Closing.

6.2 Lock-Up Agreement. The Purchaser shall have executed and delivered the Lock-Up Agreement.

7. INDEMNIFICATION

7.1 Indemnification by Company:

(a) Company hereby agrees to indemnify, defend and hold harmless Purchaser and its members, shareholders, managers, officers, directors, employees, affiliates, agents, successors and assigns (collectively, the "Purchaser Indemnitees") from and against, for and in respect of any and all Losses which any of them may sustain based upon, arising out of or otherwise in respect of (i) any inaccuracy in or breach of any representation or warranty of Company contained in Section 2 of this Agreement, and (ii) any breach of any covenant or agreement of Company contained in this Agreement.

(b) For purposes hereof, "Loss" and/or "Losses" shall mean any and all losses, liabilities, damages, deficiencies, costs or expenses, including interest, penalties and reasonable attorneys' and accountants' fees and disbursements.

(c) Promptly after receipt by Purchaser of notice of (i) any demand, claim or circumstances which would give rise to a Loss with respect to which a Purchaser Indemnitee would be entitled to indemnification pursuant to this Section 7.1 or (ii) any claim or the commencement (or threatened commencement) of any action, proceeding or investigation (an "Asserted Liability") that may result in a Loss with respect to which a Purchaser Indemnitee would be entitled to indemnification pursuant to this Section 7.1, the Purchaser Indemnitee shall promptly notify the Company in writing, and, the Company shall have the right to assume the defense thereof with counsel of its own choosing reasonably acceptable to the Purchaser Indemnitee. Any Purchaser Indemnitee shall have the right to employ separate counsel in any such proceeding and participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of such Purchaser Indemnitee except to the extent that (i) the employment thereof has been specifically authorized by the Company in writing, (ii) the Company has failed after a reasonable period of time to assume such defense and to employ counsel or (iii) in such proceeding there is, in the reasonable opinion of counsel to the applicable Purchaser Indemnitee (which may be internal counsel), a material conflict on any material issue between the position of the Company and the position of such Purchaser Indemnitee, in which case the Company shall be responsible for the reasonable fees and expenses of no more than one such separate counsel. The Company will not be liable to any Purchaser Indemnitee under this Agreement for any settlement by a Purchaser Indemnitee effected without the Company's prior written consent, which shall not be unreasonably withheld or delayed. The indemnification and other payment obligations required by this Section 7.1 shall be made by periodic payments of the amount thereof during the course of the investigation, defense, collection, enforcement or action, as and when bills are received or are incurred; provided, that if any Purchaser Indemnitee is finally judicially determined not to be entitled to indemnification or payment under this Section 7.1, such Purchaser Indemnitee shall promptly reimburse the Company for any payments that are advanced under this sentence.

8. Miscellaneous.

8.1 Termination. This Agreement may be terminated at any time prior to the Closing:

(a) by mutual written consent of Company and Purchaser;

(b)by Purchaser prior to the Closing, if there has been a breach of any representation, warranty, covenant or agreement made by Company in this Agreement, or any such representation and warranty shall have become untrue after the date hereof, such that the conditions set forth in Section 2 would not be satisfied and such breach is not curable or, if curable, is not cured within the thirty (30) days after written notice thereof is given by Purchaser to Company.

8.2 Specific Performance. The parties acknowledge and agree that the obligations of the Company under this Agreement are unique and that monetary damages may not be an adequate remedy for any breach of this Agreement. Accordingly, the Purchaser shall be entitled to seek specific performance of the terms of this Agreement, including, without limitation, the obligation of the Company to perform its covenants and agreements hereunder, and to compel the performance of any such obligation by the Company, in addition to any other remedies available to the Purchaser under this Agreement or applicable law. The right to seek specific performance shall not limit the Purchaser's right to seek other remedies, including damages, for any breach by the Company.

8.3 Survival. Subject to the limitations and other provisions of this Agreement, the representations and warranties contained herein shall survive the Closing and shall remain in full force and effect until the date that is twelve (12) months from the Closing Date. Notwithstanding the foregoing, any claims asserted in good faith with reasonable specificity (to the extent known at such time) and in writing by notice from the non-breaching party to the breaching party prior to the expiration date of the applicable survival period shall not thereafter be barred by the expiration of the relevant representation or warranty and such claims shall survive until finally resolved.

8.4 Successors and Assigns. The terms and conditions of this Agreement shall inure to the benefit of and be binding upon the respective successors and assigns of the parties. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and assigns any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement.

8.5 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via electronic mail (including pdf or any electronic signature complying with the U.S. federal E-SIGN Act of 2000, *e.g.*, www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

8.6 Notices.

(a) General. All notices and other communications given or made pursuant to this Agreement shall be in writing and shall be deemed effectively given upon the earlier of actual receipt, or (a) personal delivery to the party to be notified, (b) when sent, if sent by electronic mail during normal business hours of the recipient and if not sent during normal business hours, then on the recipient's next business day, which receipt is confirmed by the recipient (which confirmation may be by electronic mail), (c) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (d) one (1) business day after deposit with a nationally recognized overnight courier, freight prepaid, specifying next business day delivery, with written verification of receipt. All communications shall be sent to the respective parties at their address as set forth on the signature page or the Investor Questionnaire, or to such e-mail address or address as subsequently modified by written notice given in accordance with this Section 8.6. If notice is given to the Company, a copy (which copy shall not constitute notice) shall also be sent to Sichenzia Ross Ference Carmel LLP, 1185 Avenue of the Americas, 31st floor, New York, NY 10036, Attn: Gregory Sichenzia, Email: gsichenzia@srfc.law.

(b) Consent to Electronic Notice. The Purchaser consents to the delivery of any stockholder notice pursuant to the Delaware General Corporation Law (the “**DGCL**”), as amended or superseded from time to time, by electronic transmission pursuant to Section 232 of the DGCL (or any successor thereto) at the e-mail address set forth in the Investor Questionnaire, as updated from time to time by notice to the Company. To the extent that any notice given by means of electronic transmission is returned or undeliverable for any reason, the foregoing consent shall be deemed to have been revoked until a new or corrected e-mail address has been provided, and such attempted electronic notice shall be ineffective and deemed to not have been given. The Purchaser agrees to promptly notify the Company of any change in its e-mail address, and that failure to do so shall not affect the foregoing.

8.7 Amendments and Waivers. Any term of this Agreement may be amended, terminated or waived only with the written consent of the Company and the Purchaser. Any amendment or waiver effected in accordance with this Section 7.4 shall be binding upon the Purchaser and each transferee of the Shares, each future holder of all such securities, and the Company.

8.8 Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the parties hereto shall use their commercially reasonable efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction. It is hereby stipulated and declared to be the intention of the parties that they would have executed the remaining terms, provisions, covenants and restrictions without including any of such that may be hereafter declared invalid, illegal, void or unenforceable.

8.9 Entire Agreement. This Agreement (including the Exhibits hereto) constitutes the full and entire understanding and agreement between the parties with respect to the subject matter hereof, and any other written or oral agreement relating to the subject matter hereof existing between the parties are expressly canceled.

8.10 Governing Law. All questions concerning the construction, validity, enforcement, and interpretation of this Agreement and any ancillary documents, executed in connection therewith (collectively, the “**Transaction Documents**”), shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal Proceedings concerning the interpretations, enforcement, and defense of the transactions contemplated by this Agreement and any other Transaction Documents (whether brought against a party hereto or its respective affiliates, directors, officers, shareholders, partners, members, employees, or agents) shall be commenced exclusively in the state and federal courts sitting in the Borough of Manhattan, City of New York City, State of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the Borough of Manhattan, City of New York, State of New York for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such Action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If any party shall commence an action or proceeding to enforce any provisions of the Transaction Documents, then, the prevailing party in such action or proceeding shall be reimbursed by the non-prevailing party for its reasonable attorneys’ fees and other costs and expenses incurred with the investigation, preparation, and prosecution of such action or proceeding.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties have executed this Stock Purchase Agreement as of the date first written above.

COMPANY:

ALOPEXX, INC.

By: Daniel R. Vlock

Name: Daniel R. Vlock, MD

Title: Chief Executive Officer

Address: 186 Alewife Brook Parkway #1068
Cambridge, Massachusetts 02138 USA

Email:

Signature Page to Stock Purchase Agreement

IN WITNESS WHEREOF, the parties have executed this Stock Purchase Agreement as of the date first written above.

PURCHASER:

BIOTECH CONSORTIA, INC.

By: *Aria K Bhooma*
Name: Aria K. Bhooma
Title: Authorized Signatory
Address:
Email:

Signature Page to Stock Purchase Agreement

DISCLOSURE SCHEDULE

Employment Agreement

This Employment Agreement (the “**Agreement**”) is made and entered into as of December 12, 2024, by and between Daniel R Vlock (the “**Executive**”) and Alopexx, Inc., a Delaware corporation (the “**Company**”).

WHEREAS, the Company desires employ the Executive on the terms and conditions set forth herein; and

WHEREAS, the Executive desires to be employed by the Company on such terms and conditions.

NOW, THEREFORE, in consideration of the mutual covenants, promises, and obligations set forth herein, the parties agree as follows:

1. Term.

1.1 The Executive’s employment hereunder shall be effective upon signing of this agreement (the “ **Effective Date**”) and shall continue until the third anniversary thereof, unless terminated earlier pursuant to Section 5 of this Agreement; provided that, on such third anniversary of the Effective Date and each annual anniversary thereafter (such date and each annual anniversary thereof, a “**Renewal Date**”), the Agreement shall be deemed to be automatically extended, upon the same terms and conditions, for successive periods of one year, unless either party provides written notice of its intention not to extend the term of the Agreement at least ninety (90) days’ prior to the applicable Renewal Date. The period during which the Executive is employed by the Company hereunder is hereinafter referred to as the “**Employment Term**.”

