UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
for the fiscal year ended December 31, 2022
or

☐ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.**
for the transition period from _____ to _____ .
Commission File Number 001-41058

VAXXINITY, INC.

(Exact name of registrant as specified in its charter)

Delaware	**86-2083865**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

505 Odyssey Way
Merritt Island, FL 32953
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: **(254) 244-5739**
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol**	**Name of exchange on which registered**
Class A Common Stock, par value $0.0001 per share	VAXX	The Nasdaq Global Market

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

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

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

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

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

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

Large Accelerated Filer ☐ Accelerated Filer ☐ Non-Accelerated Filer ☒ Smaller Reporting Company ☒ Emerging Growth Company ☒

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

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

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

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

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

The aggregate market value of registrant's voting and non-voting outstanding common stock held by non-affiliates was approximately $94.5 million based upon the closing stock price of issuer's common stock on June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter. Shares of common stock held by each officer and director and by each person who may be deemed to be affiliates of the Company. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 15, 2023, the registrant had 112,188,911 shares of $0.0001 par value Class A common stock outstanding and 13,874,132 shares of $0.0001 par value Class B common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the following document are incorporated by reference in Part III of this Report: the registrant's definitive proxy statement relating to its 2023 Annual Meeting of Shareholders. We currently anticipate that our definitive proxy statement will be filed with the SEC no later than 120 days after December 31, 2022, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended.

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PART I

Unless otherwise indicated in this report, "Vaxxinity," "we," "us," "our," and similar terms refer to Vaxxinity, Inc. and our consolidated subsidiaries.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the year ended December 31, 2022 ("Report") contains forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies and other future conditions. In some cases, you can identify forward-looking statements because they contain words such as "anticipate," "believe," "estimate," "expect," "intend," "may," "predict," "project," "target," "potential," "seek," "will," "would," "could," "should," "continue," "contemplate," "plan," other words and terms of similar meaning and the negative of these words or similar terms.

Forward-looking statements are subject to known and unknown risks and uncertainties, many of which may be beyond our control. We caution you that forward-looking statements are not guarantees of future performance or outcomes and that actual performance and outcomes may differ materially from those made in or suggested by the forward-looking statements contained in this Report. In addition, even if our results of operations, financial condition and cash flows, and the development of the markets in which we operate, are consistent with the forward-looking statements contained in this Report, those results or developments may not be indicative of results or developments in subsequent periods. New factors emerge from time to time that may cause our business not to develop as we expect, and it is not possible for us to predict all of them. Factors that could cause actual results and outcomes to differ from those reflected in forward-looking statements include, among others, the following:

- the prospects of UB-612 and other product candidates, including the timing of data from our clinical trials for UB-612 and other product candidates and our ability to obtain and maintain regulatory approval for our product candidates;
- our ability to develop and commercialize new products and product candidates;
- our ability to leverage our Vaxxine Platform;
- the rate and degree of market acceptance of our products and product candidates;
- our status as a clinical-stage company and estimates of our addressable market, market growth, future revenue, expenses, capital requirements and our needs for additional financing;
- our ability to comply with multiple legal and regulatory systems relating to privacy, tax, anti-corruption and other applicable laws;
- our ability to hire and retain key personnel and to manage our future growth effectively;
- competitive companies and technologies and our industry and our ability to compete;
- our and our collaborators', including United Biomedical's ("UBI"), ability and willingness to obtain, maintain, defend and enforce our intellectual property protection for our proprietary and collaborative product candidates, and the scope of such protection;
- the performance of third-party suppliers and manufacturers and our ability to find additional suppliers and manufacturers;
- our ability and the potential to successfully manufacture our product candidates for pre-clinical use, for clinical trials and on a larger scale for commercial use, if approved;
- the ability and willingness of our third-party collaborators to continue research and development activities relating to our product candidates;
- general economic, political, demographic and business conditions in the United States, Taiwan and other jurisdictions;
- the potential effects of government regulation, including regulatory developments in the United States and other jurisdictions;
- ability to obtain additional financing in future offerings;

- expectations about market trends; and
- the effects of the Russia-Ukraine conflict and the COVID-19 pandemic on business operations, the initiation, development and operation of our clinical trials and patient enrollment of our clinical trials.

We discuss many of these factors in greater detail under Item 1A. "Risk Factors." These risk factors are not exhaustive and other sections of this report may include additional factors which could adversely impact our business and financial performance. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

You should read this Report and the documents that we reference in this Report and have filed as exhibits completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward- looking statements in this Report by these cautionary statements. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

Item 1. Business.

Overview

We are a purpose-driven biotechnology company committed to democratizing healthcare across the globe. Our vision is to disrupt the existing treatment paradigm for chronic diseases, increasingly dominated by drugs, particularly monoclonal antibodies ("mAbs"), which suffer from prohibitive costs and cumbersome administration. We believe our synthetic peptide vaccine platform ("Vaxxine Platform") has the potential to enable a new class of therapeutics that will improve the quality and convenience of care, reduce costs and increase access to treatments for a wide range of indications. Our Vaxxine Platform is designed to harness the immune system to convert the body into its own "drug factory," stimulating the production of antibodies with a therapeutic or protective effect. While traditional vaccines have been able to leverage this approach against infectious diseases, they have historically been unable to resolve key challenges in the fight against chronic diseases. We believe our Vaxxine Platform has the potential to overcome these challenges and has the potential to bring the efficiency of vaccines to a whole new class of medical conditions. Specifically, our technology is designed to use synthetic peptides to mimic and optimally combine biological epitopes in order to selectively activate the immune system, producing highly specific antibodies against only the desired targets, including self-antigens, making possible the safe and effective treatment of chronic diseases by vaccines. The modular and synthetic nature of our Vaxxine Platform generally provides significant speed and efficiency in candidate development and has generated multiple product candidates that we are designing to have safety and efficacy equal to or greater than the standard-of-care treatments for many chronic diseases, with more convenient administration and meaningfully lower costs. Our current pipeline consists of five chronic disease product candidates from early to late-stage development across multiple therapeutic areas, including Alzheimer's Disease ("AD"), Parkinson's Disease ("PD"), migraine and hypercholesterolemia. Additionally, we believe our Vaxxine Platform may be used to disrupt the treatment paradigm for a wide range of other chronic diseases, including any that are or could potentially be successfully treated by mAbs. We also will opportunistically pursue infectious disease treatments. When the COVID-19 pandemic struck the world in March 2020, we quickly reallocated resources to develop a vaccine candidate. We have assembled an industry-leading team with extensive experience developing and commercializing successful drugs that is committed to realizing our mission of democratizing healthcare. Our website address is www.vaxxinity.com. The information contained on, or that can be accessed through, our website is not part of, and is not incorporated into, this Report.

Limitations of the Current Healthcare Paradigm

The current healthcare paradigm favors the development of drugs that are primarily intended for the U.S. market, for niche indications and for treatment of disease rather than prevention. Furthermore, these drugs are expected to be sold at price points that are only accessible to healthcare systems in developed countries. One class of drugs in particular exemplifies the current environment: biologics, particularly mAbs. In 2019, biologics represented eight of the ten top selling drugs in the United States, of which seven were mAbs. The global market for mAbs totaled approximately $163 billion in 2019, representing approximately 70% of the total sales for all biopharmaceutical products.

While mAbs can provide life-altering care with generally favorable safety characteristics and significant health benefits for the patients who receive them, regular in-office transfusions and annual treatment costs, which can exceed hundreds of thousands of dollars, present challenges to both patients and payors. These price and administration hurdles cause mAb treatments to be available to only a fraction of the population who could benefit from them. Furthermore, mAbs are often restricted to moderate to severe disease and to later lines of treatment due to their high cost. Based on internal estimates, less than 1% of the worldwide population is treated with mAbs. Meanwhile, the alternative to mAbs treatments tends to be small molecules, which are sometimes more accessible to patients, but are often comparatively less effective with more significant side effects. Collectively, this perpetuates a profound inequity in healthcare access, domestically but even more so globally, that we believe represents a tremendous social and market opportunity.

Our Solution

Monoclonal antibodies are developed, produced and purified outside the body and then transfused into the patient on a regular basis, as frequently as bi-weekly. Therefore, mAbs are inherently less efficient than vaccines, which instead stimulate antibody production within the patient's immune system, requiring both less active material and less frequent treatments. However, while traditional vaccines have historically been successful addressing infectious diseases, previous attempts to utilize vaccines to address chronic disease have not achieved both acceptable safety and efficacy. This limitation is driven by a traditional vaccine's inability to either stimulate the requisite antibody response against harmful self-antigens, that is, break immune tolerance, or produce acceptable levels of reactogenicity, the physical manifestation of the immune response to vaccination. Our Vaxxine Platform technology contains modular components custom-designed to mimic select biology and activate the immune system, enabling our product candidates to break immune tolerance when targeting self-antigens, a property observed across multiple clinical and pre-clinical studies. Our Vaxxine Platform depends heavily on intellectual property licensed from UBI and its affiliates, a related party and a commercial partner for us, who first developed the peptide vaccine technology utilized by our Vaxxine Platform. The formulation of our peptide-based product candidates relies on contract manufacturers at this time, including both related parties as well as third-party manufacturers.

We believe our Vaxxine Platform has the potential to generate product candidates with attributes that collectively offer significant advantages over both mAbs and small molecule therapeutics, and that some of these advantages may allow for use in a first-line or a prevention setting:

- *Cost*: Monoclonal antibodies require costly and complex biological manufacturing processes. Our manufacturing process is chemically based and highly scalable and requires lower capital expenditures. In addition, we design our product candidates to generate antibody production in the body, thus requiring meaningfully less drug substance relative to mAbs, leading to commensurately lower costs.

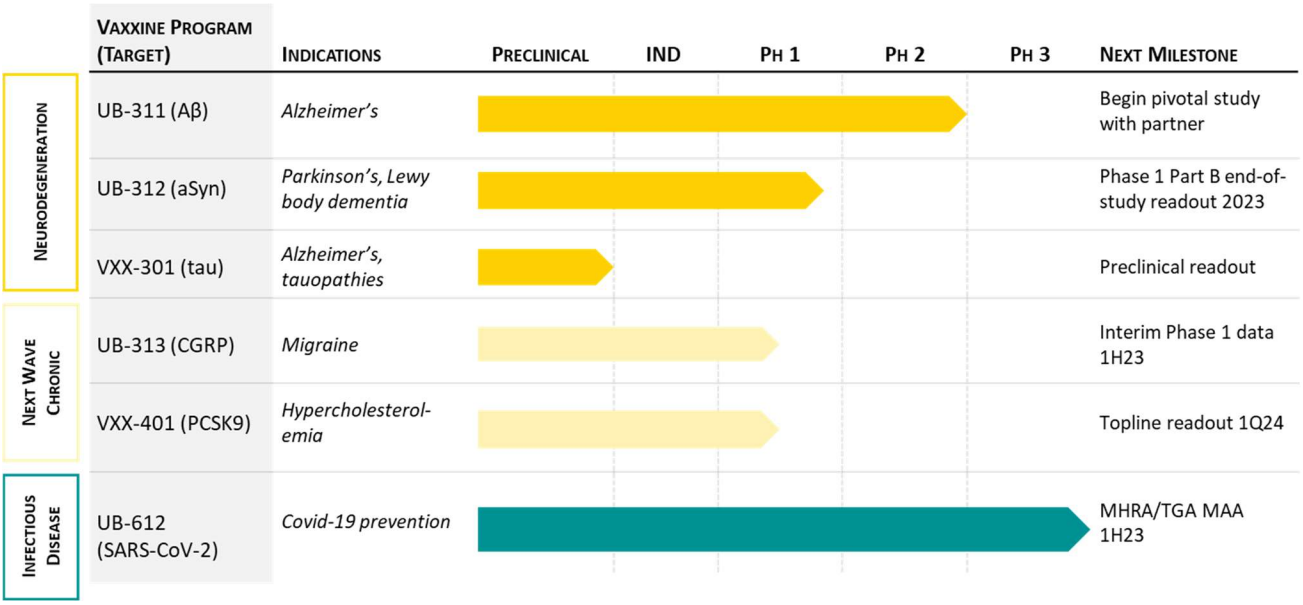
- *Administration*: Our product candidates are designed to be injected in quarterly or longer intervals via intramuscular injection similar to a flu shot. We believe this offers considerable convenience compared to mAbs, which can require up to bi-weekly dosing via intravenous infusion or subcutaneous injections, and small molecules, which often require daily dosing.

- *Efficacy*: In our clinical trials conducted to date, our product candidates have yielded high response rates (95% or above at target dose levels) for UB-311, UB-312 and UB-612, high target-specific antibodies against self-antigens (as seen in UB-311 and UB-312 clinical trials) and long durations of action for UB-311 (based on titer levels remaining elevated between doses) and UB-612 (based on half-life). See our descriptions of these clinical trials under "—Our Product Candidates." We also believe that the improved convenience of our product candidates as compared to mAbs has the potential to lead to increased adherence by patients. Furthermore, our Vaxxine Platform enables the combining of target antigens into a single formulation. For indications that could be treated more effectively with a multivalent approach, we believe our Vaxxine Platform would have an advantage over other modalities. Finally, because our Vaxxine Platform is designed to elicit endogenous antibodies, we believe our product candidates may lessen or avoid altogether the phenomenon of anti-drug antibodies which has limited the efficacy of certain mAbs over time.

- *Safety*: Based on our clinical trials to date, our product candidates have been well tolerated. We aim to offer product candidates with safety profiles at least comparable to the competing mAb or small molecule alternative for the relevant disease.

Our Pipeline

The following chart reflects our current product candidate pipeline:



As used in the chart above, "IND" signifies a program has begun investigational new drug ("IND")-enabling studies.

Our pipeline consists of five lead programs focused on chronic disease, particularly neurodegenerative disorders, in addition to other neurology and cardiovascular indications.

Neurodegenerative Disease Programs:

- *UB-311*: Targets toxic forms of aggregated amyloid-beta ("Aβ") in the brain to fight AD. Phase 1, Phase 2a and Phase 2a Long Term Extension ("LTE") trials have shown UB-311 to be well tolerated in mild-to-moderate AD subjects over three years of repeat dosing, with a safety profile comparable to placebo, with no cases of amyloid-related imaging abnormalities-edema ("ARIA-E") observed in the main Phase 2a trial, and only one case of ARIA-E in the LTE trial, which was clinically not significant according to the study investigator. UB-311 was also shown to be immunogenic, with a high responder rate and antibodies that bind to the desired target. We held an End of Phase 2 meeting with the U.S. Food and Drug Administration ("FDA") and have aligned upon a large scale efficacy trial, which, pending data, could potentially support initial licensure of UB-311 for the treatment of early AD. The FDA granted UB-311 Fast Track Designation in the second quarter of 2022. The expected timing of the Phase 2b initiation will be determined based upon the timing of a strategic partnership.

- *UB-312*: Targets toxic forms of aggregated α-synuclein in the brain and peripheral tissues to fight PD and other synucleinopathies, such as Lewy body dementia ("LBD") and multiple system atrophy ("MSA"). Part A of a Phase 1 trial in healthy volunteers has been completed and has shown UB-312 to be well tolerated, with no significant safety findings, and immunogenic, with a high responder rate and antibodies that cross the blood-brain barrier ("BBB"). No serious adverse events were observed in Part A of the Phase 1 trial. We have completed an end-of-treatment analysis of the ongoing Part B of the Phase 1 trial in PD patients, which has similarly shown UB-312 to be well tolerated and immunogenic, with anti-α-synuclein antibodies observed in the serum and CSF of PD patients. We anticipate the completion of Part B of the trial in PD patients in mid-2023.

- *VXX-301*: We are developing an anti-tau product candidate that has the potential to address multiple neurodegenerative conditions, including AD, by targeting abnormal tau proteins alone and in potential combination with other pathological proteins such as Aβ to combat multiple pathological processes at once. Our lead candidate targets multiple epitopes of tau.

Next Wave Chronic Disease Programs:

- *UB-313*: Targets Calcitonin Gene-Related Peptide ("CGRP") to fight migraines. We have completed enrollment in a first-in-human Phase 1 clinical trial, which began in September 2022, and anticipate a topline readout in the mid-2023.

- *VXX-401*: Targets proprotein convertase subtilisin/kexin type 9 serine protease ("PCSK9") to lower low-density lipoprotein ("LDL") cholesterol and reduce the risk of cardiac events. As of March 2023, we have begun dosing of subjects in a first-in-human clinical trial of VXX-401 in Australia.

Given the global COVID-19 pandemic and our Vaxxine Platform's applicability to infectious disease, we also have advanced a product candidate that addresses SARS-CoV-2.

COVID-19

- *UB-612*: Employs a "multitope" subunit protein-peptide approach to neutralizing the SARS-CoV-2 virus, meaning the product candidate is designed to activate both antibody and cellular immunity against multiple viral epitopes. A Phase 3 trial evaluating UB-612 as a heterologous boost against SARS-CoV-2, head-to-head versus homologous boosts of VNT162b2 (mRNA), ChAdOx1-S (adenovirus), and BIBP (inactivated virus), was initiated in the first half of 2022 with funding support from the Coalition of Epidemic Preparedness Innovations ("CEPI"). In December 2022, we announced positive topline data: UB-612 met primary and key secondary endpoints, eliciting non-inferior neutralizing antibody titers and seroconversion rates ("SCR(s)"), defined as a 4-fold or greater increase in neutralizing antibodies from baseline, against both Wuhan and Omicron BA.5 variants as compared to BNT162b2, and superior neutralizing antibody titers and SCRs against both variants as compared to ChAdOx1-S and BIBP. Preliminary safety data show that UB-612 has been generally well tolerated with no serious adverse events reported through day 57 of data cut-off. The trial is ongoing, with long-term safety and immunogenicity follow-up planned through 12 months. Phase 1 and Phase 2 trials of UB-612 have also shown UB-612 to be well tolerated, with over 7,500 doses administered to over 3,750 subjects. In March 2023 we completed rolling submissions for conditional/provisional authorization with regulatory authorities in the United Kingdom and Australia, who will review under their established work share agreement.

We believe our Vaxxine Platform has application across a multitude of chronic and infectious disease indications beyond our existing pipeline. We are developing additional product candidates that we believe may address significant unmet needs both within and beyond our current pipeline's therapeutic areas.

Our Team

We have assembled an experienced group of executives with deep scientific, business and leadership expertise in pharmaceutical and vaccine discovery and development, manufacturing, regulatory and commercialization. Mei Mei Hu, our co-founder and Chief Executive Officer, has been a member of the executive committee of UBI since 2010. Our board of directors is chaired by our co-founder Louis Reese, who has been a member of the executive committee of UBI since 2014. Our research efforts are guided by highly experienced scientists and physicians on our leadership team including Dr. Ulo Palm, our Chief Medical Officer, and Dr. Jean-Cosme Dodart, our Senior Vice President of Research. Our leadership team contributes a diverse range of experiences from leading companies including Allergan, Amgen, Eli Lilly, LEO, Merck, Novavax, Novartis, and Schering-Plough, and were executives in multiple successful mAb and vaccine launches. As of December 31, 2022, we have assembled an exceptional team of approximately 92 employees, the majority of whom hold Ph.D., M.D., J.D. or Master's degrees. We also have a highly experienced scientific advisory board consisting of leading doctors and scientists in relevant therapeutic areas.

Our Strategy

Our mission is to develop product candidates that improve the quality of care for chronic diseases and are accessible to all patients across the globe. In order to achieve this mission, we seek to:

- *Advance our chronic disease pipeline through clinical stage development*: We plan to advance UB-311, UB-312, UB-313, and VXX-401 through clinical stage development for the treatment of chronic diseases, either ourselves or with a strategic partner. We believe that our differentiated Vaxxine Platform will enable our product candidates, if approved and successfully commercialized, to potentially disrupt the treatment paradigm for their respective indications. However, there can be no guarantee that we will obtain regulatory approval or commercialize of any such product candidates.

- *Expand our pipeline of product candidates*: Chronic diseases are prevalent globally and expected to worsen over the next several decades. In furtherance of our mission, we plan to expand our pipeline by developing new product candidates that address additional indications. In expanding our pipeline, we rely on our proprietary filtering methodology, which evaluates potential product candidates across five principal criteria – (i) probability of technical and regulatory success, (ii) addressable market, (iii) development cost, (iv) competitive dynamics and (v) disruptive potential.

- *Opportunistically develop treatments for infectious diseases*: While our core mission focuses on the treatment of chronic diseases, we are committed to bringing accessible medicines to people around the world and will address infectious diseases opportunistically. For example, when the COVID-19 pandemic struck the world, we rapidly deployed resources in pursuit of a product candidate currently embodied in UB-612.

- *Expand and scale our existing capabilities*: We are investing in our operational processes, facilities and human capital to accelerate the speed with which we can bring product candidates through the development pipeline, and to strengthen the capacity for developing more product candidates simultaneously.

- *Continue to improve our Vaxxine Platform*: In addition to, and in conjunction with, our product candidate development efforts, we are continuously working to improve and enhance the richness, breadth and effectiveness of our Vaxxine Platform. As our Vaxxine Platform further develops, we believe that we can both increase the number of product candidates in concurrent development and efficiently advance product candidates through pre-clinical and clinical development.