2. Position and Duties.

2.1 Position. During the Employment Term, the Executive shall serve as the Chief Executive Officer (“CEO”) of the Company, reporting to the Board of Directors of the Company (the “**Board**”). In such position, the Executive shall have such duties, authority, and responsibilities as shall be determined from time to time by the **Board**, which duties, authority, and responsibilities are consistent with the Executive’s position. The Executive shall, if requested, also serve as a member of the **Board** or as an officer or director of any affiliate of the Company for no additional compensation.

2.2 Duties. During the Employment Term, the Executive shall devote substantially all of Executive’s business time and attention to the performance of the Executive’s duties hereunder and will not engage in any other business, profession, or occupation for compensation or otherwise which would conflict or interfere with the performance of such services either directly or indirectly without the prior written consent of the Board. Notwithstanding the foregoing, the Executive will be permitted to (a) with the prior written consent of the Board (which consent can be withheld by the Board in its discretion) act or serve as a director, trustee, committee member, or principal of any type of business, civic, or charitable organization as long as such activities are disclosed in writing to the Company’s CEO in accordance with the Company’s CONFLICT OF INTEREST POLICY, and (b) purchase or own less than five percent (5%) of the publicly traded securities of any corporation; provided that, such ownership represents a passive investment and that the Executive is not a controlling person of, or a member of a group that controls, such corporation; provided further that, the activities described in clauses (a) and (b) do not interfere with the performance of the Executive’s duties and responsibilities to the Company..

3. Place of Performance. The principal place of Executive's employment shall be the Company's principal executive office, which is currently located in Cambridge, Massachusetts; provided that, the Executive may be required to travel on Company business during the Employment Term and the Executive may also work remotely from a home office in California for so long as it does not interfere with their employment obligations hereunder.

4. Employment Compensation.

4.1 Base Salary. During the Employment Term, the Company shall pay the Executive an annual base salary of \$525,000 in periodic installments in accordance with the Company's customary payroll practices and applicable wage payment laws, but no less frequently than bi-weekly (i.e. twice per month). The base salary shall become effective following the successful completion of an IPO or obtaining a private equity investment of more than \$10,000,000. The Executive's annual base salary, as in effect from time to time, is hereinafter referred to as "**Base Salary**".

4.2 Annual Bonus.

(a) For each calendar year of the Employment Term, the Executive shall be eligible to receive an annual performance bonus (the "**Annual Bonus**"). However, the decision to provide any Annual Bonus and the amount and terms of any Annual Bonus shall be in the sole and absolute discretion of the Compensation Committee of the Board (the "**Compensation Committee**") and consistent with reasonable industry benchmarking standards.

(b) The Annual Bonus, if any, will be paid within two and a half (2 1/2) months after the end of the applicable year.

(c) In order to be eligible to receive an Annual Bonus, the Executive must be employed by the Company on the last day of the applicable year/date that Annual Bonuses are paid.

4.3 Equity Awards. During the Employment Term, the Executive shall be eligible to participate in the Alopexx, Inc., 2021 Employee, Director and Consultant Equity Incentive Plan (the "Plan") or any successor plan, subject to the terms of the Plan or successor plan, as determined and approved by the Board or the Compensation Committee, in its discretion. Executive's initial equity grant, subject to the termination provisions of Section 5, shall be up to 3% of the fully-diluted ownership of the Company and will be subject to the approval of the Compensation Committee including vesting terms and conditions.

4.4 Fringe Benefits and Perquisites. During the Employment Term the Executive shall be entitled to fringe benefits and perquisites consistent with the practices of the Company and governing benefit plan requirements (including plan eligibility provisions), and to the extent the Company provides similar benefits or perquisites (or both) to similarly situated executives of the Company.

4.5 Employee Benefits. During the Employment Term, and not during the Consulting Period, the Executive shall be entitled to participate in all employee benefit plans, practices, and programs maintained by the Company, as in effect from time to time (collectively, “**Employee Benefit Plans**”), to the extent consistent with applicable law and the terms of the applicable Employee Benefit Plans. The Company reserves the right to amend or terminate any Employee Benefit Plans at any time in its sole discretion, subject to the terms of such Employee Benefit Plan and applicable law.

4.6 Vacation; Paid Time Off. During the Employment Term, the Executive shall be entitled to four (4) weeks per year of paid time off (“PTO”) in accordance with Company policy as may be in effect from time to time, which PTO may be taken at such times and in such increments as the Executive may choose upon approval by the CEO.

4.7 Business Expenses. The Executive will be reimbursed for all reasonable and necessary out-of-pocket business, entertainment, and travel expenses incurred by the Executive in connection with the performance of the Executive’s duties hereunder in accordance with the Company’s expense reimbursement policies and subject to Executive’s submission of an expense report on a weekly basis to obtain reimbursement.

4.8 Corporate Credit Card. Pursuant to current Company policies and procedures, the Company may elect to issue Executive a corporate credit card to be utilized during the Employment Term in connection with any reasonable and necessary out-of-pocket business expenses which Executive may incur in connection with the performance of Executive’s duties.

4.9 Clawback Provisions. Notwithstanding any other provisions in this Agreement to the contrary, any incentive-based or other compensation paid to the Executive under this Agreement or any other agreement or arrangement with the Company which is subject to recovery under any law, government regulation, or stock exchange listing requirement will be subject to such deductions and clawback as may be required to be made pursuant to such law, government regulation, or stock exchange listing requirement (or any policy adopted by the Company pursuant to any such law, government regulation or stock exchange listing requirement). To the extent any such recovery is not related to fraud or similar financial activity referred to in the definition of Cause in Section 5.2 below and permitted by law, regulation or stock-exchange listing requirement, such recovery shall be for the amount of compensation actually received by Executive after Executive’s payment of taxes (federal, state, local) on any such compensation.

5. Termination of Employment.

5.1 Generally. Executive’s employment with the Company will continue in accordance with the terms of this Agreement for the Employment Term, unless it is terminated by one of the following events: (i) by the Company for Cause (as defined below) at any time, subject to its satisfaction of the notice and due process provisions described in Section 5(2)(a) below, or without Cause upon thirty (30) days’ prior written notice to Executive; (ii) by Executive upon thirty (30) days’ prior written notice to the Company; (iii) immediately upon Executive’s death or termination by the Company due to Disability (as defined below) or (iv) by the Company with written notice from the Company upon the failure to consummate an IPO. Upon a termination of Executive’s employment for any reason, Executive will be paid (A) any unpaid Base Salary through the date of termination of employment (the “Termination Date”); (B) reimbursement for any unreimbursed reasonable and necessary business expenses incurred through the Termination Date; (C) any accrued but unused vacation time in accordance with Company policy; and (D) all other accrued payments, benefits or fringe benefits to which Executive is entitled under the terms of any applicable compensation arrangement or benefit, equity or fringe benefit plan or program or grant or this Agreement (collectively, A through D are referred to as the “Accrued Benefits”). In addition, upon a termination of Executive’s employment for any reason, Executive agrees to promptly resign from any position as an officer, director or fiduciary of the Company or any of its affiliates and to execute any documentation necessary to effectuate such resignations.

5.2 Definitions. The following definitions apply for purposes of this Agreement:

(a)“Cause” means Executive’s (A) willful misconduct or gross negligence in the performance of Executive’s duties to the Company; (B) repeated failure to follow the directives of the CEO (other than as a result of death or Disability); (C) indictment for, conviction of, or pleading of guilty or nolo contendere to (1) a felony or (2) any misdemeanor crime involving moral turpitude; (D) performing any material act of theft, embezzlement, fraud, malfeasance or misappropriation of the Company’s property; (E) use of illegal drugs or abuse of alcohol that materially impairs Executive’s ability to perform Executive’s duties as contemplated hereunder; (F) breach of any fiduciary duty owed to the Company (including, without limitation, the duty of care and the duty of loyalty); or (G) material breach of this Agreement or any other written agreement with the Company, or a material violation of the Company’s code of conduct, employee handbook, or other similar written policy. Any determination of Cause by the Company will be made by a resolution approved by a majority of the members of the Board, provided that no such determination may be made until Executive has been given written notice detailing the specific Cause event and a period of thirty (30) days following receipt of such notice to cure such event (if susceptible to cure) to the satisfaction of the Board. Notwithstanding anything to the contrary contained herein, Executive’s right to cure will not apply with respect to provisions (C) or (D) of this Section 5(2)(a) or if there are habitual or repeated breaches of the same provision in the same respects by Executive.

(b)Disability” means Executive’s inability, with or without reasonable accommodation, to perform Executive’s material duties hereunder due to a physical or mental injury, infirmity or incapacity for one hundred eighty (180) days (including weekends and holidays) in any three hundred sixty-five (365) day period as determined by the Company in its reasonable discretion. Executive (or Executive’s representative) will cooperate in all respects with the Company if a question arises as to whether Executive has become disabled (including, without limitation, submitting to reasonable examinations by one or more medical doctors and other health care specialists selected by the Company and authorizing such medical doctors and other health care specialists to discuss Executive’s condition with the Company).

5.3 Notice of Termination. Any termination of the Executive’s employment hereunder by the Company or by the Executive during the Employment Term (other than termination pursuant to Section 5.1 on account of the Executive’s death) shall be communicated by written notice of termination (“**Notice of Termination**”) to the other party hereto in accordance with Section 21. The Notice of Termination shall specify:

- (a) The termination provision of this Agreement relied upon;
- (b) To the extent applicable, the facts and circumstances claimed to provide a basis for termination of the Executive's employment under the provision so indicated; and
- (c) The applicable Termination Date.

5.4 Termination Date. The Executive's "**Termination Date**" shall be:

- (a) If the Executive's employment hereunder terminates on account of the Executive's death, the date of the Executive's death;
- (b) If the Executive's employment hereunder is terminated on account of the Executive's Disability, the date that it is determined that the Executive has a Disability;
- (c) If the Company terminates the Executive's employment hereunder for Cause, the date the Notice of Termination is delivered to the Executive;

(d) If the Company terminates the Executive's employment hereunder without Cause, the date specified in the Notice of Termination, which shall be no less than one year following the date on which the Notice of Termination is delivered; provided that, the Company shall have the option to provide the Executive with a lump sum payment equal to One Year's Base Salary in lieu of such notice, which shall be paid in a lump sum on the Executive's Termination Date and for all purposes of this Agreement, the Executive's Termination Date shall be the date on which such Notice of Termination is delivered. In addition, the Executive shall be provided with health care benefits (under COBRA) for one year after such termination;

(e) If the Executive terminates his employment hereunder, the date specified in the Executive's Notice of Termination, which shall be no less than ninety (90) days following the date on which the Notice of Termination is delivered; provided that, the Company may waive all or any part of the ninety (90) day notice period for no consideration by giving written notice to the Executive and for all purposes of this Agreement, the Executive's Termination Date shall be the date determined by the Company; and

(f) If the Executive's employment hereunder terminates because either party provides notice of non-renewal pursuant to Section 1, the Renewal Date immediately following the date on which the applicable party delivers notice of non-renewal.

5.5 Change In Control

- (a) Change In Control is defined as:

A person (or more than one person acting as a group) (1) acquires directly or beneficially more than 50% of the outstanding voting securities of the Company (not including any additional ownership acquired by a person that already owned more than 50% of the outstanding voting securities), (2) acquires directly or beneficially more outstanding voting securities than any other person (or more than one person acting as a group) (3) acquires ownership of substantially all of the assets of the Company. For the purposes herein, a "person" shall be considered a natural person, corporation, partnership, limited liability company or any similar such corporate organizational form.

(b) If a Change of Control occurs, and in connection with such Change in Control the Executive is terminated without Cause, the Executive will receive full vesting of all stock options, other equity-based awards and shares of the Company's stock granted or awarded to the Executive pursuant to any Company compensation or benefit plan or arrangement that have not yet vested, effective upon the effective termination date of the Executive.

(c) Upon any termination without cause, the Executive shall be entitled to receive: either, at the Company's option, in a lump sum payment or over the course of one year from the effective date of the Change in Control:

- (i) 150% payment of Executive's Base Salary
- (ii) 150% payment of Executive's most recently paid (or earned if approved by the Compensation Committee but not yet paid) annual Bonus
- (iii) Eighteen months (18) continuation of Health Benefits.
- (iv) full vesting of all stock options, other equity-based awards and shares of the Company's stock granted or awarded to the Executive pursuant to any Company compensation or benefit plan or arrangement that have not yet vested, effective upon the Executive's execution of a Release Agreement.

5.6 Return of Company Property. On the date of Executive's termination of employment with the Company for any reason (or at any time prior thereto at the Company's request), Executive will return all property belonging to the Company or its affiliates (including, but not limited to, any Company-provided laptops, computers, cell phones, wireless electronic mail devices or other equipment, or documents and property belonging to the Company).

6. Cooperation. The parties agree that certain matters in which the Executive will be involved during the Employment Term may necessitate the Executive's cooperation in the future. Accordingly, following the termination of the Executive's employment for any reason, to the extent reasonably requested by the Board, the Executive shall cooperate with the Company in connection with matters arising out of the Executive's service to the Company; provided that, the Company shall make reasonable efforts to minimize disruption of the Executive's other activities. The Company shall reimburse the Executive for reasonable expenses incurred in connection with such cooperation.

7. Confidential Information. During the course of the Executive's employment with the Company, Executive will have access to Confidential Information. For purposes of this Agreement, "Confidential Information" means all data, information, ideas, concepts, discoveries, trade secrets, inventions (whether or not patentable or reduced to practice), innovations, improvements, know-how, developments, techniques, methods, processes, treatments, drawings, sketches, specifications, designs, patterns, models, plans and strategies, and all other confidential or proprietary information or trade secrets in any form or medium (whether merely remembered or embodied in a tangible or intangible form or medium) whether now or hereafter existing, relating to or arising from the past, current or potential business, activities and/or operations of the Company or any of its affiliates, including, without limitation, any such information relating to or concerning finances, sales, marketing, advertising, transition, promotions, pricing, personnel, customers, suppliers, vendors, partners and/or competitors. Executive agrees that he will not, directly or indirectly, use, make available, sell, disclose or otherwise communicate to any person, other than in the course of Executive's assigned duties and for the benefit of the Company, either during the period of Executive's employment or at any time thereafter, any Confidential Information or other confidential or proprietary information received from third parties subject to a duty on the Company's or its subsidiaries' or affiliates' part to maintain the confidentiality of such information. The foregoing will not apply to information that (i) is or was known to the public prior to its disclosure to Executive; (ii) becomes generally known to the public subsequent to disclosure to Executive through no wrongful act of Executive or any representative of Executive; or (iii) Executive is required to disclose by applicable law, regulation, recognized subpoena power, any governmental authority or agency or any other legal process (provided that, to the extent permitted by applicable law, regulation, recognized subpoena power, any governmental authority or agency or any other legal process, Executive provides the Company with prior notice of the contemplated disclosure and cooperate with the Company at its expense in seeking a protective order or other appropriate protection of such information). The terms and conditions of this Agreement will remain strictly confidential, and Executive hereby agrees not to disclose the terms and conditions hereof to any person or entity, other than (A) immediate family members, (B) legal advisors or personal tax or financial advisors, or (C) prospective future employer (solely, in the case of (C), for the purpose of disclosing the limitations on Executive's conduct imposed by the provisions of this Agreement) who, in each case, agree to keep such information confidential. Nothing in this Agreement shall be interpreted or applied to prohibit the making of any good faith report to any governmental agency or other governmental entity concerning any acts or omissions that Executive reasonably believes to constitute a possible violation of federal or state law or making other disclosures that are protected under the whistleblower provisions of applicable federal or state law or regulation.

7.1 Nothing in this Agreement is intended to or shall be interpreted to prohibit disclosure of information to the limited extent permitted by and in accordance with the federal Defend Trade Secrets Act of 2016 ("DTSA"). Stated otherwise, disclosures that are protected by the DTSA do not violate this Agreement. The DTSA provides that: "(1) An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that – (A) is made – (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal." The DTSA further provides that: "(2) An individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual – (A) files any document containing the trade secret under seal; and (B) does not disclose the trade secret, except pursuant to court order."

8. Non-Solicitation; Non-Interference. During the Employment Term and for a period of twelve (12) months thereafter (no matter which of the reasons for termination specified in Section 5 above applies), Executive agrees that he will not, except in the furtherance of Executive's duties hereunder, directly or indirectly, individually or on behalf of any other person, firm, corporation or other entity, (i) solicit, aid or induce any employee, representative or agent of the Company to leave such employment or retention or to accept employment with or render services to or with any other person, firm, corporation or other entity unaffiliated with the Company, or take any action to materially assist or aid any other person, firm, corporation or other entity in identifying, hiring or soliciting any such employee, representative or agent, or (ii) interfere, or aid or induce any other person or entity in interfering, with the relationship between the Company and any of their respective vendors, joint ventures or licensors. An employee, representative or agent will be deemed covered by this Section 8 while so employed or retained and for a period of six (6) months thereafter.

9. Non-disparagement. Both during Consulting Period and the Employment Term and at all times thereafter (no matter which of the reasons for termination specified in Section 5 above applies), regardless of the reason for termination, Executive agrees not to make negative comments about or otherwise disparage the Company or any of its respective officers, directors, employees, shareholders, members, agents or products other than in the good faith performance of Executive's duties to the Company while Executive is employed by the Company.

The foregoing will not restrict or impede Executive from exercising protected legal rights to the extent that such rights cannot be waived by agreement or from providing truthful statements in response to any governmental agency, rulemaking authority, subpoena power, legal process, required governmental testimony or filings, or judicial, administrative or arbitral proceedings (including, without limitation, depositions in connection with such proceedings), provided that such compliance does not exceed that required by the law, regulation, or order. The Executive shall promptly provide written notice of any such order to the CEO.

10. Acknowledgement. The Executive acknowledges and agrees that the services to be rendered by the Executive to the Company are of a special and unique character; that the Executive will obtain knowledge and skill relevant to the Company's industry, methods of doing business and marketing strategies by virtue of the Executive's employment; and that the restrictive covenants and other terms and conditions of this Agreement are reasonable and reasonably necessary to protect the legitimate business interest of the Company.

The Executive further acknowledges that the benefits provided to the Executive under this Agreement, including the amount of the Executive's compensation, reflects, in part, the Executive's obligations and the Company's rights under Sections 7 and 8 of this Agreement; that the Executive has no expectation of any additional compensation, royalties, or other payment of any kind not otherwise referenced herein in connection herewith; and that the Executive will not suffer undue hardship by reason of full compliance with the terms and conditions of Sections 7 and 8 of this Agreement or the Company's enforcement thereof.

11. Remedies. In the event of a breach or threatened breach by the Executive of Sections 7 and 8 of this Agreement, the Executive hereby consents and agrees that the Company shall be entitled to seek, in addition to other available remedies, a temporary or permanent injunction or other equitable relief against such breach or threatened breach from any court of competent jurisdiction, and that money damages would not afford an adequate remedy, without the necessity of showing any actual damages, and without the necessity of posting any bond or other security. The aforementioned equitable relief shall be in addition to, not in lieu of, legal remedies, monetary damages, or other available forms of relief.