- *Maximize the value of our product candidates through potential partnerships*: We currently retain worldwide rights for the majority of our product candidates and will consider entering into development and commercialization partnerships with third parties that align with our mission on an opportunistic basis.

Background and Limitations of Traditional Vaccines and Monoclonal Antibodies

The immune system, the body's mechanism for fighting off potential threats, is comprised of cells that form the innate and adaptive immune responses. The main purpose of the innate immune system is to immediately prevent the spread and movement of foreign pathogens throughout the body. The adaptive immune response is specific to the pathogen presented to T-cells and B lymphocytes ("B-cells") and leads to an enhanced response upon future encounters with those antigens. Antibodies represent an important tool within the adaptive immune system's arsenal. Upon detection of a potential threat, B-cells produce antibodies that recognize, bind to and eliminate the threatening pathogen. Over time, the immune system develops the ability to produce countless types of antibodies, each finely tuned against a specific threat.

Generally, the immune system is able to function effectively by neutralizing viruses, bacteria and even self-generated cells and proteins from within our own bodies that could cause harm if unchecked. However, as powerful as the immune system is, there are threats that it cannot overcome on its own, generating the need for medicine. Conventional forms of medicine include small molecules (e.g., antibiotics), which can inhibit or promote action within the body by, for instance, binding to a receptor on the surface of a cell, or directly inducing toxic effects upon bacteria. These medicines do not necessarily modulate the immune system directly in order to work. Instead, they work alongside it. While small molecules have provided substantial benefits to human health, they are typically not designed to interact with the immune system. They may also have limited efficacy in cases where an immune response to a target can be used against a chronic condition.

Vaccines

In the first part of the twentieth century, vaccines revolutionized healthcare by directly interacting with, and modulating, the immune system — training it to recognize a dangerous pathogen by introducing the immune system to a relatively harmless form of the pathogen, its toxins or one of its surface proteins, thereby promoting the body's own production of binding antibodies. Once immunized to a specific pathogen, the immune system can recognize it and generate the antibodies to fight it more quickly and robustly.

Traditional vaccine technologies have generally focused on the prevention of bacterial and viral infections and not on chronic disease. In chronic disease settings, the disease-causing agents frequently come from within the body. These self-antigens are proteins that become too abundant, misfolded or aggregated such that they can no longer perform their healthy function and even may induce toxic effects. The body can sometimes produce antibodies against such proteins, but this often falls short of providing the right types of antibodies in the right concentrations to ward off disease. Historically, vaccine technologies developed to target these proteins have been unable to break immune tolerance — that is, the immune system's general avoidance of reactivity towards self-antigens — with an acceptable level of reactogenicity. The challenges faced by prior efforts to advance vaccine technologies for chronic diseases included low response rates, low titer levels, off- target responses and other safety concerns such as T-cell mediated inflammation.

Monoclonal Antibodies

The first mAbs were developed in the later part of the twentieth century. In contrast to vaccines, which prompt the body to produce antibodies, mAbs are antibodies manufactured outside of the patient's body and then injected or infused into the body to recognize and eliminate harmful targets. Monoclonal antibodies have revolutionized the standard-of-care treatment for many chronic diseases. However, manufacturing mAbs is often an expensive and complex process and administering mAbs is cumbersome, sometimes requiring infusions as frequently as bi-weekly. These factors have generally limited mAbs' availability to moderate-to-severe disease, to later lines of therapy and to wealthier geographies, thus denying access to a substantial portion of the patients who could benefit from them. Finally, patients on mAbs often experience a loss of effectiveness over time due to a phenomenon known as anti-drug antibodies, whereby the immune system begins to recognize therapeutic mAbs as foreign, and mounts a response against them, eventually mitigating their efficacy.

Our Vaxxine Platform

Our Vaxxine Platform is designed to stimulate the patient's own immune system to generate antibodies and overcome the limitations of traditional vaccines to target self-antigens safely and effectively in chronic diseases. Our product candidates have broken immune tolerance against self-antigens consistently. As described in the section titled "Our Product Candidates" below, across seven clinical trials, we have consistently observed that our product candidates have stimulated the development of antibodies against the desired

target at relevant doses in clinical trial subjects, including the elderly. We have observed favorable tolerability and reactogenicity of our product candidates across studies of UB-311, UB-312 and UB-612, with no significant safety findings to date. We aim to develop product candidates that are more convenient, more cost-effective and more accessible to large patient populations, with safety profiles at least comparable to, relevant mAbs and small molecule treatments. We believe our product candidates have the potential to eventually not only capture meaningful market share from mAbs and small molecules, but more importantly, to provide therapeutic benefit to large patient populations who currently receive neither form of treatment and thereby open up the broadest access to patients. This would represent an unprecedented shift in the treatment paradigm, potentially providing better global access to treatments that have been previously limited to the wealthiest nations. In particular, we believe our treatments for chronic disease could reflect the following benefits as compared with the relevant mAbs and small molecule alternatives:

Characteristics of our Product Candidates versus Monoclonal Antibodies and Small Molecules

	Vaxxinity Product Candidates	Monoclonal antibodies	Small molecules
Cost			
Stability	✓ Stable	✗ Unstable, sensitive to external factors	✓ Stable
Manufacturability	✓ Simple, scalable, chemical process	✗ Complex biologic process	✓ Simple, chemical process
Accessibility	✓ Cost-effective	✗ Expensive	✓ Cost-effective
Scalability	✓ Low CapEx, rapid	✗ Capital- and time-intensive	✓ Relatively scalable
Administration			
Dose frequency	✓ **Quarterly to annually**	✗ Bi-weekly or monthly	✗ Daily
Route	✓ IM injection	✗ IV infusion or SC	✓ Oral
Safety Mechanism	• Target-specific	• Target-specific	• Toxic off-target effects • Drug-drug interactions
Efficacy Mechanism	• Specific and targeted • Penetrates BBB ✓ Long duration of action	• Specific and targeted • Penetrates BBB ✗ Limited duration due to ADA	✗ Generally less specific than biologics • Penetrates BBB ✗ Generally shorter half-life than biologics

History and Design

Our Vaxxine Platform utilizes a peptide vaccine technology first developed by UBI and subsequently refined over the last two decades, with more than three billion doses of animal vaccines commercialized to date. UBI initiated the development of this technology for human use; the business focused on human use was then separated from UBI through two separate transactions: a spin-out from UBI in 2014 of operations focused on developing chronic disease product candidates that resulted in United Neuroscience, a Cayman Islands exempted company ("UNS"), and a second spin-out from UBI in 2020 of operations focused on the development of a COVID-19 vaccine that resulted in C19 Corp., a Delaware corporation ("COVAXX"). Our current company, Vaxxinity, Inc., was incorporated under the laws of the State of Delaware on February 2, 2021 for the purpose of acquiring UNS and COVAXX in March of 2021.

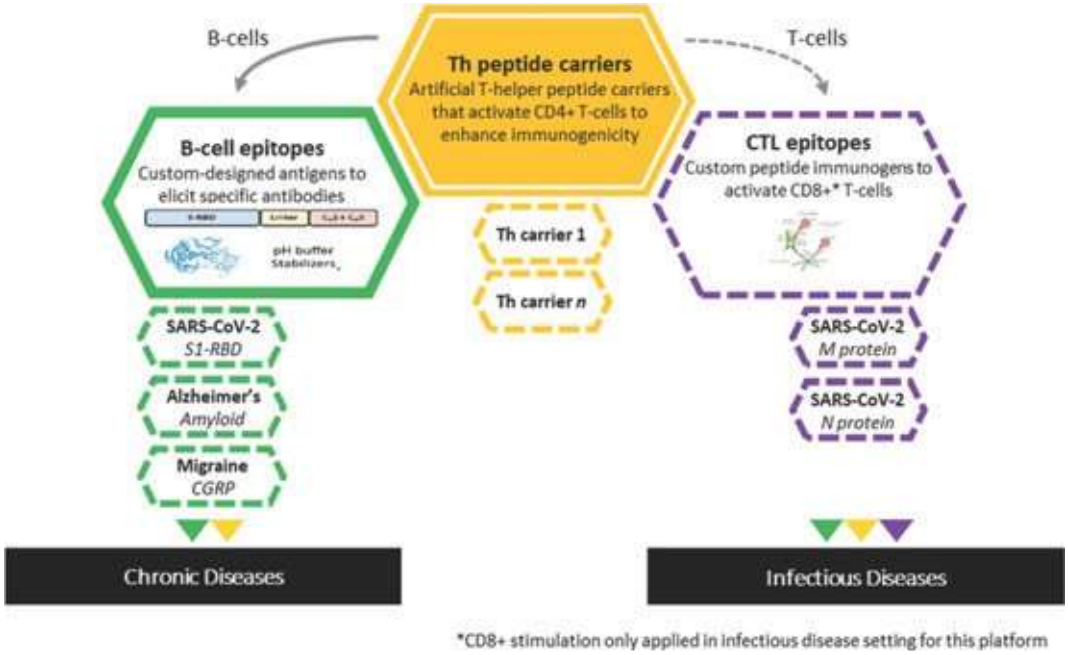
On March 2, 2021, in accordance with a contribution and exchange agreement among Vaxxinity, UNS, COVAXX and the UNS and COVAXX stockholders party thereto (the "Contribution and Exchange Agreement"), the existing equity holders of UNS and COVAXX contributed their equity interests in each of UNS and COVAXX in exchange for equity interests in Vaxxinity (the "Reorganization"). In connection with the Reorganization, (i) all outstanding shares of UNS and COVAXX preferred stock and common stock were contributed to Vaxxinity and exchanged for like shares of stock in Vaxxinity, (ii) the outstanding options to purchase shares of UNS and COVAXX common stock were terminated and substituted with options to purchase shares of Class A common stock in Vaxxinity, (iii) the outstanding warrant to purchase shares of COVAXX common stock was cancelled and exchanged for a warrant to acquire Class A common stock in Vaxxinity, and (iv) the outstanding convertible notes and a related party not payable were contributed to Vaxxinity and the former holders of such notes received Series A preferred stock in Vaxxinity. On December 31, 2022, COVAXX was merged into Vaxxinity in order to simplify the corporate structure.

UBI has used its capabilities in peptide technology for innovations across an array of business endeavors: antibody testing for human diagnostics, animal health vaccines and the manufacture of medical products. Its innovative products include one of the first approved peptide-based blood antibody tests in the world (for HIV), one of the first approved peptide vaccines against an infectious disease in the world in animal health (for a food-and-mouth disease virus) and one of the first approved peptide vaccines against a self-antigen in the world in animal health (an anti-luteinizing hormone-releasing hormone ("LHRH") vaccine used for the immunocastration of swine).

Grant funding from the National Institutes of Health supported some of UBI's work in the fields of vaccines and antibody testing. To commercialize its animal health vaccine business, UBI and its affiliates scaled up GMP vaccine manufacturing to over 500 million doses per year and partnered with a top-ten animal health company for commercialization of its anti-LHRH vaccine; all together, UBI's technology platform is utilized for the vaccination of approximately 25% of the global swine population annually.

We are advancing our peptide-based Vaxxine Platform to develop product candidates that target chronic diseases and COVID-19. Our Vaxxine Platform comprises a proprietary, custom, rationally designed antigen capable of evoking an immune response (an "immunogen") formulated with a proprietary CpG oligonucleotide. The immunogen contains several advanced synthetic peptide domains, including B-cell epitopes, T-helper ("Th") peptide carrier constructs and peptide linkers. This composition enables us to achieve a highly specific immune response to the target antigen, with limited inflammation and off-target effects that could cause reactogenicity. This design process has evolved into a repeatable series of well-defined steps, which has enabled the development of our current pipeline of product candidates.

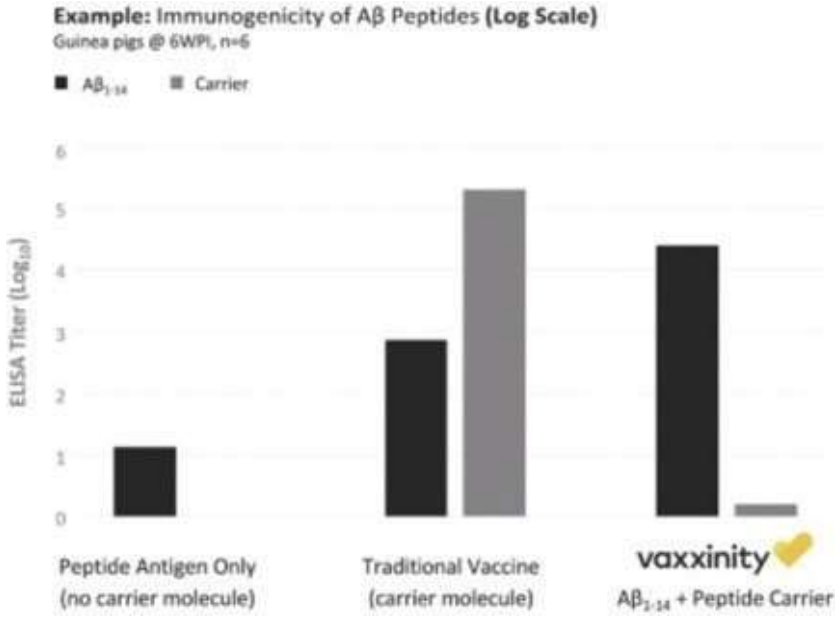
Key Elements of our Vaxxine Platform Constructs and Formulations



When developing a product candidate, we use publicly available information and sophisticated bioinformatics tools to investigate the entire protein structure of a target in a comprehensive manner to identify functional B-cell epitopes that may provide optimal antigens. We then synthesize peptides that mimic these identified antigens to elicit highly specific antibodies against these B-cell epitopes. To yield favorable tolerability profiles, we screen our product candidates for lack of toxicity as well as reactogenicity, and design them not to elicit T-cell mediated inflammation. To enhance effectiveness, we seek to optimize the size and sequence of our custom peptides to elicit a robust, specific antibody response when linked to a carrier molecule.

We then attach a proprietary carrier molecule, an artificial Th carrier peptide that delivers the synthetic peptide into cells. Traditional vaccines have faced challenges in achieving specific responses because they rely on conjugating an antigen to a large toxoid carrier molecule, to which most of the antibody response is directed, causing off-target effects such as inflammation. In our pre-clinical trials and clinical trials to date, our product candidates have displayed specific immunogenicity, or the ability to stimulate a targeted immune response, thereby greatly reducing potential off-target effects and increasing the potential for our product candidates to be well tolerated and efficacious. We have observed that our carrier molecules have produced consistent results across multiple species and against multiple targets in seven human clinical trials to date.

Our Product Candidate Does Not Induce an Antibody Response against its Carrier Molecule



The graph above illustrates that our peptide carriers induce a strong immune response against the target antigen, and a minimal immune response against themselves, as compared to traditional vaccines formulated with other types of carrier molecules.

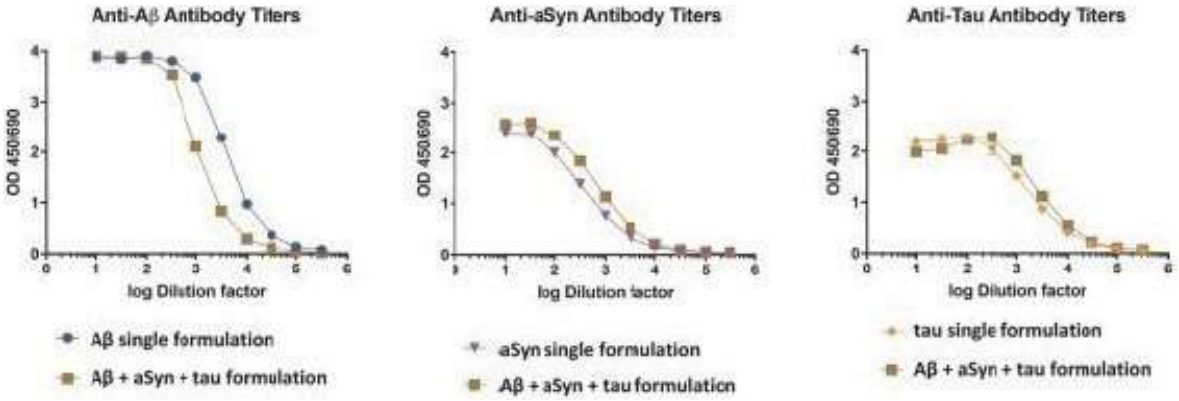
Our peptide carriers have short sequence lengths; we design them with the aim that they are not antigenic on their own and do not stimulate cytotoxic T-cells. The carriers' sequences model those found in natural pathogens, so they are recognized by T-helper cells. This encourages robust T-helper cell exposure and promotes activation of other immune cells. In turn, B-cells are exposed to the B-cell antigen and begin antibody production against the antigen, while avoiding an antibody response to the carrier.

Our library of peptide carriers enables the use of different carrier molecules or different combinations of carrier molecules, which allows us to potentially regulate the speed of immune response onset as well as the magnitude and duration of that response. For example, a longer duration of response would allow for less frequent dosing. In the case of vaccines for infectious diseases, where T-cell mediated activity is desirable, our Vaxxine Platform also affords the flexibility to design immunogen constructs that specifically promote cytotoxic T-cell activity when warranted.

We utilize proprietary linker constructs to fuse our peptide carriers with our custom peptide antigens. These linkers are designed to promote binding of both B-cell and T-helper epitopes to their respective receptors, contributing to a B-cell response. They may enhance the immune response by enabling conformational changes to optimize presentation of the B-cell epitope to antigen-presenting cells ("APCs"), such as dendritic cells ("DCs").

Our Vaxxine Platform also enables the construction of candidates that target multiple epitopes in a single formulation, whether on multiple targets or a single target. In certain cases, targeting multiple epitopes of a single target could promote increased target engagement. Combinations of therapies targeting different molecular mechanisms are common in treating neurologic, cardiovascular, psychiatric, metabolic, respiratory, infectious and oncologic disease. Our Vaxxine Platform's favorable cost of goods and efficient manufacturing process could allow for viable multi-target therapies in a single formulation. This concept could be applied in an array of potential therapeutic areas. Our current pipeline has candidates against amyloid-β, α-synuclein and tau; targeting of two or more of these at the same time might prove more effective than any single-target therapy in some patients. Pre-clinical data to date suggests that we can elicit antibody titers against all three targets in a single formulation. In contrast, multi-target therapy with mAbs would compound the cost and administration burdens as compared to single-target mAb therapy.

Immunogenicity of Single- Versus Multi-Target Formulations in Guinea Pigs



Guinea pigs (three per dose) were immunized with either single-target or multi-target formulations, then serum was drawn and antibody titers compared via enzyme immunoassays ("EIA"). Multi-target formulations elicited similar titer levels against each target as their corresponding single-target formulations. This suggests we can create product candidates with multiple neurodegenerative targets in a single formulation and achieve sustainable titer levels.

Product Candidate Formulations

In addition to our immunogen construct, each product candidate formulation includes custom CpG oligonucleotides and adjuvant selection. CpG oligonucleotides are negatively charged, and we utilize proprietary CpG configurations to stabilize the positively charged peptides. This stabilization acts to optimize display of the B-cell epitope to the immune system. In this way, the primary function of CpG oligonucleotides in our formulations is that of an excipient.

A potential secondary function of CpG is that of an adjuvant. Certain CpG configurations are known to act as immunostimulants and promote direct cytotoxic T-cell activity, while others do not. Accordingly, our selection of the specific CpG modality is highly dependent on the target indication. For infectious disease indications, the T-cell response generated by the CpG configuration is independent and in addition to that of the T-cell response generated by the peptide carrier.

The final formulation includes the addition of an adjuvant, such as a well-recognized, alum-derived Adju-Phos or Alhydrogel to further enhance the immunogenicity of our product candidate. Alum-derived adjuvants are commonly used in vaccines to promote an immune response. This is not the same adjuvant used in other companies' failed neurodegenerative vaccine candidates.

How our Product Candidates are Designed to Function

Our immunogens stimulate the body's adaptive immune system to produce antibodies against a variety of antigen targets, including secreted peptides or proteins, degenerative or dysfunctional proteins and membrane proteins, as well as infectious pathogens. The mechanism of action involves the following sequence of steps:

1. The immunogen is taken up by an APC, such as a DC. Antigen uptake leads to DC maturation and migration to the draining lymph nodes where the DCs interact with CD4+ T-helper cells.