12. Security and Access. The Executive agrees and covenants (a) to comply with all Company security policies and procedures as in force from time to time including without limitation those regarding computer equipment, telephone systems, voicemail systems, facilities access, monitoring, key cards, access codes, Company intranet, internet, social media and instant messaging systems, computer systems, email systems, computer networks, document storage systems, software, data security, encryption, firewalls, passwords, and any and all other Company facilities, IT resources, and communication technologies ("Facilities and Information Technology Resources"); (b) not to access or use any Facilities and Information Technology Resources except as authorized by the Company; and (iii) not to access or use any Facilities and Information Technology Resources in any manner after the termination of the Executive's employment by the Company, whether termination is voluntary or involuntary. The Executive agrees to notify the Company promptly in the event the Executive learns of any violation of the foregoing by others, or of any other misappropriation or unauthorized access, use, reproduction, or reverse engineering of, or tampering with any Facilities and Information Technology Resources or other Company property or materials by others.

13. Governing Law: Jurisdiction and Venue. This Agreement, for all purposes, shall be construed in accordance with the laws of Delaware, without regard to conflicts of law principles.

Any action or proceeding by either of the parties to enforce this Agreement shall be brought only in a state or federal court located in the state of Massachusetts, county of Suffolk. The parties hereby irrevocably submit to the exclusive jurisdiction of such courts and waive the defense of inconvenient forum to the maintenance of any such action or proceeding in such venue.

14. Entire Agreement. Unless specifically provided herein, this Agreement contains all of the understandings and representations between the Executive and the Company pertaining to the subject matter hereof and supersedes all prior and contemporaneous understandings, agreements, representations, and warranties, both written and oral, with respect to such subject matter. The parties mutually agree that the Agreement can be specifically enforced in court [an arbitral forum] and can be cited as evidence in legal proceedings alleging breach of the Agreement.

15. Modification and Waiver. No provision of this Agreement may be amended or modified unless such amendment or modification is agreed to in writing and signed by the Executive and by the CEO of the Company. No waiver by either of the parties of any breach by the other party hereto of any condition or provision of this Agreement to be performed by the other party hereto shall be deemed a waiver of any similar or dissimilar provision or condition at the same or any prior or subsequent time, nor shall the failure of or delay by either of the parties in exercising any right, power, or privilege hereunder operate as a waiver thereof to preclude any other or further exercise thereof or the exercise of any other such right, power, or privilege.

16. Severability. Should any provision of this Agreement be held by a court [or arbitral forum] of competent jurisdiction to be enforceable only if modified, or if any portion of this Agreement shall be held as unenforceable and thus stricken, such holding shall not affect the validity of the remainder of this Agreement, the balance of which shall continue to be binding upon the parties with any such modification to become a part hereof and treated as though originally set forth in this Agreement.

The parties further agree that any such court is expressly authorized to modify any such unenforceable provision of this Agreement in lieu of severing such unenforceable provision from this Agreement in its entirety, whether by rewriting the offending provision, deleting any or all of the offending provision, adding additional language to this Agreement, or by making such other modifications as it deems warranted to carry out the intent and agreement of the parties as embodied herein to the maximum extent permitted by law.

The parties expressly agree that this Agreement as so modified by the court shall be binding upon and enforceable against each of them. In any event, should one or more of the provisions of this Agreement be held to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provisions hereof, and if such provision or provisions are not modified as provided above, this Agreement shall be construed as if such invalid, illegal, or unenforceable provisions had not been set forth herein.

17. Captions. Captions and headings of the sections and paragraphs of this Agreement are intended solely for convenience and no provision of this Agreement is to be construed by reference to the caption or heading of any section or paragraph.\

18. Counterparts. This Agreement may be executed in separate counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument.

19. Successors and Assigns. This Agreement is personal to the Executive and shall not be assigned by the Executive. Any purported assignment by the Executive shall be null and void from the initial date of the purported assignment. The Company may assign this Agreement to any successor or assign (whether direct or indirect, by purchase, merger, consolidation, or otherwise) to all or substantially all of the business or assets of the Company. This Agreement shall inure to the benefit of the Company and permitted successors and assigns.

20. Notice. Notices and all other communications provided for in this Agreement shall be in writing and shall be delivered personally or sent by registered or certified mail, return receipt requested, or by overnight carrier to the parties at the addresses set forth below (or such other addresses as specified by the parties by like notice):

If to the Company:

Alopexx, Inc.
Attention: Daniel Vlock
President and Chief Executive Officer
186 Alewife Brook Pkwy #1068
Cambridge, MA 02138

21. Representations of the Executive. The Executive represents and warrants to the Company that:

(a) The Executive's acceptance of employment with the Company and the performance of duties hereunder will not conflict with or result in a violation of, a breach of, or a default under any contract, agreement, or understanding to which the Executive is a party or is otherwise bound.

(b) The Executive's acceptance of employment with the Company and the performance of duties hereunder will not violate any non-solicitation, non-competition, or other similar covenant or agreement of a prior employer.

22. Withholding. The Company shall have the right to withhold from any employment compensation amounts payable hereunder any Federal, state, and local taxes in order for the Company to satisfy any withholding tax obligation it may have under any applicable law or regulation.

23. Survival. Upon the expiration or other termination of this Agreement, the respective rights and obligations of the parties hereto shall survive such expiration or other termination to the extent necessary to carry out the intentions of the parties under this Agreement.

24. Acknowledgement of Full Understanding. THE EXECUTIVE ACKNOWLEDGES AND AGREES THAT THE EXECUTIVE HAS FULLY READ, UNDERSTANDS AND VOLUNTARILY ENTERS INTO THIS AGREEMENT. THE EXECUTIVE ACKNOWLEDGES AND AGREES THAT THE EXECUTIVE HAS HAD AN OPPORTUNITY TO ASK QUESTIONS AND CONSULT WITH AN ATTORNEY OF THE EXECUTIVE'S CHOICE BEFORE SIGNING THIS AGREEMENT.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first above written.

EXECUTIVE	ALOPEXX, INC.
Signature: _____ Print Name: Daniel Vlock _____	By _____

Employment Agreement

This Employment Agreement (the “**Agreement**”) is made and entered into as of August 30, 2021, by and between Thomas Thomas (the “**Executive**”) and Alopexx, Inc., a Delaware corporation (the “**Company**”).

WHEREAS, the Company desires to initially engage the Executive as a consultant (the “Consulting Period”) and then, upon the completion of an initial public offering (“IPO”), employ the Executive on the terms and conditions set forth herein; and

WHEREAS, the Executive desires to be employed by the Company on such terms and conditions.

NOW, THEREFORE, in consideration of the mutual covenants, promises, and obligations set forth herein, the parties agree as follows:

1. Term.

1.1 The Executive’s initial engagement during the Consulting Period shall be to perform duties of the Chief Financial Officer as a consultant, to be paid \$ 100,000 (the “Consulting Fee”) over a three-month period with pre-paid monthly installments of \$33,333.34, renewable on a month-to-month basis upon a written renewal executed by both parties hereto after the end of the initial three-month term. At the option of the Executive, upon delivery of a written notice to the Company, defer 50% payment of the Consulting Fee and 1/4th of the Consulting Fee prior to pricing of the IPO, Executive has the option to convert the remaining 50% Consulting Fee into Company Stock at the last pre IPO price. with a capital raise of greater than \$25,000,000 or the remaining 50% Consulting Fee is paid in cash at the end of the three-month term provided that any amounts owed to the Executive during the Consulting Period hereunder shall not be payable to Executive until the earlier of the five (5) business days after which the Company closes on its bridge financing with private investors prior to the IPO or October 31, 2021.

1.2 After the Consulting Period, the Executive’s employment hereunder shall be effective contemporaneous with the completion of the IPO (the “**Effective Date**”) and shall continue until the third anniversary thereof, unless terminated earlier pursuant to Section 5 of this Agreement; provided that, on such third anniversary of the Effective Date and each annual anniversary thereafter (such date and each annual anniversary thereof, a “**Renewal Date**”), the Agreement shall be deemed to be automatically extended, upon the same terms and conditions, for successive periods of one year, unless either party provides written notice of its intention not to extend the term of the Agreement at least ninety (90) days’ prior to the applicable Renewal Date. The period during which the Executive is employed by the Company hereunder is hereinafter referred to as the “**Employment Term**.”

2. Position and Duties.

2.1 Position. During the Consulting Period and the Employment Term, the Executive shall serve as the Chief Financial Officer of the Company, reporting to Daniel Vlock, President and Chief Executive Officer (“CEO”). In such position, the Executive shall have such duties, authority, and responsibilities as shall be determined from time to time by the CEO, which duties, authority, and responsibilities are consistent with the Executive’s position. The Executive shall, if requested, also serve as a member of the board of directors of the Company (the “**Board**”) or as an officer or director of any affiliate of the Company for no additional compensation.

2.2 Duties. During the Consulting Period and the Employment Term, the Executive shall devote substantially all of Executive's business time and attention to the performance of the Executive's duties hereunder and will not engage in any other business, profession, or occupation for compensation or otherwise which would conflict or interfere with the performance of such services either directly or indirectly without the prior written consent of the Board. Notwithstanding the foregoing, the Executive will be permitted to (a) with the prior written consent of the Board (which consent can be withheld by the Board in its discretion) act or serve as a director, trustee, committee member, or principal of any type of business, civic, or charitable organization as long as such activities are disclosed in writing to the Company's CEO in accordance with the Company's CONFLICT OF INTEREST POLICY, and (b) purchase or own less than five percent (5%) of the publicly traded securities of any corporation; provided that, such ownership represents a passive investment and that the Executive is not a controlling person of, or a member of a group that controls, such corporation; provided further that, the activities described in clauses (a) and (b) do not interfere with the performance of the Executive's duties and responsibilities to the Company. In addition, the Executive may continue to serve on the board of Directors of Opiant Pharmaceuticals, Inc. and operate a preexisting winery operation for so long as it does not interfere with their employment obligations hereunder.

3. Place of Performance. The principal place of Executive's employment shall be the Company's principal executive office, which is currently located in Cambridge, Massachusetts; provided that, the Executive may be required to travel on Company business during the Employment Term and the Executive may also work remotely from a home office in California for so long as it does not interfere with their employment obligations hereunder.

4. Employment Compensation.

4.1 Base Salary. During the Employment Term, the Company shall pay the Executive an annual base salary of \$400,000 in periodic installments in accordance with the Company's customary payroll practices and applicable wage payment laws, but no less frequently than bi-weekly (i.e. twice per month). The Executive's annual base salary, as in effect from time to time, is hereinafter referred to as "**Base Salary**".

4.2 Annual Bonus.

(a) For each calendar year of the Employment Term, the Executive shall be eligible to receive an annual performance bonus (the "**Annual Bonus**"). However, the decision to provide any Annual Bonus and the amount and terms of any Annual Bonus shall be in the sole and absolute discretion of the Compensation Committee of the Board (the "**Compensation Committee**") and consistent with reasonable industry benchmarking standards.

(b) The Annual Bonus, if any, will be paid within two and a half (2 1/2) months after the end of the applicable year.

(c) In order to be eligible to receive an Annual Bonus, the Executive must be employed by the Company on the last day of the applicable year/date that Annual Bonuses are paid.

4.3 Equity Awards. During the Employment Term, the Executive shall be eligible to participate in the Alopexx, Inc., 2021 Employee, Director and Consultant Equity Incentive Plan (the "Plan") or any successor plan, subject to the terms of the Plan or successor plan, as determined and approved by the Board or the Compensation Committee, in its discretion. Executive's initial equity grant, subject to the termination provisions of Section 5, shall be up to 3% of the fully-diluted ownership of the Company and will be subject to the approval of the Compensation Committee including vesting terms and conditions.

4.4 Fringe Benefits and Perquisites. During the Employment Term, and not during the Consulting Period, the Executive shall be entitled to fringe benefits and perquisites consistent with the practices of the Company and governing benefit plan requirements (including plan eligibility provisions), and to the extent the Company provides similar benefits or perquisites (or both) to similarly situated executives of the Company.

4.5 Employee Benefits. During the Employment Term, and not during the Consulting Period, the Executive shall be entitled to participate in all employee benefit plans, practices, and programs maintained by the Company, as in effect from time to time (collectively, "**Employee Benefit Plans**"), to the extent consistent with applicable law and the terms of the applicable Employee Benefit Plans. The Company reserves the right to amend or terminate any Employee Benefit Plans at any time in its sole discretion, subject to the terms of such Employee Benefit Plan and applicable law.

4.6 Vacation: Paid Time Off. During the Employment Term, the Executive shall be entitled to four (4) weeks per year of paid time off ("PTO") in accordance with Company policy as may be in effect from time to time, which PTO may be taken at such times and in such increments as the Executive may choose upon approval by the CEO.

4.7 Business Expenses. The Executive will be reimbursed for all reasonable and necessary out-of-pocket business, entertainment, and travel expenses incurred by the Executive in connection with the performance of the Executive's duties hereunder in accordance with the Company's expense reimbursement policies and subject to Executive's submission of an expense report on a weekly basis to obtain reimbursement.

4.8 Corporate Credit Card. Pursuant to current Company policies and procedures, the Company may elect to issue Executive a corporate credit card to be utilized during the Employment Term in connection with any reasonable and necessary out-of-pocket business expenses which Executive may incur in connection with the performance of Executive's duties.

4.9 Clawback Provisions. Notwithstanding any other provisions in this Agreement to the contrary, any incentive-based or other compensation paid to the Executive under this Agreement or any other agreement or arrangement with the Company which is subject to recovery under any law, government regulation, or stock exchange listing requirement will be subject to such deductions and clawback as may be required to be made pursuant to such law, government regulation, or stock exchange listing requirement (or any policy adopted by the Company pursuant to any such law, government regulation or stock exchange listing requirement). To the extent any such recovery is not related to fraud or similar financial activity referred to in the definition of Cause in Section 5.2 below and permitted by law, regulation or stock-exchange listing requirement, such recovery shall be for the amount of compensation actually received by Executive after Executive's payment of taxes (federal, state, local) on any such compensation.

5. Termination of Employment.

5.1 Generally. Executive's employment with the Company will continue in accordance with the terms of this Agreement for the Employment Term, unless it is terminated by one of the following events: (i) by the Company for Cause (as defined below) at any time, subject to its satisfaction of the notice and due process provisions described in Section 5(2)(a) below, or without Cause upon thirty (30) days' prior written notice to Executive; (ii) by Executive upon thirty (30) days' prior written notice to the Company; (iii) immediately upon Executive's death or termination by the Company due to Disability (as defined below) or (iv) by the Company with written notice from the Company upon the failure to consummate an IPO. Upon a termination of Executive's employment for any reason, Executive will be paid (A) any unpaid Base Salary through the date of termination of employment (the "Termination Date"); (B) reimbursement for any unreimbursed reasonable and necessary business expenses incurred through the Termination Date; (C) any accrued but unused vacation time in accordance with Company policy; and (D) all other accrued payments, benefits or fringe benefits to which Executive is entitled under the terms of any applicable compensation arrangement or benefit, equity or fringe benefit plan or program or grant or this Agreement (collectively, A through D are referred to as the "Accrued Benefits"). In addition, upon a termination of Executive's employment for any reason, Executive agrees to promptly resign from any position as an officer, director or fiduciary of the Company or any of its affiliates and to execute any documentation necessary to effectuate such resignations.

5.2 Definitions. The following definitions apply for purposes of this Agreement:

(a) "Cause" means Executive's (A) willful misconduct or gross negligence in the performance of Executive's duties to the Company; (B) repeated failure to follow the directives of the CEO (other than as a result of death or Disability); (C) indictment for, conviction of, or pleading of guilty or nolo contendere to (1) a felony or (2) any misdemeanor crime involving moral turpitude; (D) performing any material act of theft, embezzlement, fraud, malfeasance or misappropriation of the Company's property; (E) use of illegal drugs or abuse of alcohol that materially impairs Executive's ability to perform Executive's duties as contemplated hereunder; (F) breach of any fiduciary duty owed to the Company (including, without limitation, the duty of care and the duty of loyalty); or (G) material breach of this Agreement or any other written agreement with the Company, or a material violation of the Company's code of conduct, employee handbook, or other similar written policy. Any determination of Cause by the Company will be made by a resolution approved by a majority of the members of the Board, provided that no such determination may be made until Executive has been given written notice detailing the specific Cause event and a period of thirty (30) days following receipt of such notice to cure such event (if susceptible to cure) to the satisfaction of the Board. Notwithstanding anything to the contrary contained herein, Executive's right to cure will not apply with respect to provisions (C) or (D) of this Section 5(2)(a) or if there are habitual or repeated breaches of the same provision in the same respects by Executive.

(b)Disability” means Executive’s inability, with or without reasonable accommodation, to perform Executive’s material duties hereunder due to a physical or mental injury, infirmity or incapacity for one hundred eighty (180) days (including weekends and holidays) in any three hundred sixty-five (365) day period as determined by the Company in its reasonable discretion. Executive (or Executive’s representative) will cooperate in all respects with the Company if a question arises as to whether Executive has become disabled (including, without limitation, submitting to reasonable examinations by one or more medical doctors and other health care specialists selected by the Company and authorizing such medical doctors and other health care specialists to discuss Executive’s condition with the Company).

5.3 Notice of Termination. Any termination of the Executive’s employment hereunder by the Company or by the Executive during the Employment Term (other than termination pursuant to Section 5.1 on account of the Executive’s death) shall be communicated by written notice of termination (“**Notice of Termination**”) to the other party hereto in accordance with Section 21. The Notice of Termination shall specify:

- (a) The termination provision of this Agreement relied upon;
- (b) To the extent applicable, the facts and circumstances claimed to provide a basis for termination of the Executive’s employment under the provision so indicated; and
- (c) The applicable Termination Date.

5.4 Termination Date. The Executive’s “**Termination Date**” shall be:

- (a) If the Executive’s employment hereunder terminates on account of the Executive’s death, the date of the Executive’s death;
- (b) If the Executive’s employment hereunder is terminated on account of the Executive’s Disability, the date that it is determined that the Executive has a Disability;
- (c) If the Company terminates the Executive’s employment hereunder for Cause, the date the Notice of Termination is delivered to the Executive;

(d) If the Company terminates the Executive’s employment hereunder without Cause, the date specified in the Notice of Termination, which shall be no less than one hundred eighty fl--&Gt days one year following the date on which the Notice of Termination is delivered; provided that, the Company shall have the option to provide the Executive with a lump sum payment equal to One Year’s Base Salary in lieu of such notice, which shall be paid in a lump sum on the Executive’s Termination Date and for all purposes of this Agreement, the Executive’s Termination Date shall be the date on which such Notice of Termination is delivered. In addition, the Executive shall be provided with health care benefits (under COBRA) for one year after such termination;

(e) If the Executive terminates his employment hereunder, the date specified in the Executive's Notice of Termination, which shall be no less than ninety (90) days following the date on which the Notice of Termination is delivered; provided that, the Company may waive all or any part of the ninety (90) day notice period for no consideration by giving written notice to the Executive and for all purposes of this Agreement, the Executive's Termination Date shall be the date determined by the Company; and

(f) If the Executive's employment hereunder terminates because either party provides notice of non-renewal pursuant to Section 1, the Renewal Date immediately following the date on which the applicable party delivers notice of non-renewal.

5.5 Change In Control

(a) Change In Control is defined as:

A person (or more than one person acting as a group) (1) acquires directly or beneficially more than 50% of the outstanding voting securities of the Company (not including any additional ownership acquired by a person that already owned more than 50% of the outstanding voting securities), (2) acquires directly or beneficially more outstanding voting securities than any other person (or more than one person acting as a group) (3) acquires ownership of substantially all of the assets of the Company. For the purposes herein, a "person" shall be considered a natural person, corporation, partnership, limited liability company or any similar such corporate organizational form.