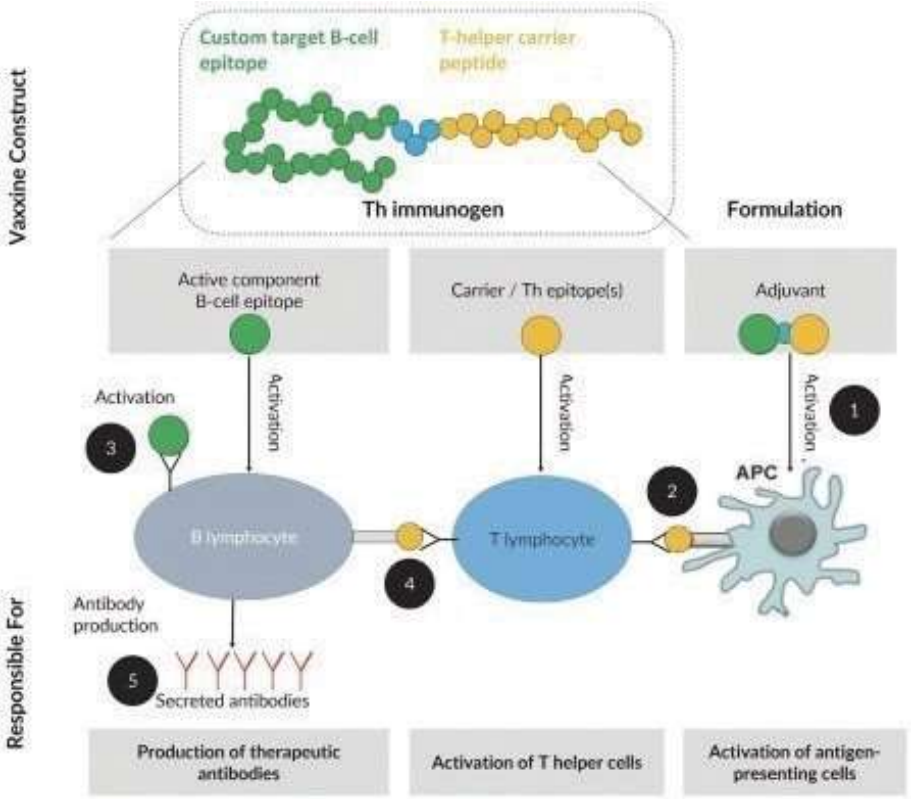
2. DCs engulf and process the antigen internally and present the T-helper epitope on major histocompatibility complex ("MHC") Class II molecules. The presentation activates immunogen-specific CD4+ T-helper cells causing them to mature, proliferate and promote B-cell stimulatory activity.

3. B-cells with receptors that recognize the target B-cell epitope bind, internalize and process the immunogen. The binding of the B-cell receptor to the immunogen provides the first activation signal to the B-cells.

4. When B-cells function as APCs and present the T-helper epitope on MHC Class II molecules, interaction with immunogen-specific CD4+ T-helper cells provides a second activation signal to B-cells, which causes them to differentiate into plasma cells.

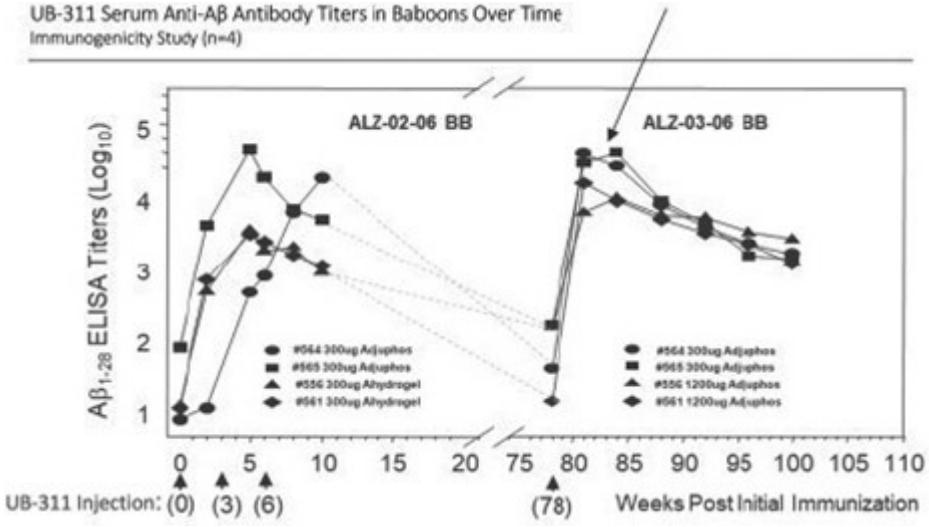
5. B-cell epitope-specific plasma cells produce high affinity antibodies against the target B-cell epitope. Of particular importance for targets located in the central nervous system ("CNS"), these antibodies are produced in sufficient concentrations to cross the BBB.

Overview of How our Product Candidates Function



Importantly, from both clinical trials and pre-clinical studies, we have observed the rapid expansion of antibodies upon administration of a booster of our product candidates. Based on the available data to date, we can infer that while antibody titers decline with time after administration, a small number of memory B-cells and antibody secreting cells are maintained in the lymphoid organs, spleen or bone marrow. We believe this is important because if a patient misses a dose of our product candidate, they may be able to recall the antibody response, and therefore the therapeutic effect of the antibodies, with a single booster, even after a long period of time has passed.

Vaxxine Platform Immunogenicity upon Re-dosing



As shown in the above graph, a rapid antibody response is elicited by a booster dose of UB-311 given 72 weeks after the priming regimen.

Furthermore, the antibodies elicited by our product candidates have different properties than those of mAbs targeting similar pathology. In general, we aim to achieve binding affinity, specificity and functionality similar or improved compared to mAbs targeting similar pathology. We use Bio-Layer Interferometry (ForteBio®) to compare the binding kinetics (K_{ON}, K_{OFF}, and K_D) of antibodies elicited by

our product candidates versus mAbs. We also use Western blot or slot blot to evaluate the binding specificity of antibodies elicited by our product candidates against the normal, toxic, misfolded or aggregated forms of the target protein. We use immunohistochemical analyses to observe the binding of antibodies to pathological inclusions on tissue sections, such as brain sections of patients. Moreover, we use cell-based models and animal models to measure the induced antibodies' functionality. Additionally, a major challenge in mAb drug discovery is that mAbs are prone to induce an immune response against themselves, resulting in a potential inactivation/neutralization of the mAb by the host (i.e., the patient). This is not a concern with our vaccine approach as each patient will produce its own antibodies against the target. Finally, mAbs have a potential for off-target binding, which could result in non-specific binding leading to safety and toxicity issues. We believe that this is unlikely to happen using our technology since antibodies elicited by our product candidates are designed to break immune tolerance against specific targets and should not trigger an immune response against other self-peptides or proteins.

Product Candidate Selection Process

Because our Vaxxine Platform may have applicability across a range of chronic diseases, we employ a proprietary filtering methodology to best identify new product candidates for development. We evaluate potential product candidates across five principal criteria:

- *Probability of technical and regulatory success*: We examine the probability of success for a product candidate based on stage of development and therapeutic area, and then make target-specific adjustments for design difficulty, industry knowledge and clarity of biological mechanism, general safety risk and estimated titer level required for therapeutic effect. This criterion accounts for the known validity of a given target in the relevant disease context.

- *Market opportunity*: We account for the prevalence, unmet need and drug market size for each likely indication associated with a given target, as well as the number of potential indications.

- *Development cost*: We estimate the cost of development through BLA submission, the time to submission and the number of patient-years to proof-of-concept.

- *Competitive advantages*: We evaluate the extent to which the advantages of our Vaxxine Platform compare to the current and potential future standard of care, including convenience, dosing, safety, efficacy and cost.

- *Disruptive opportunities*: We evaluate the extent to which the potential disruptive properties of our Vaxxine Platform may play a role in treatment paradigms, including the ability to "leap-frog" mAbs and treat patients in earlier lines of treatment, to be used as a prophylactic, to include multiple targets in a single formulation and to be used as an adjuvant therapy.

After assigning values to each criterion for a given product candidate, we weight each criterion according to a confidential algorithm, and thereby prioritize product candidates for development. We update these values on a regular basis based on new scientific literature, trial results and our Vaxxine Platform advancements.

As an example, in light of these criteria, AD and other neurodegenerative diseases that involve misfolded proteins are an attractive area for development. First, as the field has gained knowledge and clinical experience around the biology of targeting aberrant proteins with antibodies, the relative technical, safety and regulatory risk has decreased. For instance, with two FDA-approved products targeting Aβ for AD, Aβ has been validated as a target. Both AD and PD have high prevalence worldwide, and large unmet need with no disease-modifying products readily available to patients. Moreover, the underlying pathologies often begin years or decades before symptoms may appear and as a result, early intervention in the disease state, as well as prevention or delay of onset strategies, may be optimal and more practically achievable with a vaccine approach. While mAbs can target the pathology, they face the limitations of high cost, cumbersome and inefficient administration and limited access, and are not suited for early treatment or prevention, which we believe provides a disruptive opportunity for our Vaxxine Platform.

We do not currently evaluate oncology and infectious diseases through the above framework. We generally do not pursue oncology targets given the hyper-segmentation of subjects common in clinical development efforts in oncology that leads to relatively narrow labels, and due to the strengths of other new modalities such as cell-based therapy in this area. We only consider infectious disease opportunistically. However, our approach with respect to oncology and infection diseases could change in the future.

We believe that our Vaxxine Platform, and our strategy more generally, will create a significant opportunity for drug development well beyond our current pipeline of clinical and pre-clinical indications, in therapeutic areas including allergy (e.g., atopic dermatitis, chronic rhinosinusitis, , food allergy), autoimmune disease (e.g., psoriasis, psoriatic arthritis, Crohn's disease), pain (e.g., peripheral neuropathy, diabetic neuropathy) and bone and muscle atrophy (e.g., sarcopenia, osteoporosis, osteopenia).

Underlying Drivers of Our Platform Advantages

Our Vaxxine Platform's properties drive the unique combination of attributes that we believe will be reflected in our product candidates:

- *Cost*: Our reliance on chemically linked, custom peptide sequences fuels cost efficiencies that we expect to enable broad accessibility to our product candidates. Foremost among these relates to dosing. Monoclonal antibodies require more physical material for annual dosing because the patient needs to be delivered the externally manufactured therapeutic antibodies, which have high molecular weight. In contrast, our product candidates are designed to stimulate the body's immune system to produce its own antibodies and have relatively low molecular weight. While an annual supply of mAbs doses may include grams or tens of grams of drug substance, our current product candidates only require 1 to 2 milligrams each, or even less, leading to a relatively low annual cost of goods. In our development programs to date, we have achieved a cost of goods amounting to a small fraction of the typical cost of mAbs (as low as <1%).

- *Administration*: Administration of our product candidates generally requires three priming doses, each in the range of several hundred micrograms, followed by booster doses of a similar magnitude 2 to 4 times per year. As described in the section titled "Our Product Candidates" below, in clinical trials we have observed that our product candidates elicited a sustained antibody response, with elevated antibody levels lasting six months or longer. We believe this presents a meaningful advantage over many mAbs, which commonly require either bi-weekly or monthly injections, or monthly or quarterly infusions, and many small molecules, which commonly require a daily pill regimen.

- *Safety*: The antibodies generated by our product candidates are designed to be highly specific to the target antigen and to avoid an off-target immune response to the peptide carrier, thereby limiting inflammation and other off-target activity. We believe these characteristics have yielded the high tolerability observed in the clinical studies of our product candidates to date. Furthermore, the titer response to our product candidates is naturally titrated, which may reduce the likelihood of an antibody Cmax safety side effect, and is naturally reversible, thus avoiding an uncontrolled or permanent immune response.

- *Efficacy*: In our clinical trials conducted to date, our product candidates have yielded comparatively high response rates (95% or above at target dose levels) for UB-311, UB-312 and UB-612, high target-specific antibodies against self-antigens (as seen in UB-311 and UB-312 clinical trials) and a long duration of action for UB-311 (based on titer levels remaining elevated between doses) and UB-612 (based on half-life). Furthermore, our Vaxxine Platform enables the combining of target antigens into a single formulation. For indications that could be treated more effectively with a multivalent approach, we believe our Vaxxine Platform would have an advantage over other modalities. Finally, because our Vaxxine Platform is designed to elicit endogenous antibodies, we believe our product candidates may lessen or avoid altogether the phenomenon of anti-drug antibodies which has limited the efficacy of certain mAbs over time.

Additionally, we believe our Vaxxine Platform possesses important benefits reflected at the platform level, as opposed to the product candidate level:

- *Product Candidate Discovery*: Our Vaxxine Platform enables the efficient iteration of product candidates in the discovery phase through rapid, rational design and formulation. We are able to screen in high throughput rapidly and at low cost. Upon nominating a target for drug discovery, we can formulate several dozen product candidate compounds for preliminary in vivo immunogenicity and cross-reactivity screening within 2 to 3 months. This process allows nonviable product candidates to "fail fast" and allows us to carry top product candidates forward through subsequent pre-clinical development to lead identification. In contrast, biologics require the maintenance and adjustment of living cultures to design, formulate and iterate, and therefore discovery and early development is inherently less efficient.

- *Process Development*: Scaling the formulation of a drug product from research grade to clinical grade, then to commercial grade, typically consumes a great deal of resources. This, together with the development of assays for quality control and quality assurance, comprise process development. We leverage our manufacturing expertise, originally developed alongside UBI and certain of its affiliates, to enable rapid scale-up of the manufacture of both clinical and commercial compounds that use our Vaxxine Platform technology. Unlike process development for mAbs, which has inherent challenges such as risk of contamination in cell culture or bioreactors and time-consuming adjustments to cell lines for any formulation adjustment, our peptide platform relies on synthetic peptide chemistry, which is more reproducible and scalable, and relatively quick to manipulate for any modifications.

Our Product Candidates

Neurodegenerative Disease Programs

Neurodegenerative diseases are a collection of conditions defined by progressive nervous system dysfunction, degeneration or death of neurons, which can cause cognitive decline, functional impairment and eventually death. Neurodegeneration represents one of the most significant unmet medical needs of our time due to an aging population and lack of effective therapeutic options.

Two of the most common neurodegenerative diseases are AD and PD. In the United States, currently more than six million people suffer from AD, and approximately one million people suffer from PD according to estimates from the Alzheimer's Association and the Parkinson's Disease Foundation, respectively. As a result, AD and PD bring a heavy burden on our society's cost of care. The direct costs of caring for individuals with AD and other dementias in the United States were estimated at $305 billion in 2020 according to a

study published by the American Journal of Managed Care, and are projected to increase to $1.1 trillion by 2050 according to the Alzheimer's Association. The financial burden of PD exceeded $50 billion in the United States in 2019. Many more people around the world suffer from these two diseases and their related social and economic implications.

UB-311

An Overview of Alzheimer's Disease

Alzheimer's disease is a progressive neurodegenerative disorder that slowly affects memory and cognitive skills and eventually the ability to carry out simple tasks. Its symptoms include cognitive dysfunction, memory abnormalities, progressive impairment in activities of daily living and a host of other behavioral and neuropsychiatric symptoms. The exact cause of AD is unknown, but genetic and environmental factors are established contributors. AD affects more than six million people in the United States and 44 million worldwide. The global economic burden of AD is expected to surpass $2.8 trillion by 2030.

Many molecular and cellular changes take place in the brain of a person with AD. Aβ plaques and neurofibrillary tangles of tau protein in the brain are the pathological hallmarks of the disease. Several pathological or toxic forms of Aβ and tau seem implicated in the disease process, leading to loss of neurons and neuronal connectivity underlying the signs and symptoms of AD.

The Aβ protein involved in AD comes in several different pathological forms that accumulate in the brain parenchyma. Soluble species of Aβ (e.g., oligomers) can directly disrupt normal synaptic and neuronal functions. They may also contribute to tau pathology. Research is ongoing to better understand how, and at what stage of the disease, the various forms of Aβ influence AD.

Neurofibrillary tangles are abnormal accumulations of a protein called tau that collect inside neurons. Healthy neurons are supported internally, in part, by structures called microtubules, which help to guide nutrients and molecules from the cell body to the axon and dendrites. In healthy neurons, tau normally binds to and stabilizes microtubules. In AD, abnormal chemical changes cause tau to detach from microtubules and to stick to other tau molecules, forming threads that eventually join to form tangles. These tangles block the neuron's transport system, which harms the synaptic communication between neurons.

Converging lines of evidence suggest that AD-related brain changes may result from a complex interplay among Aβ proteins, abnormal tau, and several other factors. It appears that abnormal tau accumulates in specific brain regions involved in memory. Concurrently, Aβ clumps into plaques between neurons. As the level of Aβ reaches a tipping point, tau rapidly spreads throughout the brain. In addition to the spread of Aβ and tau, chronic inflammation and its effect on the cellular functions of microglia and astrocytes, as well as changes to the vasculature, are thought to be involved in AD's pathology and progression.

In the last two years, the FDA has approved two different mAbs that target Aβ for the treatment of AD.

Limitations of Current Therapies

Two classes of small molecules approved for the treatment of AD's symptoms are acetylcholinesterase inhibitors ("AChEIs") and glutamatergic modulators. AChEIs are designed to slow the degradation of the neurotransmitter acetylcholine, temporarily compensating for cholinergic deficits. Glutamatergic modulators are designed to block sustained, low-level activation of the N-methyl-D-aspartate ("NMDA") receptor, without inhibiting the normal function of the receptor in memory and cognition. However, these therapeutic products only address the symptoms of AD and do not modify or alter the progression of the underlying disease.

Aducanumab, marketed under the trade name Aduhelm, is a mAb developed by Biogen, Inc. ("Biogen") that targets aggregated forms of Aß. The FDA approved aducanumab in June 2021, making it the first approved immunotherapy for AD, the first new FDA-approved treatment since 2003 and, importantly, the first to receive accelerated approval based on a biomarker. By approving aducanumab on the basis of biomarker evidence, we believe the FDA set a precedent for developers of anti-Aβ immunotherapies.

Despite the milestone in the treatment of AD that aducanumab's approval represents, the drug has several limitations. Approximately one-third of patients experience ARIA-E related adverse events, which can manifest as symptoms ranging from headaches to confusion to coma. In addition, the drug must be administered monthly via intravenous infusion in healthcare facilities specifically configured to support an hours-long infusion process with healthcare professionals trained to administer infusion therapies, creating a burden for patients and additional costs resulting from the complex administration process. Because of the risk of developing ARIA-E, physicians who prescribe aducanumab must titrate dosing and carefully monitor each patient using magnetic resonance imaging ("MRI"). This process is costly and burdensome The combination of price, side effects, extra costs, and extra administration burden highlight the challenges of mAbs. The Center for Medicare & Medicaid Services ("CMS") decided not to cover aducanumab, leading to its commercial failure.

Soon after the FDA's approval of aducanumab, Eli Lilly and Company ("Lilly") announced that it would file for approval of its anti-Aβ mAb, donanemab, in 2022 on the basis of Phase 2 data. In January 2023, the FDA declined accelerated approval of donanemab due to

an insufficiently sized safety database in its Phase 2 trial; however, Lilly has announced its intention to file for approval later in 2023 on the basis of Phase 3 data.

In January 2023, the FDA granted accelerated approval to lecanemab, another mAb targeting Aβ, jointly developed by Biogen and Eisai Co., Ltd. ("Eisai"). Over 12.5% of patients on lecanemab experience ARIA-E, and physicians who prescribe lecanemab must monitor each patient using MRI. Lecanemab must be administered every two weeks as an intravenous infusion in healthcare facilities specifically configured to support an hours-long infusion process with healthcare professionals trained to administer infusion therapies, creating a burden for patients and additional costs resulting from the complex administration process. Biogen and Eisai have announced that their wholesale acquisition cost ("WAC") launch price in the U.S. will be $26,500 for the drug product only, which does not include administration and ongoing monitoring costs. It remains to be seen whether and to what extent CMS will reimburse treatment of AD patients with lecanemab.

We believe the above examples signify not only the validity of targeting toxic forms of Aβ as a target in AD, but also the practical limitations of mAbs, which so far despite approval have remained unable to serve a population with high unmet need.

Our Product Candidate: UB-311

We are developing a novel product candidate, UB-311, as a potential disease-modifying therapy for the treatment of AD. We completed a Phase 1 open label trial (V118-AD) and a Phase 2a randomized, double-blinded, placebo-controlled trial (the "Phase 2a Main Trial"). We believe that UB-311 may offer several differentiators versus the approved mAbs, including the preferential targeting of aggregated Aβ oligomers over monomers, longer durability suggesting greater overall exposure, or area under the curve ("AUC"), improved convenience in dosing and administration, a safety and tolerability profile comparable to placebo with potentially limited ARIA-E, and an ability to broaden patient access with greater cost-effectiveness and scalability. No signs of ARIA-E related adverse events were reported in the Phase 2a Main Trial despite more than two-thirds of the study participants being APOE4 carriers. *Post hoc* exploratory analyses of UB-311's Phase 2a clinical data also suggest that quarterly dosing of UB-311 might slow cognitive decline in some subjects by up to 50% when compared to placebo, as measured by Clinical Dementia Rating Sum of Boxes ("CDR-SB"), Alzheimer's Disease Assessment Scale – Cognitive Subscale ("ADAS-Cog"), Alzheimer's Disease Cooperative Study – Activities of Daily Living ("ADCS-ADL") and Mini-Mental State Examination ("MMSE") scores, all clinically validated measures of cognition or function in AD. In this small Phase 2a study, these were secondary measures, as the study was not designed to assess cognitive decline. Although our Phase 2a trial was a proof-of-concept study, not powered to demonstrate significant changes in any endpoint, we believe the data are suggestive of potential therapeutic efficacy and may lead to clinical benefit.