(b) If a Change of Control occurs, and in connection with such Change in Control the Executive is terminated without Cause, the Executive will receive full vesting of all stock options, other equity-based awards and shares of the Company's stock granted or awarded to the Executive pursuant to any Company compensation or benefit plan or arrangement that have not yet vested, effective upon the effective termination date of the Executive.

(c) Upon any termination without cause, the Executive shall be entitled to receive: either, at the Company's option, in a lump sum payment or over the course of one year from the effective date of the Change in Control:

- (i) 100% payment of Executive's Base Salary
- (ii) 100% payment of Executive's most recently paid (or earned if approved by the Compensation Committee but not yet paid) annual Bonus
- (iii) One Year continuation of Health Benefits (COBRA benefits).

5.6 Return of Company Property. On the date of Executive's termination of employment with the Company for any reason (or at any time prior thereto at the Company's request), Executive will return all property belonging to the Company or its affiliates (including, but not limited to, any Company-provided laptops, computers, cell phones, wireless electronic mail devices or other equipment, or documents and property belonging to the Company).

6. Cooperation. The parties agree that certain matters in which the Executive will be involved during the Employment Term may necessitate the Executive's cooperation in the future. Accordingly, following the termination of the Executive's employment for any reason, to the extent reasonably requested by the Board, the Executive shall cooperate with the Company in connection with matters arising out of the Executive's service to the Company; provided that, the Company shall make reasonable efforts to minimize disruption of the Executive's other activities. The Company shall reimburse the Executive for reasonable expenses incurred in connection with such cooperation.

7. Confidential Information. During the course of the Consulting Period and the Executive's employment with the Company, Executive will have access to Confidential Information. For purposes of this Agreement, "Confidential Information" means all data, information, ideas, concepts, discoveries, trade secrets, inventions (whether or not patentable or reduced to practice), innovations, improvements, know-how, developments, techniques, methods, processes, treatments, drawings, sketches, specifications, designs, patterns, models, plans and strategies, and all other confidential or proprietary information or trade secrets in any form or medium (whether merely remembered or embodied in a tangible or intangible form or medium) whether now or hereafter existing, relating to or arising from the past, current or potential business, activities and/or operations of the Company or any of its affiliates, including, without limitation, any such information relating to or concerning finances, sales, marketing, advertising, transition, promotions, pricing, personnel, customers, suppliers, vendors, partners and/or competitors. Executive agrees that he will not, directly or indirectly, use, make available, sell, disclose or otherwise communicate to any person, other than in the course of Executive's assigned duties and for the benefit of the Company, either during the period of Executive's employment or at any time thereafter, any Confidential Information or other confidential or proprietary information received from third parties subject to a duty on the Company's or its subsidiaries' or affiliates' part to maintain the confidentiality of such information. The foregoing will not apply to information that (i) is or was known to the public prior to its disclosure to Executive; (ii) becomes generally known to the public subsequent to disclosure to Executive through no wrongful act of Executive or any representative of Executive; or (iii) Executive is required to disclose by applicable law, regulation, recognized subpoena power, any governmental authority or agency or any other legal process (provided that, to the extent permitted by applicable law, regulation, recognized subpoena power, any governmental authority or agency or any other legal process, Executive provides the Company with prior notice of the contemplated disclosure and cooperate with the Company at its expense in seeking a protective order or other appropriate protection of such information). The terms and conditions of this Agreement will remain strictly confidential, and Executive hereby agrees not to disclose the terms and conditions hereof to any person or entity, other than (A) immediate family members, (B) legal advisors or personal tax or financial advisors, or (C) prospective future employers (solely, in the case of (C), for the purpose of disclosing the limitations on Executive's conduct imposed by the provisions of this Agreement) who, in each case, agree to keep such information confidential. Nothing in this Agreement shall be interpreted or applied to prohibit the making of any good faith report to any governmental agency or other governmental entity concerning any acts or omissions that Executive reasonably believes to constitute a possible violation of federal or state law or making other disclosures that are protected under the whistleblower provisions of applicable federal or state law or regulation.

7.1 Nothing in this Agreement is intended to or shall be interpreted to prohibit disclosure of information to the limited extent permitted by and in accordance with the federal Defend Trade Secrets Act of 2016 ("DTSA"). Stated otherwise, disclosures that are protected by the DTSA do not violate this Agreement. The DTSA provides that: "(1) An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that - (A) is made - (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal." The DTSA further provides that: "(2) An individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual- (A) files any document containing the trade secret under seal; and (B) does not disclose the trade secret, except pursuant to court order."

8. Non-Solicitation; Non-Interference. During the Consulting Period and the Employment Term and for a period of twelve (12) months thereafter (no matter which of the reasons for termination specified in Section 5 above applies), Executive agrees that he will not, except in the furtherance of Executive's duties hereunder, directly or indirectly, individually or on behalf of any other person, firm, corporation or other entity, (i) solicit, aid or induce any employee, representative or agent of the Company to leave such employment or retention or to accept employment with or render services to or with any other person, firm, corporation or other entity unaffiliated with the Company, or take any action to materially assist or aid any other person, firm, corporation or other entity in identifying, hiring or soliciting any such employee, representative or agent, or (ii) interfere, or aid or induce any other person or entity in interfering, with the relationship between the Company and any of their respective vendors, joint ventures or licensors. An employee, representative or agent will be deemed covered by this Section 8 while so employed or retained and for a period of six (6) months thereafter.

9. Nondisparagement. Both during Consulting Period and the Employment Term and at all times thereafter (no matter which of the reasons for termination specified in Section 5 above applies), regardless of the reason for termination, Executive agrees not to make negative comments about or otherwise disparage the Company or any of its respective officers, directors, employees, shareholders, members, agents or products other than in the good faith performance of Executive's duties to the Company while Executive is employed by the Company.

The foregoing will not restrict or impede Executive from exercising protected legal rights to the extent that such rights cannot be waived by agreement or from providing truthful statements in response to any governmental agency, rulemaking authority, subpoena power, legal process, required governmental testimony or filings, or judicial, administrative or arbitral proceedings (including, without limitation, depositions in connection with such proceedings), provided that such compliance does not exceed that required by the law, regulation, or order. The Executive shall promptly provide written notice of any such order to the CEO.

10. Acknowledgement. The Executive acknowledges and agrees that the services to be rendered by the Executive to the Company are of a special and unique character; that the Executive will obtain knowledge and skill relevant to the Company's industry, methods of doing business and marketing strategies by virtue of the Executive's employment; and that the restrictive covenants and other terms and conditions of this Agreement are reasonable and reasonably necessary to protect the legitimate business interest of the Company.

The Executive further acknowledges that the benefits provided to the Executive under this Agreement, including the amount of the Executive's compensation, reflects, in part, the Executive's obligations and the Company's rights under Sections 7 and 8 of this Agreement; that the Executive has no expectation of any additional compensation, royalties, or other payment of any kind not otherwise referenced herein in connection herewith; and that the Executive will not suffer undue hardship by reason of full compliance with the terms and conditions of Sections 7 and 8 of this Agreement or the Company's enforcement thereof.

11. Remedies. In the event of a breach or threatened breach by the Executive of Sections 7 and 8 of this Agreement, the Executive hereby consents and agrees that the Company shall be entitled to seek, in addition to other available remedies, a temporary or permanent injunction or other equitable relief against such breach or threatened breach from any court of competent jurisdiction, and that money damages would not afford an adequate remedy, without the necessity of showing any actual damages, and without the necessity of posting any bond or other security. The aforementioned equitable relief shall be in addition to, not in lieu of, legal remedies, monetary damages, or other available forms of relief.

12. Security and Access. The Executive agrees and covenants (a) to comply with all Company security policies and procedures as in force from time to time including without limitation those regarding computer equipment, telephone systems, voicemail systems, facilities access, monitoring, key cards, access codes, Company intranet, internet, social media and instant messaging systems, computer systems, email systems, computer networks, document storage systems, software, data security, encryption, firewalls, passwords, and any and all other Company facilities, IT resources, and communication technologies ("Facilities and Information Technology Resources"); (b) not to access or use any Facilities and Information Technology Resources except as authorized by the Company; and (iii) not to access or use any Facilities and Information Technology Resources in any manner after the termination of the Executive's employment by the Company, whether termination is voluntary or involuntary. The Executive agrees to notify the Company promptly in the event the Executive learns of any violation of the foregoing by others, or of any other misappropriation or unauthorized access, use, reproduction, or reverse engineering of, or tampering with any Facilities and Information Technology Resources or other Company property or materials by others.

13. Governing Law: Jurisdiction and Venue. This Agreement, for all purposes, shall be construed in accordance with the laws of Delaware, without regard to conflicts of law principles.

Any action or proceeding by either of the parties to enforce this Agreement shall be brought only in a state or federal court located in the state of Massachusetts, county of Suffolk. The parties hereby irrevocably submit to the exclusive jurisdiction of such courts and waive the defense of inconvenient forum to the maintenance of any such action or proceeding in such venue.

14. Entire Agreement. Unless specifically provided herein, this Agreement contains all of the understandings and representations between the Executive and the Company pertaining to the subject matter hereof and supersedes all prior and contemporaneous understandings, agreements, representations, and warranties, both written and oral, with respect to such subject matter. The parties mutually agree that the Agreement can be specifically enforced in court [an arbitral forum] and can be cited as evidence in legal proceedings alleging breach of the Agreement.

15. Modification and Waiver. No provision of this Agreement may be amended or modified unless such amendment or modification is agreed to in writing and signed by the Executive and by the CEO of the Company. No waiver by either of the parties of any breach by the other party hereto of any condition or provision of this Agreement to be performed by the other party hereto shall be deemed a waiver of any similar or dissimilar provision or condition at the same or any prior or subsequent time, nor shall the failure of or delay by either of the parties in exercising any right, power, or privilege hereunder operate as a waiver thereof to preclude any other or further exercise thereof or the exercise of any other such right, power, or privilege.