UB-311 is formulated for intramuscular administration on a dosing schedule of every three or six months. In addition, manufacturing costs lower than those of mAbs may support meaningfully lower pricing and access to larger patient populations. We believe such advantages of UB-311, if ever approved for use, could position it not only to disrupt the emerging mAb-based treatment for early AD as both a monotherapy and adjuvant therapy to existing mAbs, but also to open up a new paradigm for prevention of AD (i.e., for potential prophylactic use to delay or interrupt early disease onset).

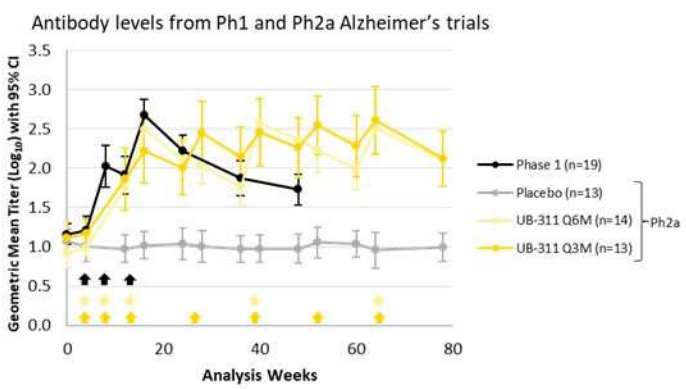
Clinical Development

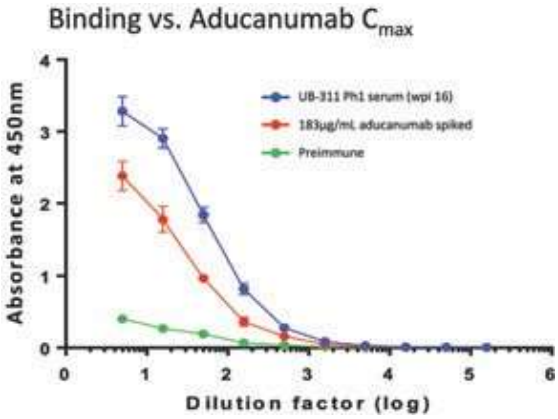
We completed a randomized, double-blind, placebo-controlled Phase 2a trial of two dosing regimens of UB-311 in subjects with mild AD. The primary objective of this trial was to assess safety and immunogenicity. Secondary measures for exploratory analyses included assessment of changes in the CDR-SB, ADAS-Cog, ADCS-ADL and MMSE scales, along with amyloid PET imaging evaluations. This study was intended for proof-of-concept, so no statistical hypothesis testing was planned, and exploratory analyses were performed to evaluate trends as described below.

A total of 43 patients diagnosed with mild AD were randomized (1:1:1) to one of three treatment groups: UB-311 quarterly dosing, or "Q3M," receiving a total of seven doses, UB-311 every six-month dosing, or "Q6M," receiving a total of five doses, and placebo. The Q3M cohort, which included 14 subjects, received an initial regimen of three 300μg injections, one injection at the trial start, one at week 4 and the final at week 12, followed by four single 300μg booster doses administered in three-month intervals over the subsequent 12 months. The Q6M cohort, which included 15 subjects, involved the same initial schedule of three 300μg injections administered over the first 12-week period, followed by the administration of two 300μg booster doses given at six-month intervals. The placebo group comprised 14 subjects.

In the Phase 2a Main Trial, UB-311 generated an immune response as measured by ELISA in 28 out of 29 subjects. Across this trial and the Phase 1 trial, 47 of the 48 subjects (98%) that received UB-311 registered an immune response (which we define as a 95% confidence interval separation from placebo) as measured by ELISA. The intramuscular injection produced appreciable antibody titers against Aβ. The antibody titers remained elevated through the trial's duration. Moreover, *in vitro* studies demonstrate that UB-311 generated serum antibody titers against Aβ oligomers, comparable to or greater than those measured after maximum therapeutic dosing with an approved mAb. We believe these results underscore the significant promise of our therapeutic approach.

Generation of Antibodies Repeatable Across Clinical Studies, and Antibodies Bind Target with High Specificity as Compared to Monoclonal Antibody



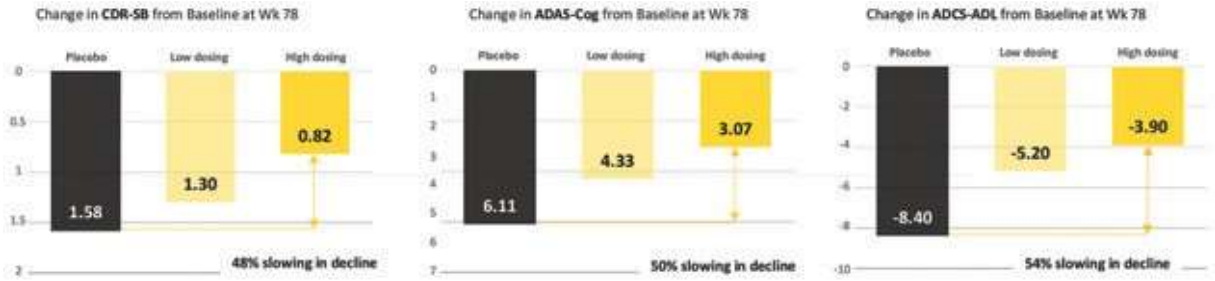


Across Phase 1 and Phase 2a trials, UB-311 generated an over 95% response rates in subjects. In a comparative in vitro study with aducanumab, we observed that UB-311 elicited titer levels comparable to mAbs.

Phase 1 and Phase 2a trials of UB-311 demonstrated a repeatable anti-Aβ titer response. In an *in vitro* comparison of titers in serum from subjects dosed with UB-311 versus pre-immune serum spiked with aducanumab at the published C_{max} concentration following 10mg/kg administration (183µg/mL), antibodies generated by UB-311 bond to Aβ oligomers similarly to or greater than the mAb as measured by EIA.

Exploratory analyses of clinical and imaging measures were conducted. Trends of changes in disease assessment scores suggest slowing of cognitive decline. Changes in the CDR-SB assessment at week 78 of the Phase 2a Main Trial showed a 48% slowing in cognitive decline from baseline relative to the placebo group; changes in ADAS-Cog measurements showed a 50% slowing in decline relative to placebo and showed a 54% slowing in decline in ADCS-ADL relative to placebo.

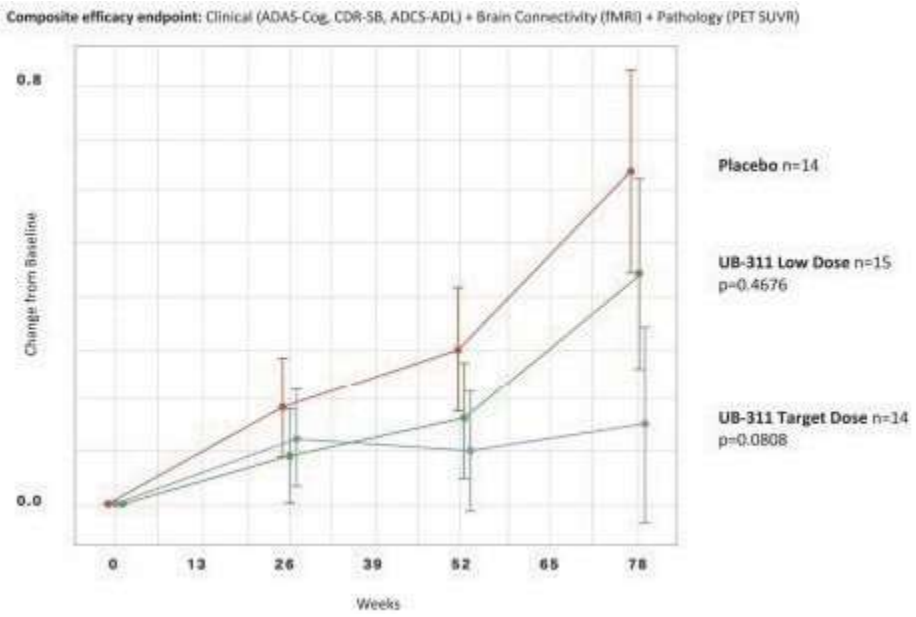
UB-311 Phase 2a Suggests Slowing of Cognitive Decline in Mild Alzheimer's Subjects (mITT)



UB-311 Phase 2a secondary endpoint data suggested possible slowing of clinical decline by up to 50% in subjects with mild AD. These are exploratory analyses, and no statistical inference was performed.

In addition, functional MRI suggested marginal increases in connectivity in some brain regions and PET imaging showed a modest reduction in amyloid plaque burden as measured by standard uptake value ratio. We believe these clinical and biomarker endpoints suggest a causal effect of UB-311 impacting the underlying molecular pathology of the disease and slowing of clinical decline. Together, these findings offer some evidence that UB-311 may exhibit disease-modifying effects.

UB-311 Phase 2a Analysis of Clinical and Biomarker Endpoints Suggests Overall Disease-Modifying Effect



Compared to placebo, UB-311 low-frequency dosing and high-frequency dosing demonstrated slowing of overall disease progression in an independent analysis conducted by Pentara Corporation.

The Phase 2a Main Trial recapitulated the safety and tolerability profile of UB-311 that was observed in an earlier Phase 1 trial. No subjects discontinued trial participation due to a treatment emergent adverse effect ("TEAE"). No ARIA-E was observed in quarterly MRI scans. Aβ-related imaging abnormalities related to microhemorrhages or hemosiderosis seemed similar between the UB-311 treatment groups and placebo group. In the Phase 2a Main Trial, six serious adverse events were observed, including three in the Q6M dosing arm and one in the Q3M dosing arm. None were deemed related or likely related to UB-311.

Titers generated by UB-311 ramped up gradually over the course of several months, as opposed to titers following the administration of anti-Aβ mAbs, which reach C_{max} very rapidly. We believe this led to the relatively low rates of ARIA-E observed in our clinical studies of UB-311 as compared to those observed in clinical studies of mAbs. No meningoencephalitis was observed.

Summary of Safety Data from UB-311 Phase 1 and Phase 2a Trials

	UB-311 Ph1	UB-311 Ph2a Main Study		
n (%)	UB-311 n=19	Placebo n=14	Low Dosing (Q6M) n=15	High Dosing (Q3M) n=14
Patients with an AE	16 (84.2)	13 (92.9)	13 (86.7)	10 (71.4)
Patients with an SAE	1 (5.3)	2 (14.3)	3 (20.0)	1 (7.1)
Patients permanently discontinuing treatment due to AE	0	1 (7.1)	0	0
Patients permanently discontinuing treatment due to ARIA	0	0	0	0
Number of all-cause deaths	0	0	0	0
ARIA-E	NR	0	0	0
ARIA-H*	NR	2 (14.3)	2 (13.3)	2 (14.3)

As depicted in the table above, UB-311 was well tolerated across Phase 1 and Phase 2a trials. The most common TEAE was site injection reactivity, and there were no discontinuations or withdrawals due to TEAEs

An extension of the Phase 2a Main Trial, the Phase 2a LTE trial, involved the continued participation by 34 of the subjects who participated in the Phase 2a Main Trial for an additional 78 weeks. The objective of the Phase 2a LTE trial was to assess the longer-term tolerability of extended treatment with UB-311. Following a non-treatment period of up to 26 weeks, participants in the LTE trial were segmented into two groups: those previously on drug in the Phase 2a Main Trial would receive two placebo doses and a single

300µg priming dose at the start of the LTE treatment period and those previously on placebo would receive three 300µg priming doses over an initial 12-week period. Due to an error by the CRO responsible for administering blinded placebo and active doses to trial subjects, which reduced the confidence of subsequently collected data, we decided to discontinue the LTE trial, having determined that we had collected sufficient data on UB-311's tolerability and immunogenicity. Analysis of the data collected before trial discontinuation indicated that UB-311 was well tolerated, with return of anti-Aβ antibody titers to peak levels achieved after a gap of as long as 12 months between doses and a continued trend toward evidence of disease modification. In the Phase 2a LTE trial, six serious adverse events were observed. One case of ARIA-E was observed in the Phase 2a LTE trial in a subject 10 weeks after receiving a dose of UB-311, which was clinically not significant according to the study investigator. No serious adverse event was deemed related or likely related to UB-311, and all such events were recovered/resolved by the end of the study. Exploratory analyses of the clinical data generated in this portion of the trial suggested that subjects in the treatment cohorts showed sustained improvement, as measured by the change in CDR-SB from baseline.

We completed an open-label Phase 1 trial of UB-311 in 19 subjects with mild-to-moderate AD between the ages of 51 to 78 years. The primary objective of the trial was to assess safety and tolerability. Secondary measures included UB-311 antibody titers along with changes in the ADAS-Cog, MMSE and the Alzheimer's Disease Cooperative Study-Clinician's Global Impression of Change disease assessment ratings. The 24-week, open label trial was designed as three intramuscular injections of 300µg, the first dose administered at the start of the trial, a second at week four and a third at week 12. An observation study included additional follow-up visits up to 48 weeks after the first injection to assess the long-term immunogenicity and safety of UB-311. In this trial, UB-311 was well tolerated, with the most common TEAE being injection site redness and swelling. No TEAE resulted in the discontinuation or withdrawal of any study participant in the trial. In the Phase 1 trial, one serious adverse event was observed: a case of herpes zoster deemed unlikely related to UB-311.

Anti-Aβ antibody titers, recorded among all study participants, approached a 100-fold increase during weeks 16 to 48 after administration of the third 300µg injection at week 12, demonstrating the ability of UB-311 to elicit a strong immune response. Durability of the response was reflected in elevated anti-Aβ antibody titers measurable well beyond the 24-week duration of the trial.

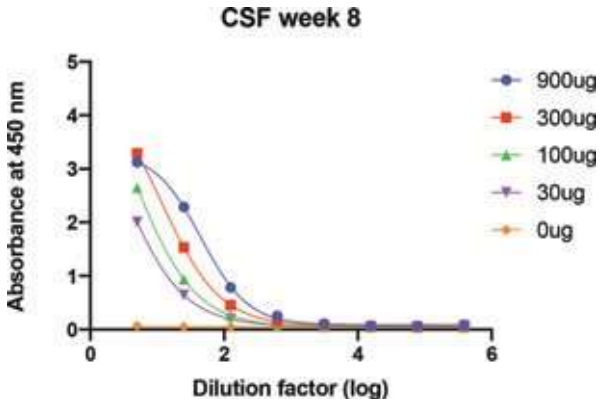
In a Western blot assay, we observed that UB-311 elicited antibody titers specific to toxic forms of Aβ with minimal binding to normal, non-plaque-causing, forms of Aβ.

Pre-Clinical Data

Pre-clinical trials of UB-311 included multiple antibody titer studies involving mice, guinea pigs, macaques and baboons. Application of specific transgenic animal models was intended to emulate both therapeutic and preventive treatment paradigms. These trials demonstrated that UB-311 generated high antibody titers across multiple species that selectively target aggregated Aβ and both slow the accumulation of and reduce existing Aβ pathology.

We also observed the ability of UB-311 induced antibodies to penetrate the BBB, as well as preferentially bind to toxic Aβ aggregates. In our study of UB-311 in cynomolgus monkeys, we tested five escalating dose levels of UB-311: 0µg, 30µg, 100µg, 300µg and 900µg. Each dose level was administered on weeks zero, three and six by intramuscular injection and the cerebrospinal fluid ("CSF"): serum ratio of UB-311 calculated on week eight (two weeks after the last dose). This analysis concluded that UB-311 antibody titers were detectable in the CSF in a dose-dependent manner with CSF: serum antibody ratios of 0.1% to 0.2%, ratios similar to published data for mAbs in development for neurodegenerative diseases.

UB-311 Shows Dependent Response in CSF in Pre-Clinical Study



The above graphs demonstrates that UB-311 induces enough antibodies for BBB penetration, across five dose levels in a pre-clinical study with cynomolgus monkeys.

Development Plans for UB-311

We have completed a pre-Phase 3 meeting with the FDA and obtained guidance on the further development of UB-311.

Subject to the FDA's review, we plan to conduct a randomized, double-blinded, placebo-controlled Phase 2b efficacy trial of UB-311 in approximately 900 subjects with early AD. The Phase 2b trial will include subjects diagnosed with early AD with MMSE scores between 22 and 30. We will also screen to enrich for positive amyloid PET, positive tau PET and positive plasma p-tau181, in quantities consistent with an early AD population. Subjects in the active arm will receive UB-311 as three 300μg priming doses at weeks 0, 4 and 12, followed by four 300μg booster doses every three months thereafter. The primary objective of this trial will be to assess the effect of UB-311 on the decline of cognitive and functional performance as measured by the CDR-SB over the 78-week treatment period. Secondary endpoints will include the changes from baseline measurements of other validated clinical outcomes scores. The effect of UB-311 on specific AD biomarkers will also be evaluated, including neurofilament light arm ("NfL"), p-tau, total-tau, brain amyloid as measured by PET, Aβ-40 and Aβ-42, hippocampal volume and whole brain volume as measured by MRI, and an assessment of certain CSF biomarkers. We plan to collaborate the development of UB-311 with a strategic partner and plan to initiate the Phase 2b trial in collaboration with such strategic partner.

Assuming positive results in the Phase 2b trial, we intend to initiate (with the same partner) a Phase 3 trial in subjects with early AD. The Phase 3 program may involve one, but more likely two, clinical trials, conducted at multiple international sites. Assuming positive results in the Phase 2b trial, we may also seek FDA approval under the accelerated approval pathway, which allows for earlier approval of drugs that treat serious conditions, and that fill an unmet medical need based on a surrogate endpoint. If such Phase 2b trial and the Phase 3 program are successful, they may together provide sufficient data to enable BLA filing with the FDA, but there can be no guarantee that these trials will lead to positive data or that we will not need to conduct additional trials or studies prior to a BLA filing with the FDA.

We believe UB-311 could also have a potential therapeutic benefit in a prophylactic setting for the prevention of AD in at-risk subjects. We may seek to further develop UB-311 for the prevention of AD.

UB-312

An Overview of Parkinson's Disease

Parkinson's disease currently affects approximately one million people in the United States and more than 10 million people worldwide. The economic burden of PD is estimated at $52 billion in the United States alone. PD is a chronic and progressive neurodegenerative disorder that affects predominately dopamine-producing ("dopaminergic") neurons in the substantia nigra area of the brain. Although the mechanisms responsible for the dopaminergic cell loss in PD are not fully elucidated, several lines of evidence suggest that α-synuclein plays a central role in the neurodegenerative process.

Alpha-synuclein is a protein highly expressed in neurons, mostly at presynaptic terminals, suggesting a role in synaptic vesicle trafficking, synaptic functions and in regulation of neurotransmitter release at the synapse. Duplications, point mutations or single nucleotide polymorphisms in the gene encoding α-synuclein are known to cause or increase the risk of developing PD or LBD. Mutations have been shown to primarily alter the secondary structure of α-synuclein, resulting in misfolded and aggregated forms of α-synuclein (i.e., pathological forms). While mutations in the α-synuclein gene are rare, aggregates of α-synuclein in the form of Lewy bodies ("LB") and Lewy neurites are common neuropathological hallmarks of both familial and sporadic PD, suggesting a key role of α-synuclein in PD neuropathogenesis. Moreover, preformed fibrils of α-synuclein can induce the formation of LB-like inclusions and cellular dysfunction in cell-based assays as well as in pre-clinical animal models. Together, these data strongly suggest that targeting pathological forms of α-synuclein has therapeutic potential.

Limitations of Current Therapies

Most approved therapeutic products are aimed at compensating for the dopaminergic deficits and only provide symptomatic relief. While existing products can indeed provide meaningful symptomatic relief, they often produce significant side effects and lose their beneficial effects overtime. On the other hand, there are no currently approved disease-modifying therapeutics for PD.

Immunotherapy approaches targeting α-synuclein have been shown to ameliorate α-synuclein pathology as well as functional deficits in mouse models of PD and are now being investigated in the clinic. These include passive immunization therapy using humanized or human anti-α-synuclein mAbs or active immunization therapy aimed at inducing a humoral response against pathological α-synuclein. These approaches have thus far demonstrated good tolerability profiles in Phase 1 clinical trials. A Phase 2 clinical trial in PD subjects with prasinezumab, a mAb that preferentially recognizes oligomeric and fibrillar forms of α-synuclein, suggested reduced motor function decline in subjects as compared with placebo; however, this Phase 2 trial did not meet its primary or secondary endpoints. Further trials of prasinezumab in different patient populations remain ongoing. Even if approved as therapeutic for PD, we expect prasinezumab would be burdened by the general challenges of cost and administration.

Our Product Candidate: UB-312

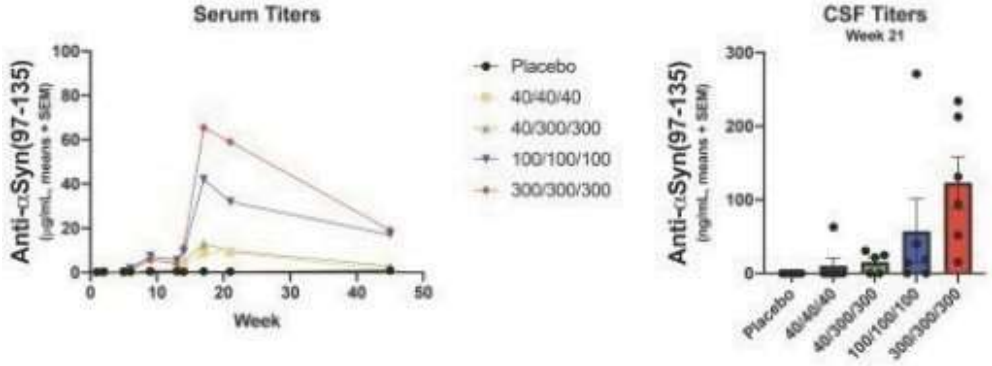
We are developing UB-312, an anti-α-synuclein product candidate, as a treatment for PD and other synucleinopathies. We believe that UB-312 has the potential to be established as a disease-modifying treatment modality for PD, and possibly for LBD and MSA. Pre-clinical data indicated that UB-312 elicits antibodies that preferentially recognize pathological forms of a-synuclein and improves motor performance in mouse models of α-synucleinopathies. Preliminary clinical data from our ongoing Phase 1 trial indicate that UB-312 elicits antibody levels sufficient to cross the BBB (i.e., detectable in CSF). In 2018, the European Medical Agency ("EMA") granted UB-312 orphan designation for MSA.

Clinical Development

We have completed Part A of a randomized, placebo-controlled, double-blind, dose-escalating, single- center Phase 1 clinical trial of UB-312 in which 50 healthy volunteers between the ages of 40 and 85 years received three intramuscular doses of either UB-312 or placebo. During this 44-week Part A trial, subjects received three doses (on weeks 1, 5 and 13) with escalating doses ranging from 40μg to 2,000μg. Immunogenicity was evaluated by measuring changes in serum anti-α-synuclein antibody concentrations during the course of the study. Data from Part A indicated that UB-312 is generally well tolerated, with no significant safety findings. Data from Part A also suggested that UB-312 is highly immunogenic, with all individuals in the 300μg/dose group showing detectable anti-α-synuclein antibodies in both serum and CSF samples. CSF: serum ratios appeared similar to those observed in UB-311 non-human primate studies (approximately 0.2%), and to those observed in clinical trials of mAbs. Based on these results, we are now evaluating two dosing regimens of UB-312 in Part B of the Phase 1 trial: three doses of 300μg, and one dose of 300μg followed by two doses of 100μg. Part B, which began enrollment in January 2022, is evaluating UB-312 and placebo in 20 PD subjects. In addition to the endpoints evaluated in Part A, an exploratory endpoint involving a clinical assessment using the Movement Disorder Society – Unified Parkinson's Disease Response Score will be used.

The Michael J. Fox Foundation ("MJFF") is funding a 2-year collaborative project between Vaxxinity, the Mayo Clinic, and University of Texas Houston using CSF collected from individuals enrolled in Part B of the Phase 1 trial of UB-312. This work is evaluating the potential of protein misfolding cyclic amplification ("PMCA") to assess target engagement and will also aim to characterize the anti-α-synuclein antibodies produced after immunization with UB-312. Demonstrating whether pathological forms of α-synuclein are detectable in the CSF of PD subjects, and whether UB-312-derived antibodies alter CSF levels of α-synuclein seeds measured by PMCA, might provide a meaningful surrogate marker of target engagement.

UB-312 Demonstrated Dose-Dependent Response in Phase 1 Part A Trial Including Penetration of Titers into CSF



Across four cohorts, UB-312 demonstrated a dose-dependent immunogenic response. Antibodies generated by UB-312 were readily detectable in CSF, indicating BBB penetration with a CSF: serum ratio of approximately 0.2%.

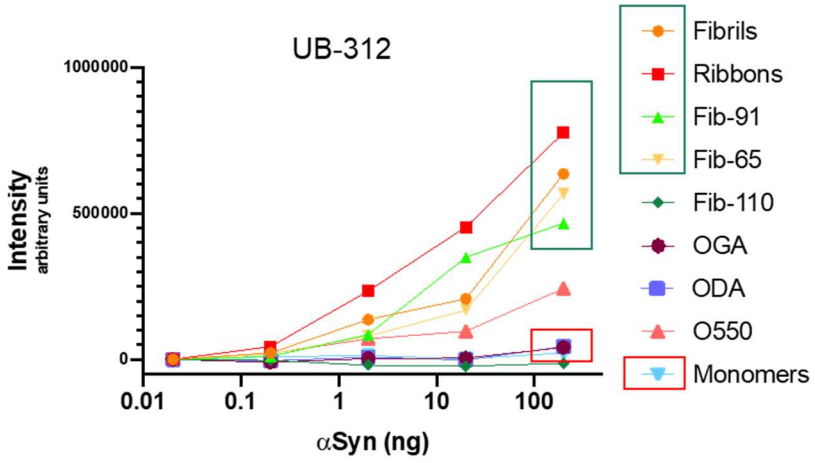
We paused dosing in high dose cohorts in Part A of the trial after one subject developed an adverse effect ("AE") of special interest (i.e., Grade 3 flu-like symptoms) shortly after receiving the second 1000μg dose of UB-312. Although this AE was transient and not a serious adverse event ("SAE"), data collected until that point suggested that the 100μg and 300μg dose levels were well tolerated and yielded relatively high anti-α- synuclein titers. During the evaluation of the AE, the COVID-19 pandemic was becoming increasingly pervasive throughout Europe, increasing the risk to healthy volunteers participating in the trial. We therefore did not resume dose escalation and selected 100μg and 300μg doses for Part B in PD subjects.

An end-of-treatment analysis of the ongoing Part B of the Phase 1 trial in PD patients was completed in the fourth quarter of 2022. This analysis has shown UB-312 to be well tolerated and immunogenic, with anti-α-synuclein antibodies observed in the serum and CSF of PD patients. Three serious adverse events were observed in Part B, which remains blinded, meaning it remains unknown in which treatment group they occurred (UB-312 or placebo).

Pre-Clinical Data

We have conducted pre-clinical studies of UB-312 across multiple animal species, including mice and guinea pigs. These trials demonstrated that our product candidates, including UB-312, generated high antibody titers to α-synuclein across animal species. In addition, in vitro studies provided evidence that anti-α-synuclein antibodies produced after UB-312 immunization are highly selective to pathological α-synuclein, and do not bind to normal α-synuclein.

UB-312 Demonstrates Selective Binding Towards α-Synuclein Fibrils and Ribbons

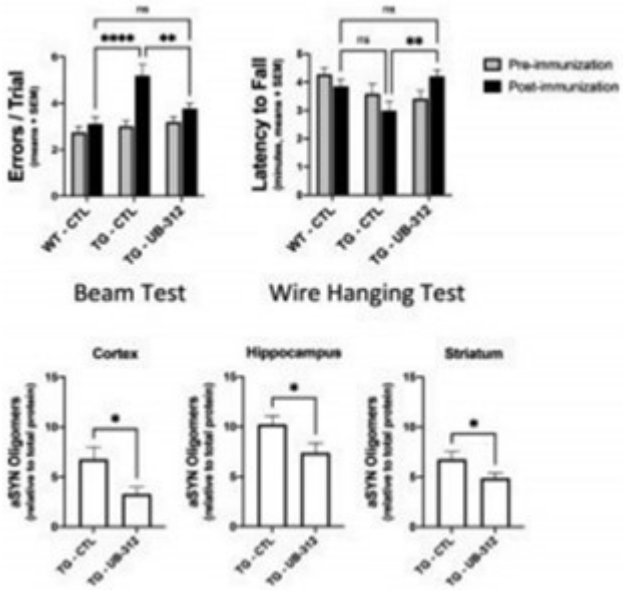


This in vitro slot blot analysis of sera from guinea pigs dosed with UB-312 demonstrates that antibodies induced by UB-312 bind to α-synuclein fibrils and ribbons, the toxic forms of α-synuclein believed to underlie PD, more strongly than they bind to monomers, the normal form of α-synuclein in the body. We believe this preference will allow UB-312 antibodies to avoid altering normal functions of α-synuclein and selectively neutralize the toxic species (Nimmo et al., Alzheimers Res Ther. 2020;12:159).

Anti-α-synuclein antibodies produced by UB-312 immunization specifically bind pathogenic species of α-synuclein, including aggregated fibrils, oligomers and ribbons, while demonstrating low affinity for the monomer. This species selectivity contrasted with Syn-1, a commercial research mAb used as a control, which failed to differentiate the toxic variants.

In an in vivo study of UB-312 using a transgenic mouse model of PD, we demonstrated prevention of motor deficits in treated animals, which was associated with significant reduction of brain oligomeric forms of α- synuclein. We believe this data supports the potential of UB-312 to prevent behavioral motor deficits and reduce toxic forms of α-synuclein.

UB-312 Demonstrates Improvement in Motor Symptoms in Pre-Clinical Study



UB-312 immunization in a transgenic mouse model (α-synuclein overexpression) demonstrates improvement in beam test and wire hanging test, and reductions in α-synuclein oligomers in various brain regions (Nimmo et al., Acta Neuropathol. 2022;143:55-73).

We have also observed by immunohistochemistry that serum antibodies from guinea pigs dosed with UB-312 can bind to aberrant α-synuclein in PD, LBD and MSA brain sections.

Finally, antibodies derived from UB-312 showed no off-target binding on human tissue sections. UB-312-treated transgenic mice showed no signs of neuroinflammation, and GLP toxicity studies in rats indicated a good non-clinical safety and tolerability profile. We believe our preclinical data suggest that UB-312 may potentially induce a well-tolerated, strong and specific IgG response against pathological forms of a-synuclein in PD subjects.

Development Strategy

While certain portions of this Phase 1 trial were interrupted by the COVID-19 pandemic, Part A in 50 healthy volunteers was completed in 2020, and we began dosing PD subjects in Part B in early 2022. In Part B we have included exploratory endpoints potentially relevant to PD, such as total and free α-synuclein in serum and CSF, in addition to T-cell ELISpot analyses and antibody characterization. We expect to complete Part B in mid-2023.

Other Neurodegeneration Programs

We are actively engaged in additional initiatives related to neurodegenerative disorders. One of these programs focuses specifically on tau-protein pathology and its involvement in diseases such as AD and related tauopathies. We believe that targeting different pathological tau variants simultaneously may enhance treatment efficacy, which will most likely require targeting multiple epitopes concomitantly. Using our Vaxxine Platform, we have constructed multi-epitope product candidates that have successfully demonstrated immunogenicity and in vitro activity in various models.

We are also investigating the use of a multi-target of product candidates targeting Aβ, α-synuclein, and tau, as multiple proteins could be implicated in neurodegenerative diseases.

Next Wave Chronic Disease Treatments

Pathological endogenous proteins ("self-proteins") drive a wide range of chronic diseases. While mAbs and small molecules have provided therapeutic benefits in the treatment of these diseases, inherent limitations of these drug classes have restricted access and adherence to these treatment modalities globally.

Our next wave chronic disease program is initially focused on migraine and hypercholesterolemia. Monoclonal antibodies have been approved in both therapeutic areas; however, their high costs have limited access and generally limited use to relatively severe disease. We aim to develop product candidates in these therapeutic areas that could offer similar efficacy as mAbs at a meaningfully lower cost and improved administrative convenience to patients, thereby potentially allowing for access to broader patient populations versus mAbs, and greater efficacy than small molecules.

UB-313

An Overview of Migraine

Migraine is a chronic and debilitating disorder characterized by recurrent attacks lasting four to 72 hours with multiple symptoms, including typically one-sided, pulsating headaches of moderate to severe pain intensity that are associated with nausea or vomiting, sensitivity to sound and sensitivity to light. Over 90% of the patients are unable to function normally during a migraine attack. Many experience comorbid conditions such as depression, anxiety and insomnia.

The Migraine Research Foundation ranks migraine as the world's third most prevalent illness. The disease affects 39 million individuals in the United States and approximately one billion individuals globally. Patients generally suffer from chronic or episodic migraines. Chronic migraine is defined as 15 headache days or more per month, while episodic migraine is defined as fewer than 15 headache days per month. Both acute and prophylactic treatments are used to address chronic and episodic migraines.

CGRP's Role in Migraine

CGRP is a neuropeptide found throughout the body, including in the spinal cord. CGRP activates CGRP receptor in the trigeminovascular system, which is located within pain-signaling pathways, intracranial arteries and mast cells. Activation of the CGRP receptor has been demonstrated to induce migraine in migraineurs. Multiple anti-CGRP therapies have been approved for the treatment of migraine.

Limitations of Current Therapies

Since the early 1990s, there has been minimal improvement in the standard treatment for migraine. Treatments are characterized as elite acute or prophylactic. Triptans are the current first-line prescription therapy for the acute treatment of migraine, with over 15 million annual prescriptions written in the United States.

Prophylactic medications approved for migraine include beta blockers, such as propranolol, topiramate, sodium valproate and botulinum toxin, branded as Botox. However, many of these medications provide limited clinical benefit. In addition, they are often not well tolerated, with AEs such as cognitive impairment, nausea, fatigue and sleep disturbance.

Therapeutics targeting the CGRP pathway represent an emerging treatment paradigm. Three anti-CGRP mAbs were approved by the FDA in 2018 for the prophylactic treatment of migraine in adults. These mAbs, erenumab-aooe (Aimovig), fremanezumab-vfrm (Ajovy) and galcanezumab-gnlm (Emgality), are all administered subcutaneously. Their side effects are generally mild, including pain and redness at the site of injection, nasal congestion and constipation. Studies show that these mAbs reduce the number of headache days by 50% or more in approximately 50% of patients. Sales for marketed and clinical-stage anti-CGRP therapeutics are projected to reach approximately $7.4 billion by 2026. Despite the commercial success that this class represents, many of these treatments require frequent administration, creating inconvenience for patients.

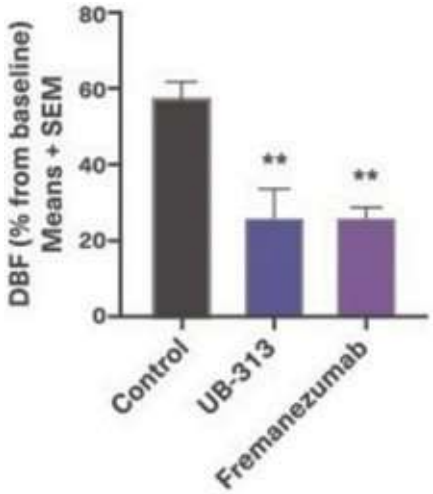
Our Product Candidate: UB-313

We are developing UB-313 as a prophylactic treatment initially for chronic migraine. We believe UB-313 has the potential to improve upon the current treatments for chronic migraine in multiple aspects: we expect UB-313 will require administration quarterly to annually in contrast to monthly to quarterly for currently marketed mAbs and frequent administration for small molecules. Furthermore, a potential long durability of response may offer physicians and patients the option to administer UB-313 in an office setting, which can potentially improve adherence. We expect the cost of UB-313 treatment, if approved, to be lower than that of mAbs for migraine.

Pre-Clinical Studies

We have completed both in vitro and in vivo pre-clinical studies of UB-313. We used an in vivo proof-of-concept capsaicin-induced dermal blood flow model in mice to demonstrate target engagement of the marketed CGRP-targeting mAbs. In this model, we observed similar rates in reduction of dermal blood flow as fremanezumab in a head-to-head comparison against fremanezumab.

UB-313 Reduces Capsaicin-Induced Dermal Blood Flow in Mice



***Dunnett's: Ctl vs Vac 1p < 0.05; Ctl vs Vac 2 p < 0.05*

In this preliminary study, dermal blood flow measurements were taken 17 weeks following the first dose of UB-313. There were 3 to 11 animals per treatment group. Reduced dermal blood flow indicates target engagement with CGRP. UB-313 reduced dermal blood flow versus the control with an approximately similar magnitude to fremanezumab, which was administered 24 hours prior to the capsaicin test.

We observed similar results in a capsaicin / dermal blood flow model in rats, comparing a rat version of UB-313 head-to-head against galcanezumab.

Our *in vivo* studies of UB-313 have involved multiple animal species. High immunogenicity was observed in all pre-clinical species tested. Characterization of the antibodies produced after immunization with UB-313 indicated that they have limited, if any, off-target potential, are primarily IgG1 and IgG2, potently bind to CGRP and potently block CGRP activity *in vitro*. We refer to potency as the amount of drug required to produce a pharmacological effect of given intensity and is not a measure of therapeutic efficacy. In a comparison of binding affinities with fremanezumab and galcanezumab, UB-313-induced IgG antibodies demonstrated comparable binding affinities.

UB-313 Demonstrated Induced Antibodies Comparable to Approved CGRP mAbs

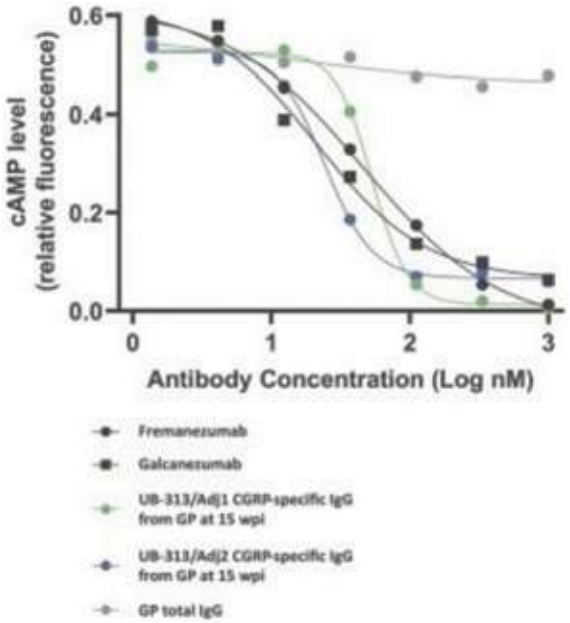
	Kon (10^6 $M^{-1}s^{-1}$)	Koff (10^{-6} s^{-1})	KD (pM)	Fold	Published KD (pM)
UB-313-Adj.2*	3.7	42	**11**	2.3	N/A
UB-313-Adj.1*	5.6	62	**11**	2.3	N/A
Fremanezumab^	0.36	1.7	**4.8**	1	2
Galcanezumab^	1.0	11	**11**	2.2	31

*CGRP-specific IgG purified from GP sera at 15 weeks after first dose
^old lot; reported values from 1-2 experiments

We evaluated UB-313 formulations with two different adjuvants in comparison to fremanezumab and galcanezumab; both formulations demonstrated comparable IgG to these two approved CGRP mAbs.

Additional *in vitro* studies using human SK-N-MC cells demonstrated that UB-313-induced IgG antibodies also had comparable *in vitro* activity to CGRP-targeted mAbs.

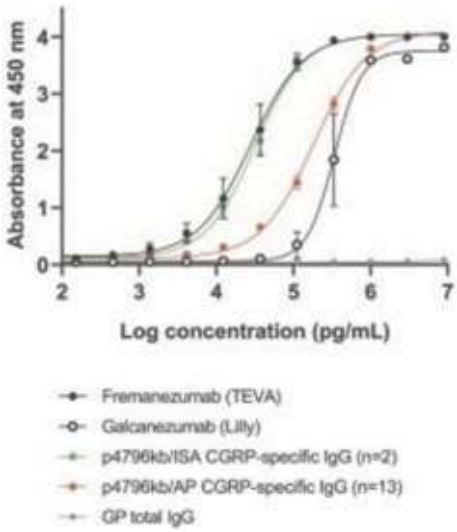
UB-313 Induced IgGs Have Comparable In Vitro Activities to Marketed CGRP mAbs



In a cyclic AMP ("cAMP") production assay conducted in human SK-N-MC cells, antibodies taken from the serum of guinea pigs 15 weeks following the first injection of UB-313 demonstrated similar properties to two approved CGRP mAbs.

Moreover, the binding potency of UB-313 was determined to be comparable to these mAbs.

UB-313 Induced IgGs Demonstrate Comparable Binding Potencies to Marketed CGRP mAbs



Antibodies taken from the serum of guinea pigs 15 weeks following the first injection of UB-313 demonstrated similar binding potencies to two approved CGRP mAbs as measured by ELISA.

Development Strategy

A single-site, randomized, placebo-controlled, first-in-human Phase 1 clinical trial is underway in 40 healthy volunteers, designed to measure the safety, tolerability, and immunogenicity of multiple priming dose regimens of UB-313, was initiated in September 2022. The study is also measuring dermal blood flow following a capsaicin challenge at multiple timepoints, a well-established model for CGRP target engagement and efficacy in the preventive treatment of migraine. The trial is fully enrolled, and we expect a topline readout in the first half of 2023.