16. Severability. Should any provision of this Agreement be held by a court [or arbitral forum] of competent jurisdiction to be enforceable only if modified, or if any portion of this Agreement shall be held as unenforceable and thus stricken, such holding shall not affect the validity of the remainder of this Agreement, the balance of which shall continue to be binding upon the parties with any such modification to become a part hereof and treated as though originally set forth in this Agreement.

The parties further agree that any such court is expressly authorized to modify any such unenforceable provision of this Agreement in lieu of severing such unenforceable provision from this Agreement in its entirety, whether by rewriting the offending provision, deleting any or all of the offending provision, adding additional language to this Agreement, or by making such other modifications as it deems warranted to carry out the intent and agreement of the parties as embodied herein to the maximum extent permitted by law.

The parties expressly agree that this Agreement as so modified by the court shall be binding upon and enforceable against each of them. In any event, should one or more of the provisions of this Agreement be held to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provisions hereof, and if such provision or provisions are not modified as provided above, this Agreement shall be construed as if such invalid, illegal, or unenforceable provisions had not been set forth herein.

17. Captions. Captions and headings of the sections and paragraphs of this Agreement are intended solely for convenience and no provision of this Agreement is to be construed by reference to the caption or heading of any section or paragraph.

18. Counterparts. This Agreement may be executed in separate counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument.

19. Successors and Assigns. This Agreement is personal to the Executive and shall not be assigned by the Executive. Any purported assignment by the Executive shall be null and void from the initial date of the purported assignment. The Company may assign this Agreement to any successor or assign (whether direct or indirect, by purchase, merger, consolidation, or otherwise) to all or substantially all of the business or assets of the Company. This Agreement shall inure to the benefit of the Company and permitted successors and assigns.

20. Notice. Notices and all other communications provided for in this Agreement shall be in writing and shall be delivered personally or sent by registered or certified mail, return receipt requested, or by overnight carrier to the parties at the addresses set forth below (or such other addresses as specified by the parties by like notice):

If to the Company:

Alopexx, Inc.
Attention: Dan Vlock
President and Chief Executive Officer
186 Alewife Brook Pkwy
#1068 Cambridge, MA 02138

If to the Executive:

Thomas Thomas

21. [address]Representations of the Executive. The Executive represents and warrants to the Company that:

(a) The Executive's acceptance of the consulting engagement and employment with the Company and the performance of duties hereunder will not conflict with or result in a violation of, a breach of, or a default under any contract, agreement, or understanding to which the Executive is a party or is otherwise bound.

(b) The Executive's acceptance of the consulting engagement and employment with the Company and the performance of duties hereunder will not violate any non-solicitation, non-competition, or other similar covenant or agreement of a prior employer.

22. Withholding. The Company shall have the right to withhold from any employment compensation amounts payable hereunder any Federal, state, and local taxes in order for the Company to satisfy any withholding tax obligation it may have under any applicable law or regulation.

23. Survival. Upon the expiration or other termination of this Agreement, the respective rights and obligations of the parties hereto shall survive such expiration or other termination to the extent necessary to carry out the intentions of the parties under this Agreement.

24. Acknowledgement of Full Understanding. THE EXECUTIVE ACKNOWLEDGES AND AGREES THAT THE EXECUTIVE HAS FULLY READ, UNDERSTANDS AND VOLUNTARILY ENTERS INTO THIS AGREEMENT. THE EXECUTIVE ACKNOWLEDGES AND AGREES THAT THE EXECUTIVE HAS HAD AN OPPORTUNITY TO ASK QUESTIONS AND CONSULT WITH AN ATTORNEY OF THE EXECUTIVE'S CHOICE BEFORE SIGNING THIS AGREEMENT.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS
WHEREOF, the parties
hereto have executed
this Agreement as of
the date first a

ALOPEXX, INC.

By _____
Daniel Vlock
CHIEF EXECUTIVE OFFICER

EXECUTIVE	ALOPEXX, INC.
Signature: Thomas T Thomas	By Daniel Vlock
Print Name: Thomas Thomas	Daniel Vlock CHIEF EXECUTIVE OFFICER

AMENDED AND RESTATED CONSULTING AGREEMENT

This Amended and restated Consulting Agreement dated as of December 11, 2024 by and between Alopexx, Inc. (the “Company”) and BiotechPartnering Solutions, LLC (the “Consultant”) amends and restates that certain Consulting Agreement dated as of July 1, 2021 between the Company and the Consultant.

In consideration of the following mutual covenants and obligations, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Company and Consultant agree as follows:

1. **Consulting.** The Company hereby retains Consultant, and Consultant hereby accepts such retention, commencing as of the effective date of this Agreement and continuing until the end of the term of this Agreement or until termination as provided in Section 7 of this Agreement.
2. **Services.**
 - 2.1 **Consultant’s Services.** During the term of this Agreement, Consultant will provide consulting services to the Company which shall include:
 - (a) Business Development and partnering strategy, tactics and presentation;
 - (b) Corporate Strategy, including financing strategy and financing efforts
 - (c) Identification of potential partners;
 - (d) Contact and follow-up with potential partners;
 - (e) Advice and feedback on deal terms;
 - (f) Participation in meetings, both internal and external as mutually agreed;
 - (g) Negotiation of deal terms and definitive agreement with potential partners as mutually agreed;
 - (h) Advice on commercial plans and strategy

2.3 Performance of Services. Consultant shall use her best efforts to provide the consulting services in accordance with the terms of this Agreement, to keep the Company advised of the progress of the work, to permit any representative duly authorized in writing by the Company to inspect from time to time such results of said consulting services as are susceptible of inspection, and to keep records of consulting hours worked, which records the Company's duly authorized representative may examine upon reasonable notice to Consultant.

3. **Consulting Fees.** As consideration and compensation for Consultant's obligations and consulting services under this Agreement, the Company shall:

(a) Pay Consultant a monthly Retainer Fee of \$25,000, for any and all consulting services provided under this Agreement. The Retainer Fee will be payable in advance on the first business day of each month;

(b) Grant Consultant options to purchase 100,000 shares of common stock of Alopexx, Inc. at an exercise price of \$0.06 per share, subject to the terms and conditions of the Alopexx 2021 Equity Incentive Plan to be adopted by the Company and an Award Agreement to be issued to Consultant; and

Nothing in this Agreement shall be construed to impose any obligation upon the Company, or any of its parents, assigns, successors, subsidiaries, divisions, and/or affiliated companies, to make any payments or grant any stock options to Consultant if for any reason she fails to, or is unable to, provide the consulting services described herein.

A form 1099 will be issued by the Company to Consultant in connection with the payments and grants made pursuant to this Agreement. The Consultant shall be responsible for the payment of all local, state and federal taxes resulting from the payments or grants referenced in this Section. In addition, the Consultant will indemnify and hold harmless the Company from and against any and all claims, liabilities, suits and penalties for any amounts assessed by or due to any federal, state or local government with respect to such payments or grants, if any.

4. **Expenses.** Consultant shall receive reimbursement for any costs or expenses reasonably incurred by Consultant, subcontractors or any assistants that directly arise out of or relate to providing the Services to the Company; provided, however, that individual costs and expenses equal to or greater than U.S. \$1,000 must be authorized by the Company's representative before incurring the expense. As a condition to receipt of reimbursement, Consultant shall be required to submit to the Company reasonable written evidence that the amounts involved were expended and directly related to Services provided under this Agreement. Such costs or expenses may include travel costs, international telephone calls, fax, couriers, photocopies, report preparation as well as investor/partnering meeting fees. The Company will reimburse Consultant's expenses upon invoicing.
5. **Independent Contractor Status.**
- 5.1 In providing services under the terms of this Agreement, Consultant is acting in the capacity of an independent contractor and not as an employee of the Company. In such capacity, Consultant is not eligible to participate in the Company's employee benefits programs, including but not limited to, group insurance, retirement, vacation, and such other pay benefits. As an independent contractor, Consultant assumes full responsibility for making all proper federal, state, and local income, professional, and social security tax payments in connection with compensation received this Agreement, and filing all appropriate tax returns and other forms with respect thereto.
- 5.2 Nothing in this Agreement shall be construed to restrict either the Company or Consultant from contracting and/or doing business with any other persons or entities.

- 5.3 The Company shall have the right to review Consultant's performance of consulting services for the limited purposes of assuring that such services have been performed and confirming that such results were satisfactory, but shall not otherwise control the manner, means, or method by Consultant provides or performs the services. Consultant shall not undertake any consulting services without the approval of the Company's Chief Executive Officer.
6. **Reports.** Consultant shall keep adequate records of all work done under this Agreement and shall turn such records over to the Company upon termination of this Agreement, if requested, together with any documents, records, drawings, or other papers developed or acquired in connection with this Agreement.
7. **Term and Termination.**
- 7.1 **Term.** The term of this Agreement shall be for 12 months from the Agreement's effective date, unless renewed or otherwise extended by mutual written agreement, or unless terminated earlier as provided in this Section.
- 7.2 **Termination.** This Agreement may be terminated by either party thirty (30) days after written notice of intent to terminate. If this Agreement terminates, the Company will pay the Consultant all Retainer Fees accrued on a prorated basis and reimburse the Consultant for all reasonable out-of-pocket expenses incurred through the date the termination of this Agreement becomes effective.
- 7.3 Termination or expiration of this Agreement or any renewal or extension thereof shall not operate to terminate Consultant's obligations under paragraphs 8, 9, and 10 of this Agreement.