VXX-401

An Overview of Hypercholesterolemia

Hypercholesterolemia is the presence of high levels of cholesterol in the blood and typically results from a combination of environmental and genetic factors. Cholesterol is transported in the blood plasma within particles called lipoproteins. Lipoproteins are classified by their density: very low-density lipoprotein, intermediate density lipoprotein, LDL and high-density lipoprotein ("HDL"). All lipoproteins carry cholesterol, but elevated levels of lipoproteins other than HDL, particularly LDL, are associated with the development of cardiovascular disease. Approximately 2 billion people worldwide have elevated levels of LDL, potentially putting them at risk for cardiovascular disease.

Although hypercholesterolemia itself is asymptomatic, elevation of serum cholesterol can over time lead to atherosclerosis. Over many years, elevated serum cholesterol contributes to formation of atheromatous plaques in the arteries. These plaque deposits can in turn lead to progressive narrowing of the involved arteries. Smaller plaques may rupture and cause a clot to form and obstruct blood flow. A sudden blockage of a coronary artery may result in a heart attack. A blockage of an artery supplying the brain can cause a stroke. If the development of the stenosis or occlusion is gradual, blood supply to the tissues and organs slowly diminishes until organ function becomes impaired.

PCSK9 is mainly expressed in the liver and, to a lesser extent, in the small intestine, kidney, pancreas and the CNS. The LDL receptors ("LDLR") at the cell surface bind and initiate ingestion of LDL particles from extracellular fluid into cells, leading to a reduction in serum LDL levels. PCSK9 protein plays a major regulatory role in cholesterol homeostasis, mainly by reducing LDLR levels on the plasma membrane, which leads to decreased metabolism of LDL by the cells. Inhibition of PCSK9 prevents this reduction in LDLR levels on the plasma membrane, and in consequence the cellular process of internalizing LDL particles, resulting in a reduction of LDL.

Limitations of Current Therapies

Statins are the most commonly used drugs to treat hypercholesterolemia and result in a pronounced reduction in LDL. The unambiguous benefits of statins, together with the prevalence of coronary heart disease, have made statins the most highly prescribed drug class in developed countries. However, many patients are unable to achieve targeted lipid levels despite intensive statin therapy. In addition, continued patient adherence to statin therapy, which is necessary to maintain a lower risk for cardiac events, is variable but considered to be low – as low as 30% to 40% after two years in persons following a myocardial infarction. Importantly, at the transcriptional level,

statins up-regulate not only LDLR, but also PCSK9, causing the so-called paradox of statin treatment. Although statins induce a beneficial increase in LDLR, they also increase PCSK9, thus leading to LDLR degradation, which indirectly increases LDL, mitigating the overall LDL reduction that statins otherwise cause. Given the limitations in efficacy and adherence, targeting PCSK9 in combination with statins treatment is an emerging treatment paradigm for hypercholesterolemia.

Two mAbs that inhibit activity have received FDA approval, alirocumab (Praluent) and evolocumab (Repatha). These drugs were initially approved to treat the genetic condition heterozygous familial hypercholesterolemia, although the approved indications were expanded after the publication of studies demonstrating that the use of a PCSK9 inhibitor in conjunction with a statin significantly reduced the risk for major cardiovascular events, including heart attack, stroke, unstable angina requiring hospitalization or death from coronary heart disease. In addition, inclisiran (Leqvio), an siRNA inhibitor of PCSK9 synthesis, was approved by the EMA in late 2020 for the treatment of heterozygous familial hypercholesterolemia in addition to other dyslipidemia.

While alirocumab and evolucumab have demonstrated clinical benefit, their commercial potential has been limited by their pricing. Both launched with a wholesale acquisition price exceeding $14,000 annually, but prices for both were subsequently reduced in 2018. Nevertheless, this drug class generated sales of approximately $1.3 billion in 2020 and is expected to grow to approximately $5.2 billion by 2026, including the addition of inclisiran to the market. In addition, both are administered bi-weekly (evolocumab also allows for the option of taking a higher dose monthly), which represents what we believe to be a frequent and inconvenient administration schedule for patients. While inclisiran represents an improved administration schedule compared to alirocumab and evolucumab, as it must be administered twice annually, we believe that it may encounter similar pricing challenges due to the published cost effectiveness price.

Our Product Candidate: VXX-401

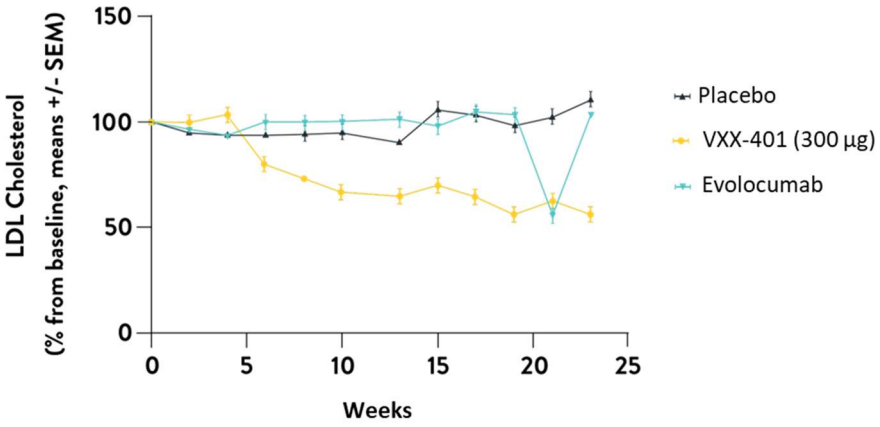
We are developing VXX-401, an anti-PCSK9 product candidate to treat hypercholesterolemia. We are dedicated to developing a product candidate that has long-acting treatment duration, which we believe will offer a more convenient treatment regimen compared to the up to bi-weekly dosing required by some mAbs. We believe that lower manufacturing costs commensurate with the requirement of meaningfully less drug substance relative to mAbs, coupled with our ability to achieve commercial scale production rapidly may promote expanded use of this drug class as a first-line therapy, allowing for treating a greater number of hypercholesterolemia patients than currently treated with mAbs.

Pre-Clinical Studies

In August 2022 we announced the selection of VXX-401 as our lead anti-PCSK9 vaccine candidate. In pre-clinical studies, VXX-401 generated therapeutic titer levels of anti-PCSK9 antibodies, a high response rate among dosed animals, and robust reduction in LDL across multiple species.

In two studies of VXX-401 in cynomolgus monkeys, VXX-401 reduced LDL-c by up to 54%, an effect sustained for a long duration. In the first study, 3 monkeys received six 300µg IM injections of VXX-401, and 6 monkeys started on placebo with the same schedule. At week 19 (final dose), 3 of the 6 placebo monkeys were given 3mg/kg evolocumab to determine the comparability of the magnitude of LDL reduction with VXX-401. LDL in monkeys treated with evolocumab reduced to approximately the level of those treated with VXX-401, then returned to near-baseline, while LDL levels in the VXX-401-treated group remained low.

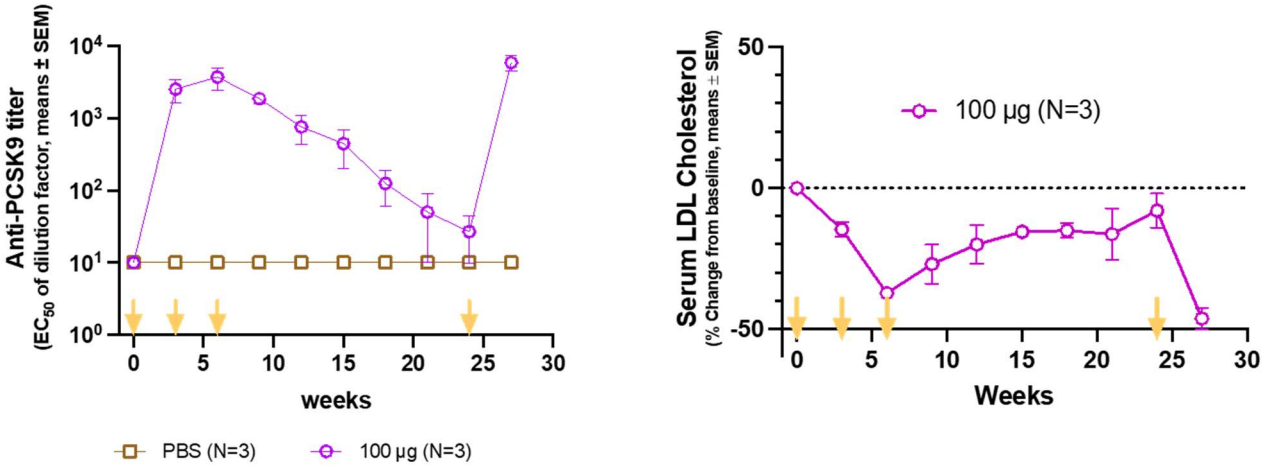
VXX-401 Reduces LDL up to 54% vs. Placebo, Comparable to a Single Dose of an Approved MAb



The VXX-401 group (n=3) received a non-optimized vaccine formulation containing the same peptide immunogen as the VXX-401 clinical vaccine candidate and experienced up to a 54% reduction in serum LDL-c from baseline. The placebo and VXX-401 groups received IM injections at weeks 0, 3, 6, 13, 16, and 19. The evolocumab group received placebo IM injections at weeks 0, 3, 6, 13, and 16, and a dose of evolocumab at week 19.

In the second study we explored a range of doses in 15 cynomolgus monkeys, which received either 0, 10, 30, 100, 300, or 900µg/dose by 0.5mL IM injection at weeks 0, 3, and 6, with follow-up through week 24. In this study we found that three doses of VXX-401 could product a sustained reduction of serum LDL, returning to near-baseline after 24 weeks. Furthermore, animals received a booster dose of VXX-401 at week 24, which triggered a rapid anti-PCSK9 antibody response and a corresponding reduction in serum LDL.

Reduction in LDL Correlates with Anti-PCSK9 Antibodies Elicited by VXX-401



The left-hand panel shows the generation of serum anti-PCSK9 antibody titers in cynomolgus monkeys treated with 100µg VXX-401 at weeks 0, 3, 6, and 24 as measured by EIA. These levels correlate with serum LDL level over time, as depicted in the right-hand panel, represented as a difference from controls. An adjuvant control group (n=3, not shown), was also included in the study; animals in the adjuvant group did not produce an anti-PCSK9 antibody response, similar to the PBS control group.

A GLP toxicology study was completed in monkeys, which demonstrated that 5 doses of VXX-401 were safe and well tolerated, with no clinical observations and no pathological findings. Importantly, we found that LDL reduction in VXX-401-treated monkeys in this study was consistent with observations from preclinical efficacy studies, and supportive of moving VXX-401 into clinical trials.

Development Strategy

We have initiated a first-in-human Phase 1 clinical trial of VXX-401 in Australia in the first quarter of 2023. In this trial we aim to evaluate 48 subjects with elevated cholesterol, monitoring for safety, immunogenicity, and relevant biomarkers. We expect a topline readout by early 2024. In a potential subsequent Phase 2 trial we may test VXX-401 alone and in combination with statins.

Next Stage Development Candidates

In addition to our initial focus on migraines and hypercholesterolemia, we believe our Vaxxine Platform can generate product candidates for a range of chronic diseases. We are evaluating opportunities across multiple disease areas, including allergy (e.g., atopic dermatitis, chronic rhinosinusitis, food allergy), autoimmune (e.g., psoriasis, psoriatic arthritis), pain (e.g., peripheral neuropathy, diabetic neuropathy) and bone and muscle deterioration (e.g., sarcopenia, osteoporosis, osteopenia) indications as they may apply to geriatrics and space travel health.

COVID-19 Program

An Overview of COVID-19

COVID-19, caused by SARS-CoV-2, has rapidly swept throughout the world. The World Health Organization ("WHO") declared COVID-19 a public health emergency of international concern. As of January 2023, there have been more than 694 million confirmed COVID-19 cases and more than 6.7 million deaths worldwide. Common symptoms of COVID-19 are fever, cough, lymphocytopenia and chest radiographic abnormality. A proportion of patients recovering from COVID-19 continue shedding virus for days, and asymptomatic carriers may also transmit SARS-CoV-2, indicating a risk of a continuous and long-term pandemic.

SARS-CoV-2 is an enveloped, single-stranded, positive-sense RNA virus belonging to the family *Coronavidae* within the genus β-coronavirus. The genome of SARS-CoV-2 encodes one large Spike ("S") protein that plays a pivotal role during viral attachment to the host receptor, angiotensin converting enzyme 2 ("ACE2"), and entry into host cells. The S protein is the major principal antigen target for vaccines against human coronavirus, including SARS-Co-V-2. Neutralizing antibodies targeting the receptor binding domain ("RBD") subunit of the S protein block the virus from binding to host cells. Over 90% of all neutralizing antibodies produced in response to infection are directed to the RBD subunit, and mAbs that have shown therapeutic activity target epitopes on the RBD.

Fifty vaccines are authorized for use in one or more countries around the world. Most of these vaccines are based on the S protein of the SARS-CoV-2, but rely on different mechanisms for presentation or expression of the S antigen, including whole inactivated virus, defective adenovirus vectors, or mRNA. All have been shown to be safe and effective in placebo- controlled clinical trials. Antiviral drugs and mAbs have limited availability and effectiveness.

COVID-19 Vaccine Market

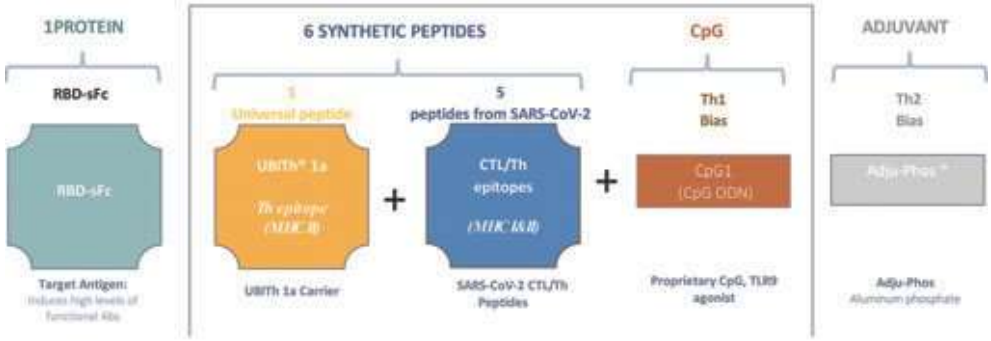
As of January 2023, over five billion people have been fully vaccinated against COVID-19. Nearly all of these people received at least one of three types of vaccine technologies: mRNA, adenovirus vector, or inactivated virus. As SARS-CoV-2 continues to evolve and spread, the market for booster vaccinations has also grown, with over 2.6 billion doses sold to date.

We expect demand for booster vaccinations that are safe and well tolerated, offer long lasting immunity against emerging variants, and allow for manageable storage and shipping conditions will last for the foreseeable future, particularly in low- and middle-income countries ("LMICs"). We also anticipate demand for more types of vaccine technologies, beyond the readily available mRNA, adenovirus vector, and inactivated virus vaccine options.

UB-612: Our COVID-19 Vaccine Initiative

We are developing UB-612 as a product candidate for boosting immunity to COVID-19 in vaccinated individuals. UB-612 is designed to activate both antibody and cellular immunity against multiple viral targets. The vaccine is composed of a recombinant S1-RBD-sFc fusion protein combined with rationally designed synthetic Th and CTL epitope peptides selected from the S2 domain of the spike, membrane ("M"), and nucleocapsid ("N") proteins. These peptides bind to MHC class I and II receptors without significant genetic restriction, so that they may be recognized broadly by the vast majority of the human population. Our mixture of peptides is designed to elicit T-cell activation, memory recall and effector functions similar to those of natural SARS-CoV-2 infection. The S1-RBD-sFc fusion protein incorporates essential B-cell epitopes that promote the generation of neutralizing antibodies to the RBD of SARS-CoV-2. UB-612 is formulated with Adju-Phos, an adjuvant widely used in many approved vaccines globally. For added safety, synthetic peptides in UB-612 are adsorbed by our propriety CpG1 excipient, a Toll-like receptor 9 agonist molecule, known to help to stimulate balanced T-cell immunity in humans. UB-612 can be stored and shipped at 2° to 8°C (conventional cold chain refrigerated temperatures). An EUA application for UB-612 was denied by the TFDA in August 2021 because the neutralizing antibody response generated by UB-612 delivered in an accelerated two-dose primary immunization schedule, as compared to that of a designated adenovirus vectored vaccine, did not meet the TFDA's specified evaluation criteria. We are now pursuing a path to authorization for UB-612 as a heterologous boost and have agreement with two high-income country regulators about our development approach.

Components of the UB-612 Multitope Vaccine Product Candidate



UB-612's construct contains an S1-RBD-sFc fusion protein for its B-cell epitopes, plus five synthetic Th/CTL peptides for class I and II MHC molecules derived from SARS-CoV-2 S2, M and N proteins, and the UBITh1a peptide. These components are formulated with CpG1, which binds the positively charged peptides by dipolar interactions and also serves as an adjuvant, which is then bound to Adju-Phos adjuvant to constitute the UB-612 product candidate.

Clinical Development

In March 2022, Vaxxinity initiated a Phase 3 pivotal trial to compare the immune responses stimulated by homologous boosts mRNA (BNT162b2), adenovirus (ChAdOx1-S), inactivated virus (Sinopharm BIBP) COVID-19 vaccines, to a heterologous boost of UB-612. This is an active-controlled, randomized trial being conducted in the United States, Panama, and Philippines under a platform protocol in 944 subjects 16 years and older who completed a two-dose primary immunization with one or more of the comparator vaccines mentioned above. Eligible subjects have been randomized into one of two treatment arms to receive a single dose of UB-612 or an active comparator. The primary objective of the study is to determine non-inferiority of UB-612-stimulated neutralizing antibodies against those of the comparator vaccines. CEPI is co-funding this trial, which is expected to conclude in the second half of 2023.

Following positive topline results announced in December 2022, we have completed submissions for conditional/provisional authorization with the Medicines and Healthcare products Regulatory Agency ("MHRA") in the UK, and the Therapeutic Goods Administration ("TGA") in Australia in March 2023. We expect that, if successful, these authorizations may enable the commercialization of UB-612 in multiple countries including select LMICs.

Heterologous Booster Data: Phase 3 Trial Topline Results

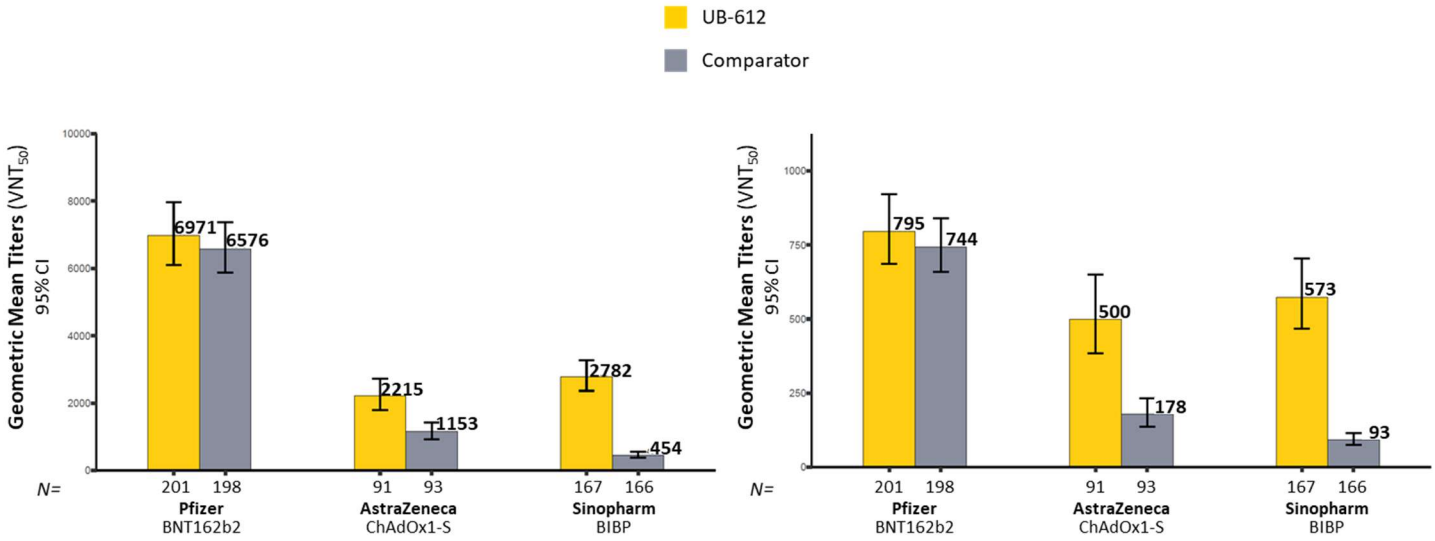
In the ongoing global pivotal Phase 3 trial, UB-612 elicited strong neutralizing antibodies against SARS-CoV-2 when compared head-to-head to three globally authorized platform vaccines administered as homologous boosters, successfully meeting primary and key secondary immunogenicity endpoints at topline readout. The primary endpoints of the trial are safety and live virus neutralizing antibody titers against the Wuhan strain of SARS-CoV-2 at day 29. Secondary immunogenicity endpoints include neutralizing antibody titers against Omicron BA.5 at day 29, SCRs at day 29, and kinetics of neutralizing and RBD binding IgG antibody responses through 12 months. The primary objective of the study is to determine non-inferiority of UB-612-stimulated neutralizing antibodies against those of the comparator vaccines, where statistical non-inferiority is defined by the lower bound of the 95% confidence interval ("CI") of the geometric mean titer ratio ("GMR") > 0.67. When delivered as a heterologous booster in populations previously vaccinated with Pfizer-BioNTech's BNT162b2, AstraZeneca's ChAdOx1-S, or Sinopharm's BIBP, UB-612 was shown to generate neutralizing antibody titers 28 days after administration that were:

- Statistically non-inferior to, and directionally higher than, BNT162b2: 1.04 GMR against Wuhan (95% CI: 0.89, 1.21; p=0.6147), 1.11 GMR against Omicron BA.5 (95% CI: 0.94, 1.31; p=0.2171)

- Statistically superior to ChAdOx1-S: 1.92-fold higher geometric mean titers against Wuhan with UB-612 (GMR=1.92; 95% CI: 1.44, 2.56; p<0.0001), 2.85-fold higher against Omicron BA.5 (GMR=2.85; 95% CI: 2.00, 4.05; p<0.0001)

- Statistically superior to BIBP: 5.77-fold higher geometric mean titers against Wuhan with UB-612 (GMR=5.77; 95% CI: 4.62, 7.20; p<0.0001), 5.93-fold higher against Omicron BA.5 (GMR=5.93; 95% CI: 4.60, 7.65; p<0.0001)

Neutralizing Antibodies Against Wuhan (left panel) and Omicron BA.5 (right panel) at Day 29



The above results from a live virus neutralization assay at day 29 suggests that the immune response of UB-612 as a heterologous boost is non-inferior to that of BNT162b2 as a homologous boost, superior to ChAdOx1-S, and superior to BIBP. The relative performance of UB-612 versus the comparators against Omicron BA.5 is better than that against Wuhan.

SCR as measured against Wuhan and Omicron BA.5 are key secondary endpoints in the Phase 3 trial. Seroconversion was defined as a ≥4-fold increase of neutralizing antibody titers from baseline. SCR non-inferiority was defined by the lower bound of the 95% CI for the difference of the UB-612 SCR minus the comparator SCR > -10%. SCR superiority was defined by the lower bound of the 95% CI for the difference of the UB-612 SCR minus the comparator SCR > 0%. UB-612 SCR at day 29 was statistically non-inferior to, and directionally higher than, BNT162b2 against both Wuhan and Omicron BA.5, statistically superior to ChAdOx1-S with 1.9-fold higher SCR against Wuhan (23.6% absolute difference, p=0.0009) and 2.0-fold higher SCR against Omicron BA.5 (29.2% absolute difference, p<0.0001), and statistically superior to BIBP, with 8.3-fold higher SCR against Wuhan (56.8% absolute difference, p<0.0001) and 5.8-fold higher SCR against Omicron BA.5 (58.0% absolute difference, p<0.0001).

Preliminary safety data from the Phase 3 trial shows that UB-612 continues to be generally well tolerated; no serious adverse reactions were reported. The trial remains ongoing, and the long term safety profile continues to be evaluated. The trial is expected to conclude in the second half of 2023.

2-Dose Clinical Data

In early 2021, we completed an open-label dose escalation Phase 1 clinical trial to evaluate the safety, tolerability and immunogenicity of UB-612 in healthy volunteers between the ages of 20 and 55 in Taiwan. This six-month trial consisted of three 20-subject cohorts, each receiving an initial dose at the start of the trial and a second dose on day 28: one cohort received two 10μg doses, the second received two 30μg doses, and the third received two 100μg doses. The mean titer of antigen-specific antibodies to UB-612 and the seroconversion rate was evaluated throughout the duration of the trial to determine the humoral immune response and persistence of immunogenicity. In addition, T-cell responses were evaluated by interferon-γ ELISpot assay and intracellular cytokine staining by flow cytometry. The Phase 1 clinical trial was sponsored by UBIA. UBIA conducted the trial on our behalf in accordance with one of our related party master services agreements.

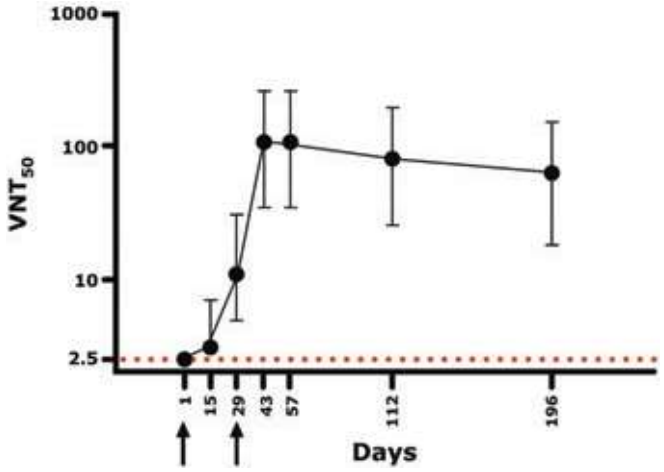
After one and two doses, UB-612 was considered to be generally safe and well tolerated, with a low frequency of solicited and unsolicited AEs, which were all Grade 1 (mild) in severity. After each vaccination, the most common AE was injection site pain, with no clear difference in reactogenicity between dose levels. In all dose groups, there was a trend towards increased reactogenicity with increase in dose. Three cases of mild allergic reactions were reported (e.g., itching at vaccine site), which were all resolved within 1-3 days. Importantly, and in distinction to certain vaccines authorized for emergency use, no other increase in AEs was seen at second dose as compared to first injection. We selected the highest dose (100μg) to take into a Phase 2 trial.

In an anti-S1-RBD ELISA assay, we observed that all three dose levels of UB-612 induced titer levels comparable to or greater than those in sera from patients hospitalized with COVID-19. Furthermore, in a cytopathic effect viral neutralization assay (CPE VNT_{50}), we observed neutralizing titers comparable to those in sera from patients hospitalized with COVID-19.

Neutralizing activities of sample sera from the Phase 1 trial were assessed against live virus variants at the Viral and Rickettsial Disease Laboratory of the California State Department of Public Health. The results indicate that UB-612 induces viral neutralizing antibody titers against the Alpha, Gamma and Delta variants of SARS-CoV-2, close to the neutralizing titer level against the original (wild-type, WT) Wuhan strain, while the titer level against the Beta variant is lower in comparison. The latter finding is anticipated by results published for other COVID-19 vaccines, as pointed out above.

Viral-neutralizing antibody titers (VNT_{50}) up to 154 days after the second dose (day 196) in the Phase 1 trial of UB-612 remained at 52% of the maximum level observed following the second dose, on average. Based on the interim six-month cutoff, the UB-612-specific neutralizing antibody half-life was estimated to be 195 days using an exponential model.

Time Course of SARS-CoV-2 Antibody Neutralization Responses after Vaccination



Data from a micro-neutralization assay of sera from subjects who received two 100μg doses of UB-612 yielded an estimated neutralizing titer half-life of 195 days (CI: 136, 349) using an exponential model.

A randomized, placebo-controlled, multi-center Phase 2 trial of UB-612 in 3,850 healthy volunteers aged 12 to 85 was conducted in Taiwan. Subjects in this trial receive two doses of 100μg UB-612, or placebo, 28 days apart. The objectives of this trial include the analysis of safety and immunogenicity of UB-612, in particular, antigen-specific antibodies to UB-612, the seroconversion rate and lot-to-lot consistency of antibody responses. An interim analysis of data from this Phase 2 trial in healthy volunteers 18 years and older based on the data cut-off date of June 27, 2021 was submitted to the TFDA as part of a filing for an EUA in Taiwan. The EUA was denied in August 2021 by the TFDA.

In data from the Phase 2 trial, UB-612 appears well tolerated. AEs were generally mild, and no UB-612-related SAEs were observed. Local injection site AEs occurred in half of the subjects, the most frequent being injection site pain. Systemic AEs occurred in less than half of the subjects, and the incidence was similar in the active and placebo groups, except for muscle pain which was more frequent in the active group. Aside from muscle pain, systemic reactions were comparable across the active and placebo groups, with less than 10% of subjects in either group experiencing fever or chills. Systemic AEs were similar after the first and second doses. The vast majority of AEs were mild (Grade 1), and all were self-limited. No subject had a severe (Grade 3) local reaction. The incidence of severe (Grade 3) systemic reactions was <0.1%.

The Phase 2 interim analysis suggests that Phase 1 observations on immunogenicity, neutralizing titers and tolerability are reproducible, with an overall seroconversion rate of 94.7% one month after the second dose. In a live virus (Wuhan) neutralization test, sera collected from UB-612 vaccinated younger adults (19-64 years, n=322), 28 days after the second dose (day 57) were estimated to reach geometric mean titers ("GMT") of 102 of 50% virus-neutralizing antibodies (VNT_{50}). Sera collected from a subset of subjects (n=48) 28 days after the second immunization was shown to neutralize several SARS-CoV-2 variants, with the loss of neutralization activity against Delta estimated at 1.39-fold when compared to the neutralizing antibodies against the parental Wuhan virus.

Immunization with UB-612 in both Phase 2 and Phase 1 studies led to detectable T-cell responses observed in a subset of subjects. In Phase 2, a total of 88 subjects receiving UB-612 and 12 receiving placebo were tested for T cell responses at baseline and on Day 57. Preliminary results of ELISpot (Interferon-γ and IL-4) and intracellular cytokine staining indicate robust responses to UB-612, with a strong Th1 orientation. Intracellular cytokine staining (ICS) confirmed the Th1 orientation of T cell responses. UB-612 induced measurable CD8+ T cell responses and CD107a+/Granzyme secreting cells, which are putative cytotoxic T cells.

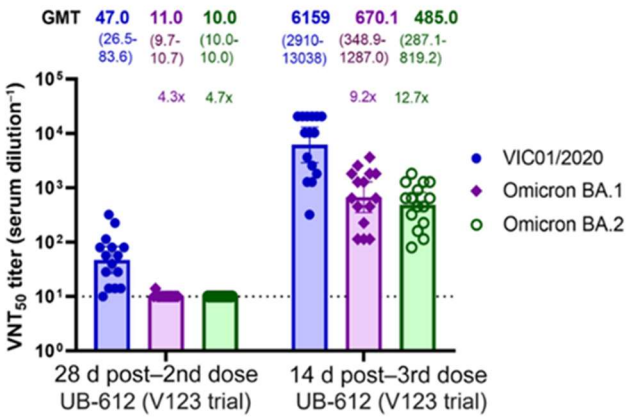
3-Dose Clinical Data

In a Phase 1 extension trial, 50 subjects from Phase 1 received a third booster dose of UB-612 approximately 7-9 months after their second dose (100μg). In this extension trial, UB-612 was generally well tolerated after a third dose, with no vaccine-related SAEs reported.

Immunogenicity and safety data from the Phase 1 extension suggests that UB-612 elicits a multi-fold increase in neutralizing antibody titers upon third dose, significantly exceeding those observed in human convalescent sera, and that the third dose is well tolerated with no vaccine-related SAEs reported. Published studies have shown a correlation between efficacy in randomized controlled trials and the ratio of neutralizing titers in sera from vaccinated subjects to titers in human convalescent sera.

In collaboration with University College London and VisMederi, we analyzed sera from subjects immunized with three doses of UB-612. Data demonstrated that UB-612 elicited a broad IgG antibody response against multiple SARS-CoV-2 variants of concern, including, Alpha, Beta, Delta, and Gamma, and Omicron, and higher levels of neutralizing antibodies against Omicron than three doses of an approved mRNA vaccine.

Third immunization with UB-612 Produces Neutralizing Antibodies Against Omicron



Phase 1 extension subjects (n=15) received primary series with UB-612 100μg. Serum is taken 28 days after the second dose and 14 days after the third booster immunization administered 7-9 months after the primary series. Live virus neutralization test against Wuhan and Omicron are performed at VisMederi; results are expressed as virus neutralization antibody GMT ± 95% CI.

An extension of the Phase 2, observer-blind, multicenter, randomized, placebo-controlled trial was sponsored by UBIA to evaluate the immunogenicity, safety, tolerability, and lot consistency of a homologous booster dose of UB-612 in adolescents, younger adults, and elderly adults. Adult subjects who completed the primary 2-dose UB-612 series in the main Phase 2 trial were unblinded around and offered a third dose of UB-612. The third dose of UB-612 stimulated both arms of adaptive immunity in subjects. The frequency of solicited and unsolicited adverse events following the third dose was consistent with the safety profile observed after the first and second doses.

Development Strategy

Based on our belief in UB-612's potential utility as a heterologous booster dose (boosting the immunity of a subject who has already received a different vaccine), we have completed rolling submissions for conditional/provisional authorization with regulatory authorities in the United Kingdom and Australia, who will review under their established work share agreement.

We expect to complete the ongoing Phase 3 trial of UB-612 as a heterologous booster in the second half of 2023, with continued support from CEPI.

Competition

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, the expertise of our executive and scientific teams, research, clinical capabilities, development experience and scientific knowledge provide us with competitive advantages, we face increasing competition from multiple sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions both in the United States and abroad.

Many of our competitors may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient enrollment for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with larger or more established companies.

Vaccines

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

Neurodegenerative Disorders

We expect that, if approved, our product candidates will compete with currently approved therapies for management of neurodegenerative diseases, such as AD and PD. In AD, four drugs are currently approved by the FDA for the treatment of symptoms of AD, based on acetylcholinesterase ("AChE") inhibition and NMDA receptor antagonism. In addition to the marketed therapies, we are aware of several companies currently developing therapies for AD, including Eisai, Lilly, Hoffman-LaRoche, Abbvie, Johnson & Johnson, and Novartis. Biogen's aducanumab was approved by the FDA in June 2021 under the accelerated approval pathway, which allows for earlier approval of drugs that treat serious conditions, and that fill an unmet medical need based on a surrogate endpoint. Aducanumab failed to achieve approval in Europe and Japan. Eisai and Biogen's lecanemab was approved by the FDA in January 2023 under an accelerated approval pathway.

Pharmaceutical treatments for PD address its symptoms only and do not treat the underlying causes of PD. The majority of prescription drugs are dopaminergic medications and act by increasing dopamine, a neurotransmitter. We are aware of several companies with product candidates at various stages of clinical development, including Sanofi, Kyowa Kirin, Cerevel Therapeutics and Hoffman-LaRoche. Hoffman-LaRoche is developing prasinezumab, a mAb, as a potential treatment for PD.

CGRP-Directed Migraine Treatments

Six migraine treatments have been approved by the FDA that target CGRP. Four of these therapeutics are mAbs and were approved to prevent or reduce the number of migraine episodes. These medications are galcanezumab (Emgality), which was developed by Lilly; erenumab (Aimovig), which was developed by Amgen in collaboration with Novartis; fremanezumab (Ajovy), which was developed by Teva; and eptinezumab (Vyepti), which was developed by Alder, acquired by Lundbeck. Ubrogepant (Ubrelvy), developed by Allergan, was approved for the treatment of acute migraine episodes; rimegepant (Nurtec), also approved for the treatment of acute migraine, is sold by Pfizer following its acquisition of Biohaven. Atogepant (Qulipta), developed by AbbVie, was approved for the preventive treatment of episodic migraine.

PCSK-9 Inhibitors

Three companies currently have PCSK-9 inhibitors approved by the FDA to treat hypercholesterolemia: Regeneron Pharmaceuticals developed alirocumab (Praluent), a mAb, in collaboration with Sanofi, and Amgen developed evolocumab (Repatha), another mAb, and Novartis is commercializing inclisiran, an RNAi construct, to down-regulate synthesis of PCSK-9.

Collaborations

From time to time, we may enter into licensing and commercialization agreements when they align with our mission, including the Platform License Agreement described under "—Intellectual Property—Platform License Agreement" and the agreement with our partner Aurobindo.

Aurobindo License Agreement

In December 2020, we entered into an exclusive license agreement with Aurobindo (as amended, the "Aurobindo Agreement") to develop and commercialize UB-612 to India and other territories. Pursuant to the Aurobindo Agreement, we granted Aurobindo an exclusive license (with certain rights reserved to us) to develop, manufacture and commercialize UB-612 in India and other countries through UNICEF and a non-exclusive license to develop, manufacture and commercialize UB-612 in other selected emerging and developing markets.

The Aurobindo Agreement may be terminated (i) by Aurobindo, without cause at any time after three years following the effective date or prior to such time if UB-612 fails to meet clinical endpoints or fails in development, (ii) by us, (a) if Aurobindo disputes the patentability, enforceability or validity of our patent rights related to the UB-612 technology, (b) in case of a suit alleging Aurobindo's use of the licensed intellectual property infringes a third party's intellectual property rights if we reasonably believe the license is no longer commercially reasonable in light of such claim or (c) without cause at any time after four years following the effective date, (iii) by either party in the event of the other party's material breach of its obligations under the Aurobindo Agreement (subject to a cure period) or (iv) by either party in the event of the other party's insolvency.

Manufacturing

The manufacture of our product candidates encompasses both the manufacture of custom components and the formulation, fill and finish of the final product. We do not currently own or operate manufacturing facilities for these processes. We currently rely upon contract manufacturing organizations, including those mentioned below, to produce our product candidates for both pre-clinical and clinical use and will continue to rely upon these relationships for commercial manufacturing if any of our product candidates obtain regulatory

approval. Although we rely upon contract manufacturers, we also have personnel with extensive manufacturing experience that can oversee the relationships with our manufacturing partners.

Historically, we have depended heavily on UBI and its affiliates for our business operations, including the provision of research, development and manufacturing services. Currently, UBIA provides testing services for UB-312 and UB-612, UBI Pharma Inc. ("UBIP") provides testing relating to formulation-fill-finish services for UB-312, and United BioPharma, Inc. ("UBP") is the sole manufacturer of protein for UB-612. Our commercial arrangements with UBI and its affiliates are described in more detail below.

Formulation-fill-finish services for UB-612 are provided by multiple contract manufacturers to ensure adequate capacity and minimize supply chain risks. For supply of our other custom components, in addition to protein manufacturing conducted by UBP, we have engaged third party CMOs, including C S Bio Co. ("CSBio") as our primary peptide supplier for UB-612 peptides and Wuxi STA for process development and manufacturing services of oligonucleotides.

UBI Group Manufacturing Partnership

We primarily rely on our relationships with third-party contract manufacturing organizations to produce product candidates for our clinical trials. Historically, we have heavily depended on UBI as a manufacturing partner for these efforts. In support of our COVID-19 program (UB-612), we have entered into a master services agreement with UBP and an additional master services agreement with UBI, UBIA and UBP. Pursuant to these agreements, UBI and its affiliates have provided research, development, testing and manufacturing services to us and continue to provide manufacturing services for our protein. Payment terms are mutually agreed in connection with each work order relating to services rendered. Our agreement with UBP will expire on the later of March 2024 and the completion of all services under the last work order executed prior to such scheduled expiration and our agreement with UBI, UBIA and UBP will expire on the later of September 2023 and the completion of all services under the last work order executed prior to such scheduled expiration. We also have a management services agreement with UBI pursuant to which UBI has provided research and prior back office administrative services to us and acts as our agent with respect to certain matters relating our COVID-19 program. UBI is compensated for its services on a cost-plus basis. The agreement terminates upon mutual agreement between the parties.

In support of our chronic disease pipeline, we have entered into master service agreements with each of UBI, UBIA and UBIP. Pursuant to these agreements, UBI currently provides limited research services to us on a cost-plus basis, UBIA provides testing services related to UB-312 clinical trial material already manufactured and UBIP has provided manufacturing, quality control, testing, validation, GMP warehousing and supply services to us for UB-312 on payment terms agreed in connection with work orders relating to the services rendered. UBI and its affiliates no longer provide clinical or manufacturing services for other programs. These agreements may all be terminated for convenience upon 180 days' notice or less.

We have also entered into a research and development services agreement with UBI. Pursuant to this agreement, UBI and its affiliates may provide research and development services to us. Service fees payable by us to UBI for research and development projects undertaken in accordance with the research and development plan would be determined by a joint steering committee and set forth in a research and development plan. Any aggregate services fees payable by us under the research and development services agreement are subject to a quarterly cap throughout the term of the agreement. The research and development services agreement expires in August 2026.

Intellectual Property

Our ability to obtain and maintain intellectual property protection for our product candidates and core technologies is fundamental to the long-term success of our business. We rely on a combination of intellectual property protection strategies, including patents, trademarks, trade secrets, license agreements, confidentiality policies and procedures, nondisclosure agreements, invention assignment agreements and technical measures designed to protect the intellectual property and commercially valuable confidential information and data used in our business.

In summary, our patent estate includes issued patents and patent applications which claims cover our Vaxxine Platform and each of our product candidates. As of December 31, 2022 our patent estate included three U.S. issued patents, twelve U.S. patent applications, five U.S. provisional patent applications, four pending Patent Cooperation Treaty ("PCT") patent applications, 60 issued non-U.S. patents and 158 pending non-U.S. patent applications.