8. **Confidentiality and Use of Information.**

- 8.1 **Confidentiality.** All information provided to Consultant by the Company shall be deemed the Company's Confidential Information ("Company CI") by Consultant. All information provided to the Company by Consultant outside of the definition of Company CI, as defined above, shall be deemed Consultant's Confidential Information (Consultant's CI) by the Company. The Company and Consultant shall exercise reasonable care to prevent disclosure to or receipt by any third party of the other party's Confidential Information except as may be authorized in writing by the other party.

The obligations of the Company and Consultant with respect to Confidential Information shall not apply to:

- a) information which at the time of disclosure is in the public domain;
- b) information which after disclosure becomes part of the public domain through no fault of the recipient, but only after, and only to the extent that, it is published or otherwise becomes part of the public domain;
- c) information which the recipient can show was already in its possession at the time of disclosure;
- d) information which the recipient can show was received from a third party who represented to the recipient that such third party had a lawful right to disclose such information; or
- e) information independently developed by employees of recipient without access to Confidential Information.

Any specific combination of features of the Confidential Information disclosed shall not be deemed to be within the foregoing exceptions merely because individual features are in the public domain or in the possession of the recipient.

- 8.2 **Confidential Information.** Confidential Information shall include, but not be limited to, data, know-how, formulae, processes, compounds, designs, sketches, photographs, plans, drawings, specifications, reports, studies, findings, inventions, ideas, discoveries or any improvements, analogs, or derivatives.
- 8.3 **Return of Confidential Information.** On termination or completion of this Agreement, each party shall return the other's Confidential Information, except each party may retain one copy of the other party's Confidential Information to enable monitoring of confidentiality requirements under this Agreement.
- 8.4 **Access to Confidential Information.** Internal dissemination of Confidential Information by either party shall be limited to those employees of either party, or any subcontractors, agents or employees contemplated in Section 2.2 above, in the case of Consultant, who are confidentially bound to each respective party to the same extent that party is bound under this Agreement, and then only on a need to know basis.

9. **Intellectual Property.**

- 9.1 All work product, creations, inventions, research, models, reports, ideas, data, trade secrets, methodologies, and all other similar intellectual property rights (including, without limitation, any related improvements, derivative works or modifications), whether or not subject to patent or copyright protection (collectively, the "Creations") that are conceived or developed by the Consultant in connection with the Services, whether conceived alone or with others, during the Term ("Company Creations") are specially commissioned "works made for hire" as the term is used in the United States Copyright Act, and the Company will be deemed the author of all Company Creations. To the extent that a Company Creation (or any portion of a Company Creation) is not deemed work made for hire under the United States Copyright Act, the Consultant hereby assigns all right, title and interest, including moral rights and goodwill, to any and all such Company Creations to the Company without additional compensation. The Consultant shall promptly deliver to the Company all papers, drawings, models, data, research, reports and other material relating to any Company Creations made, developed or created by the Consultant in the course of the Consultant's services to the Company.

- 9.2 The Consultant shall, upon the Company's request, execute any documents necessary or advisable in the opinion of the Company's counsel to direct issuance of patents or copyrights of the Company with respect to Company Creation, the expense of securing any such patent or copyright, to be borne by the Company.
- 9.3 The Company specifically acknowledges that the Consultant performs consulting services for other persons, some of whom may compete with the Company and its business. The Company acknowledges that Creations developed by the Consultant for itself or other person in connection with the services performed for other persons are excluded from the definition of Company Creations set forth in Section 9.1.
- 9.4 The Consultant shall disclose all inventions and innovations to Company, even if the Consultant does not believe that the Consultant is required under this Agreement, to assign the Consultant's interest in such invention or innovation to the Company. If the Company and the Consultant disagree as to whether an invention or innovation is included within the terms of this Agreement, it will be the responsibility of the Consultant to prove by reasonable documentary evidence that it is not included.

10. **Regulatory Compliance.**

- 10.1 **Privacy Laws:** Consultant's use and disclosure of patient health and medical information is subject to compliance with applicable state and federal privacy laws. The parties shall take all reasonable steps to protect the confidentiality of any patient health and medical information that it has access to and comply with applicable state and federal privacy laws. The obligations set forth in this Section shall survive the termination or expiration of this Agreement.
- 10.2 **Healthcare Compliance:** The parties specifically intend to comply with all applicable laws, rules and regulations, including the federal anti-kickback statute (42 U.S.C. 1320a-7b) and the related safe harbor regulations. Nothing contained in this Agreement shall be construed in any manner as an obligation or inducement for the Consultant to recommend that any person or entity purchase products or services of the Company or any entity affiliated with the Company that are reimbursable by a federal health care program.

11. **Miscellaneous.**

- 11.1 **Entire Agreement.** This Agreement constitutes the entire agreement and understanding between the Company and Consultant with respect to the subject matter, and supersedes any and all prior agreements between the parties, whether written or oral, relating to the subject matter. The Company and Consultant acknowledge that no promises, statements or representations, other than those contained in this Agreement, have been made to induce any party to enter into this Agreement. This Agreement may only be modified or amended in a writing signed by both parties.
- 11.2 **Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of Florida without regard to conflicts of laws.

- 11.3 **No Assignment.** This Agreement is not assignable by either party, whether by operation of law or otherwise, without the prior written consent of the other party.
- 11.4 **Use of Other Names.** Except as required by law, before either party uses the name of the other party or refers to the existence or terms of this Agreement in any publication or other public disclosure, it shall obtain prior written permission from the other party.
- 11.5 **Waiver.** The failure of any party to this Agreement, at any time, to require performance of any provision of this Agreement shall in no manner affect its or their rights, at a later time, to enforce the same provision. No waiver by any party hereto shall be valid unless in writing and signed by that party.
- 11.6 **Severability Clause.** If any provision of this Agreement is held to be unenforceable for any reason, such provision shall be adjusted rather than voided, if possible, in order to achieve the intent of the parties to the fullest extent possible. In any event, all other provisions of this Agreement shall be deemed valid and enforceable to the fullest extent possible.
- 11.7 **Noncompliance.** In the event that any part of this Agreement is determined to violate federal, state, or local laws, rules, or regulations, the parties agree to negotiate in good faith revisions to the provision or provisions that are in violation. In the event the parties are unable to agree to new or modified terms as required to bring the entire Agreement into compliance, either party may terminate this Agreement on sixty (60) days written notice to the other party.

11.8 **Notice.** Any notice required or permitted to be given hereunder shall be considered properly sent, if mailed by first class letter, postage pre-paid, to:

Name and Address of
Company:

Alopexx, Inc.
Attention: Daniel Vlock
186 Alewife Brook Parkway
Cambridge, MA
02138

Name and Address of
Consultant:

BiotechPartnering Solutions, LLC
Christine de los Reyes
2843 S. Bayshore Drive,
Suite 15D
Miami, Florida 33133

Any notice shall be deemed to have been given on the fifth (5th) day after it is postmarked. Either party may change the address for notification purposes, without amending this Agreement, upon written notice to the other party.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed.

Company:

Alopexx, Inc.

By: *Daniel Vlock*

Daniel Vlock

Date: ____11Dec2024_____

Consultant:

BiotechPartnering Solutions, LLC

By: *Christine de los Reyes*

Christine de los Reyes

Date: _____



INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the inclusion in this Registration Statement of Alopexx, Inc. on Form S-1 Amendment No. 15 (File NO. 333-263328) of our report dated March 14, 2024, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, with respect to our audits of the financial statements of Alopexx, Inc. as of December 31, 2023 and 2022 and for the years ended, which report appears in the Prospectus, which is part of this Registration Statement. We also consent to the reference to our Firm under the heading "Experts" in such Prospectus.

/s/ Marcum LLP

Marcum LLP
Hartford, CT
January 8, 2025

Calculation of Filing Fee Tables

Form S-1
(Form Type)

Alopexx, Inc.
(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered and Carry Forward Securities

	Security Type	Security Class Title ⁽¹⁾	Fee Calculation or Carry Forward Rule	Amount Registered ⁽²⁾	Proposed Maximum Offering Price Per Unit	Maximum Aggregate Offering Price ⁽¹⁾	Fee Rate	Amount of Registration Fee ⁽²⁾
Newly Registered Securities								
Fees previously paid	Equity	Common Stock, \$0.0001 par value per share ⁽²⁾⁽³⁾	457(o)	2,760,000, ⁽³⁾	\$ 5.00	\$ 13,800,000	0.0001476	\$ 1060.88
Fees Previously Paid	Equity	Representative's Warrants ⁽⁵⁾	457(g)	—	—	—	—	—
Fees previously Paid	Equity	Common Stock issuable upon exercise of Representative's Warrants ⁽⁴⁾	457(o)	120,000	6.25	750,000	0.0001476	\$ 110.70
Fees to be Paid	Equity	Common Stock, \$0.0001 par value per share ⁽²⁾⁽⁶⁾	457(o)	300,000	5.00	1,500,000	0.00015310	\$ 229.65
Carry Forward Securities								
Carry Forward Securities	—	—	—	—	—	—	—	—
Total Offering Amounts						\$ 16,050,000		
Total Fee Due						3,100.26		
Total Fees Previously Paid						\$ 2,870.61		
Total Fee Offsets						0		
Net Fee Due						\$ 229.65		

(1) Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(o) under the Securities Act.

(2) Calculated pursuant to Rule 457(o) under the Securities Act, based on an estimate of the proposed maximum aggregate offering price.

(3) Includes ordinary shares which may be issued upon the exercise of a 45-day option granted to the underwriters to cover over-allotments, if any, up to 15% of the total number of securities offered.

(4) We have agreed to issue to the representative of the underwriters warrants to purchase shares of common stock representing up to 5% of the common stock issued in the offering. The representative's warrants are exercisable at a per share exercise price equal to 125% of the public offering price per share of the common stock offered hereby.

(5) No fee required pursuant to Rule 457(g).

(6) This registration statement also covers the resale of 300,000 shares of common stock by the selling stockholder as named in the registration statement. Assumes an offering price of \$5.00, which is estimated solely for purposes of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.