For our product candidates targeting the prevention and treatment of neurodegenerative disease, including claims covering UB-311, UB-312, and anti-tau patent rights are provided by patents and patent applications, the majority of which are being prosecuted in the United States, Australia, Brazil, Canada, China, the EPO, Hong Kong, Indonesia, India, Israel, Japan, the Republic of Korea, Mexico, Russia, Singapore, South Africa, Taiwan and the United Arab Emirates directed to peptide vaccines for the prevention and treatment of neurodegenerative diseases. These issued patents and patent applications, if issued, are expected to expire between 2023 and 2043, excluding any patent term adjustments or patent term extensions.

For our product candidates directed to peptide immunogens targeting CGRP and formulations thereof for the prevention and treatment of migraine, including UB-313, patent rights may be provided by a patent family being prosecuted in the United States, Australia, Brazil, Canada, China, India, Indonesia, Japan, Mexico, Russia, the Republic of Korea, Singapore, Taiwan and the United Arab Emirates. These patent applications, if issued, are expected to expire in 2039, excluding any patent term adjustments or patent term extensions.

For our product candidates targeting cholesterol and cardiovascular disease, including our anti-PCSK9 product candidate targeting PCSK9 and formulations thereof for prevention and treatment of PCSK9-mediated disorders, we have pending patent applications in the United States, Australia, Brazil, Canada, India, Indonesia, Japan, Mexico, the Philippines, the Republic of Korea, Taiwan, and the United Arab Emirates. These patent applications, if issued, are expected to expire in 2041, excluding any patent term adjustment or patent term extension.

For our product candidates targeting SARS-CoV-2, including UB-612 for COVID-19, we have pending patent applications in the United States, Australia, Brazil, Canada, India, Indonesia, Japan, Pakistan, the Philippines, the Republic of Korea, Russia, Saudi Arabia, Taiwan, United Arab Emirates, and Vietnam, four pending PCT patent applications and one provisional patent applications in the United States. These patent applications, if issued, and any U.S. or non-U.S. patent issuing from the PCT or provisional patent applications, are expected to expire between 2041 and 2042, excluding any patent term adjustments or patent term extensions.

For each product candidate utilizing the Vaxxine platform, additional patent rights directed to artificial T helper cell epitopes and to a CpG delivery system are provided by patents and patent applications, the majority of which are being prosecuted in the United States, Australia, Austria, Belgium, Brazil, Canada, Chile, China, Colombia, Denmark, the EPO, France, Germany, Hong Kong, Indonesia, India, Ireland, Israel, Italy, Japan, Mexico, the Netherlands, New Zealand, Peru, Philippines, the Republic of Korea, Russia, Singapore, South Africa, Spain, Sweden, Switzerland/Liechtenstein, Taiwan, Thailand, the United Arab Emirates, the United Kingdom and Vietnam. These issued patents and patent applications, if issued, are expected to expire between 2023 and 2039, excluding any patent term adjustments or patent term extensions.

The term of individual patents depends on the countries in which they are obtained. The patent term is 20 years from the earliest effective filing date of a non-provisional patent application in most of the countries in which we file, including the United States. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent. The term of a patent that covers a drug or biological product may also be eligible for patent term extension when FDA approval is granted for a portion of the term effectively lost as a result of the FDA regulatory review period, subject to certain limitations and provided statutory and regulatory requirements are met.

In addition to our reliance on patent protection for our inventions, products and technologies, we also seek to protect our brand through the procurement of trademark rights. We own registered trademarks and pending trademark applications for our brands, including our "Vaxxinity", "United Neuroscience" and "COVAXX" brands and other related names and logos, in the United States and certain foreign jurisdictions.

Furthermore, we rely upon trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and know-how can be difficult to protect. We generally control access to and use of our trade secrets and know-how, through the use of internal and external controls, including by entering into nondisclosure and confidentiality agreements with our employees and third parties. We cannot guarantee, however, that we have executed such agreements with all applicable counterparties, that such agreements will not be breached or that these agreements will afford us adequate protection of our intellectual property and proprietary rights. Furthermore, although we take steps to protect our proprietary information and trade secrets, 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 "Risk Factors—Risks Related to Our Intellectual Property Rights."

Platform License Agreement

In August 2021, Vaxxinity entered into a license agreement (the "Platform License Agreement") with UBI and certain of its affiliates (collectively, the "Licensors") that expanded intellectual property rights previously licensed under the Original UBI Licenses (as defined below). Pursuant to the Platform License Agreement, Vaxxinity obtained a worldwide, sublicensable (subject to certain conditions), perpetual, fully paid-up, royalty-free (i) exclusive license (even as to the Licensors) under all patents owned or otherwise controlled by the Licensors or their affiliates existing as of the effective date of the Platform License Agreement, (ii) exclusive license (except as to the Licensors) under all patents owned or otherwise controlled by the Licensors or their affiliates arising after the effective date during the term of the Platform License Agreement, and (iii) non-exclusive license under all know-how owned or otherwise controlled by the Licensors or their affiliates existing as of the effective date or arising during the term of the Platform License Agreement, in each of the foregoing cases, to research, develop, make, have made, utilize, import, export, market, distribute, offer for sale, sell, have sold, commercialize or otherwise exploit peptide-based vaccines in the field of all human prophylactic and therapeutic uses, except for such vaccines related to human immunodeficiency virus (HIV), herpes simplex virus (HSE) and Immunoglobulin E (IgE). The patents and patent applications licensed under the Platform License Agreement include claims directed to a CpG delivery system, artificial T helper

cell epitopes and certain designer peptides and proteins utilized in UB-612. As partial consideration for the rights and licenses we received pursuant to the Platform License Agreement, we granted UBI a warrant to purchase 1,928,020 shares of our Class A common stock ("UBI Warrant"). The UBI Warrant is exercisable at an exercise price of $12.45 per share (subject to adjustment pursuant thereto), is not subject to vesting, and has a term of five years.

Vaxxinity has the first right to control the filing, prosecution, maintenance and enforcement of the licensed patents at Vaxxinity's own expense, subject to the Licensors' right to comment on and review any patent filings. The Platform License Agreement shall continue until the parties mutually consent in writing to terminate the agreement. Upon such termination, all licenses granted under the Platform License Agreement shall terminate and Vaxxinity will assign any regulatory documentation previously assigned to Vaxxinity back to the Licensors.

Pricing, Coverage and Reimbursement

Sales of our product candidates in the United States will depend, in part, on the extent to which third-party payors, including government health programs such as Medicare and Medicaid, commercial insurance and managed health care organizations provide coverage and establish adequate reimbursement levels for such product candidates. 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, and we may also need to provide discounts to purchasers, private health plans or government healthcare programs, as increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. 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 for commercial viability, and inadequate reimbursement rates, including significant patient cost sharing obligations, may deter patients from selecting our product candidates. Obtaining coverage and reimbursement approval of a product from a third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our product on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. In general, factors a payor considers in determining coverage and reimbursement are based on whether the product is a covered benefit under its health plan; safe, effective, and medically necessary, including its regulatory approval status; medically appropriate for the specific patient; cost-effective; and neither experimental nor investigational. 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, and the level of coverage and reimbursement can differ significantly from payor to payor. 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.

Product Approval and 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, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are developing. Any product candidate that we develop must be approved by the FDA before it may be legally marketed in the United States and by the appropriate foreign regulatory agency before it may be legally marketed in foreign countries.

U.S. Drug Development Process

In the United States, the development, manufacturing and marketing of human drugs and vaccines are subject to extensive regulation. The FDA regulates drugs under the Federal Food, Drug and Cosmetic Act ("FDCA") and implementing regulations, and biological products, including vaccines, under provisions of the FDCA and the Public Health Service Act ("PHSA"). Drugs and vaccines are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. 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 to administrative or judicial sanctions. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, debarment, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a drug or biological product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests, animal studies and formulation and stability studies according to good laboratory practices, or GLPs and other applicable regulations;
- submission to the FDA of an application for an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to the FDA's good clinical practice regulations commonly referred to as GCPs, among other requirements, to establish the safety and efficacy of the proposed drug for its intended uses;
- submission to the FDA of an NDA or BLA for a new drug;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the drug is produced to assess compliance with the FDA's cGMP, to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA audit of the nonclinical and clinical trial sites that generated the data in support of the NDA or BLA; and
- FDA review and approval of the NDA or BLA.

The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources and approvals are inherently uncertain.

Before testing any compounds with potential therapeutic value in humans, the product candidate enters the pre-clinical study stage. Pre-clinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The Consolidated Appropriations Act for 2023, signed into law on December 29, 2022, (P.L. 117-328) amended both the FDCA and PHSA to specify that nonclinical testing for drugs and biologics, respectively, may, but is not required to, include in vivo animal testing. According to the amended language, a sponsor may fulfill nonclinical testing requirements by completing various in vitro assays (e.g., cell-based assays, organ chips, or microphysiological systems), in silico studies (i.e., computer modeling), other human or non-human biology-based tests (e.g., bioprinting), or in vivo animal tests.

The conduct of the pre-clinical tests must comply with federal regulations and requirements including GLP. The sponsor must submit the results of the pre-clinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA imposes a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a product candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trial.

Clinical trials involve the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's direct control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety. Each protocol must be submitted to the FDA as part of the IND. Congress also recently amended the FDCA, as part of the Consolidated Appropriations Act for 2023, in order to require sponsors of a Phase 3 clinical trial, or other "pivotal study" of a new drug to support marketing authorization, to design and submit a diversity action plan for such clinical trial. The action plan must include the sponsor's diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. Sponsors must submit a diversity action plan to the FDA by the time the sponsor submits the relevant clinical trial protocol to the agency for review. The FDA may grant a waiver for some or all of the requirements for a

diversity action plan. It is unknown at this time how the diversity action plan may affect Phase 3 trial planning and timing or what specific information FDA will expect in such plans, but if the FDA objects to a sponsor's diversity action plan or otherwise requires significant changes to be made, it could delay initiation of the relevant clinical trial. Clinical trials must be conducted in accordance with the FDA's regulations comprising the good clinical practices requirements. Further, each clinical trial must be reviewed and approved by an independent IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and provide oversight for the clinical trial until completed.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1*. The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing may be conducted in patients;

- *Phase 2*. The drug 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; and

- *Phase 3*. Clinical trials are undertaken to further evaluate dosage, clinical efficacy 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. Generally, a well-controlled Phase 3 clinical trial is required by the FDA for approval of an NDA or BLA.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication.

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 and written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human subjects. 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 drug has been associated with unexpected serious harm to patients.

Concurrently with clinical trials, companies usually complete additional nonclinical studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final drug. For biological products in particular, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined in order to help reduce the risk of the introduction of adventitious agents. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA or BLA requesting approval to market the product. The submission of an NDA or BLA is subject to the payment of substantial fees; a waiver of such fees may be obtained under certain limited circumstances.

In addition, under the Pediatric Research Equity Act ("PREA"), an NDA or BLA or supplement to an NDA or BLA must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

The FDA reviews all NDAs or BLAs submitted to determine if they are substantially complete before it accepts them for filing. If the FDA determines that an NDA or BLA is incomplete or the application is found to be non-navigable, the filing may be refused and must be re-submitted for consideration. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA or BLA. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act ("PDUFA"), the FDA has 10 months from acceptance of filing in which to complete its initial review of a standard NDA or BLA and respond to the applicant, and six months from acceptance of filing for a priority NDA or BLA. The FDA does not always meet its PDUFA goal dates. The review process and the PDUFA goal date may be extended by three months or longer if the FDA requests or the NDA or BLA sponsor otherwise provides additional information or clarification regarding information already provided in the submission before the PDUFA goal date.

After the NDA or BLA submission is accepted for filing, the FDA reviews the NDA or BLA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA may refer applications for novel drug or biological products or drug or biological products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the drug approval process, the FDA also will determine whether a risk evaluation and mitigation strategy, or REMS is necessary to ensure that the benefits of the drug outweigh its risks and to assure the safe use of the drug. The REMS could include medication guides, physician communication plans, assessment plans and/or elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS; the FDA will not approve the NDA or BLA without a REMS, if required.

Before approving an NDA or BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA requires vaccine manufacturers to submit data supporting the demonstration of consistency between manufacturing batches, or lots. The FDA works together with vaccine manufacturers to develop a lot release protocol, the tests conducted on each lot of vaccine post-approval. Additionally, before approving an NDA or BLA, the FDA will typically inspect the sponsor and one or more clinical sites to assure that the clinical trials were conducted in compliance with IND study requirements and with GCPs. 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.

The NDA or BLA review and approval process is lengthy and difficult and the FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications, while a complete response letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. The complete response letter usually describes all of the specific deficiencies in the NDA or BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either submit new information, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post-marketing clinical trials, sometimes referred to as Phase 4 clinical trials, which are designed to further assess a product's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could impact the timeline for regulatory approval or otherwise impact ongoing development programs.

Expedited Development and Review Programs

The FDA is authorized to designate certain products for expedited development or review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include fast track designation, breakthrough therapy designation and priority review designation.

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new drugs and biologics that meet certain criteria. Specifically, new drugs and biologics are eligible for fast track designation if they are intended to treat a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast

track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor can request the FDA to designate the product for fast track status any time before receiving NDA or BLA approval, but ideally no later than the pre-NDA or pre-BLA meeting.

Additionally, a drug or biologic may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The benefits of breakthrough therapy designation include the same benefits as fast track designation, plus intensive guidance from the FDA to facilitate an efficient drug development program.

Any product submitted to the FDA for marketing, including under a fast track or breakthrough therapy designation program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval.

Any product is eligible for priority review if it treats a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. Priority review reduces the review time for an initial or supplemental marketing application by four months.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Fast track designation, priority review, and breakthrough therapy designation do not change the standards for approval but may expedite the development or approval process.

Accelerated Approval Pathway

A product may be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies based on an effect on 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 ("IMM") that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of accelerated approval, the FDA requires that a sponsor of a drug or biologic receiving accelerated approval subsequently provide additional data confirming the anticipated clinical benefit, for example by performing adequate and well-controlled post-marketing clinical trials. If clinical benefit is not confirmed, accelerated approval may be revoked.

In addition, as part of the Consolidated Appropriations Act for 2023, Congress provided FDA additional statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval. Under these recent amendments to the FDCA, the agency may require a sponsor of a product granted accelerated approval to have a confirmatory trial underway prior to approval. The sponsor must also submit progress reports on a confirmatory trial every six months until the trial is complete, and such reports will be published on FDA's website. Failure to conduct required post-approval studies, or to confirm the predicted clinical benefit of the product during post-marketing studies, allows the FDA to withdraw approval of the drug or biologic. Congress also recently amended the law to give FDA the option of using expedited procedures to withdraw product approval if the sponsor's confirmatory trial fails to verify the claimed clinical benefits of the product.

Granting of an EUA

The Commissioner of the FDA, under delegated authority from the Secretary of the U.S. Department of Health and Human Services ("DHHS") may, under certain circumstances, issue an Emergency Use Authorization, or EUA that would permit the use of an unapproved drug product or unapproved use of an approved drug product. Before an EUA may be issued, the Secretary must declare an emergency based on one of the following grounds:

- a determination by the Secretary of the Department of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological or nuclear agent or agents;

- a determination by the Secretary of the Department of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces of attack with a specified biological, chemical, radiological or nuclear agent or agents; or

- a determination by the Secretary of the DHHS that a public health emergency that affects, or has the significant potential to affect, national security and that involves a specified biological, chemical, radiological or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agent.

In order to be the subject of an EUA, the FDA Commissioner must conclude that, based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective in diagnosing, treating or preventing a disease attributable to the agents

described above, that the product's potential benefits outweigh its potential risks and that there is no adequate approved alternative to the product.

Although an EUA cannot be issued until after an emergency has been declared by the Secretary of DHHS, the FDA strongly encourages an entity with a possible candidate product, particularly one at an advanced stage of development, to contact the FDA center responsible for the candidate product before a determination of actual or potential emergency. Such an entity may submit a request for consideration that includes data to demonstrate that, based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective in diagnosing, treating or preventing the serious or life-threatening disease or condition. This is called a pre-EUA submission and its purpose is to allow FDA review considering that during an emergency, the time available for the submission and review of an EUA request may be severely limited.

Post-Approval Requirements

Any drug or biological products for which we or our collaborators receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet.

Failure to comply with FDA requirements can have negative consequences, including adverse publicity, enforcement letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses.

Manufacturers of our product candidates are required to comply with applicable FDA manufacturing requirements contained in the FDA's cGMP regulations. cGMP regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. Following approval, the FDA continues to monitor vaccine quality through real-time monitoring of lots by requiring manufacturers to submit certain information for each vaccine lot. Vaccine manufacturers may only distribute a lot following release by the FDA. Drug manufacturers 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 and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA or BLA, including withdrawal of the product from the market. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented, and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

U.S. Patent-term Extension

Depending upon the timing, duration and specifics of FDA approval of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments to the FDCA. The Hatch-Waxman Amendments permit extension of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. Patent-term extension, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent-term extension period is generally one-half the time between the effective date of an IND and the submission date of an NDA or BLA plus the time between the submission date of an NDA or BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, or USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for extension of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA or BLA.

U.S. Foreign Corrupt Practices Act

In general, the Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, prohibits offering to pay, paying, promising to pay, or authorizing the payment of money or anything of value to a foreign official in order to influence any act or decision of the foreign official in his or her official capacity or to secure any other improper advantage in order to obtain or retain business for or with, or in order to direct business to, any person. The prohibitions apply not only to payments made to "any foreign official," but also those made to "any foreign political party or official thereof," to "any candidate for foreign political office" or to any person, while knowing that all or a portion of the payment will be offered, given, or promised to anyone in any of the foregoing categories. "Foreign officials" under

the FCPA include officers or employees of a department, agency, or instrumentality of a foreign government. The term "instrumentality" is broad and can include state-owned or state-controlled entities.

Importantly, United States authorities that enforce the FCPA, including the Department of Justice, deem most health care professionals and other employees of foreign hospitals, clinics, research facilities and medical schools in countries with public health care or public education systems to be "foreign officials" under the FCPA. When we interact with foreign health care professionals and researchers in testing and marketing our products abroad, we must have policies and procedures in place sufficient to prevent us and agents acting on our behalf from providing any bribe, gift or gratuity, including excessive or lavish meals, travel or entertainment in connection with marketing our future products and services or securing required permits and approvals such as those needed to initiate clinical trials in foreign jurisdictions. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the maintenance of books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and the development and maintenance of an adequate system of internal accounting controls for international operations. The Securities and Exchange Commission is involved with the books and records provisions of the FCPA.

Regulation in Europe and Other Regions

In addition to regulations in the United States, we and our collaborators are subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products.

Whether or not we or our collaborators obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the European Union, for example, a CTA must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed.

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 GCPs and the applicable regulatory requirements and the ethical principles on human subjects research that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug or biological product under European Union regulatory systems, we or our strategic partners must submit a marketing authorization application. The application in the European Union is similar to that required in the United States, with the exception of, among other things, country-specific document requirements.

For other countries outside of the European Union, such as countries in Asia, Europe and Latin America, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCPs and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

Employees and Human Capital Resources

As of December 31, 2022, we employed 87 full-time employees and 2 part-time employees. Of these 87 full-time employees, 83 were located in the United States, 2 were located in Ireland, 1 was located in Taiwan and 1 was located in the UK. As of March 15, 2023, we employed 76 full-time employees and 1 part-time employee. Of these 76 full-time employees, 72 were located in the United States, 2 were located in Ireland, 1 was located in Taiwan and 1 was located in the UK. None of our employees are represented by a labor union or are party to a collective bargaining agreement, and we have had no labor-related work stoppages.

Compensation, Benefits, Recruitment and Retention Strategy

We aim to focus on attracting, motivating and retaining talented employees with relevant experience who can contribute to the sustained performance of the Company and its day-to-day operations.

We believe our total compensation package helps recruit and retain our employees. We strive to provide compensation and benefits that are competitive to market and create incentives to attract and retain employees. Our compensation package includes market-competitive pay, broad-based stock grants, health care and 401(k) plan benefits, paid time off and family leave, among others. We also provide annual incentive bonus opportunities that are tied to both company performance as well as individual performance to foster a pay-for-performance culture.

Scientific Advisory Board

We have assembled a highly qualified scientific advisory board composed of advisors who have deep expertise in the fields of biologics and vaccine development, as well as in the relevant therapeutic areas for our product candidates.

Immunology & Vaccinology

- Thomas P. Monath, M.D.
- Wayne Koff, Ph.D.
- Stanley A. Plotkin, M.D.

Neurology

- Brad Boeve, M.D.
- Richard Mohs, Ph.D.
- Jeffrey Cummings, M.D.
- Eric Reiman, M.D.
- Nick Fox, M.D.
- Stephen D. Silberstein, M.D.

Cardiovascular

- Kausik K. Ray, M.D.
- Stephen Nicholls, Ph.D.
- Frederick Raal, Ph.D.
- Dirk von Lewinski, M.D.
- Thomas Fleming, Ph.D.
- Parviz Ghahramani, Ph.D.

Item 1A. Risk Factors.

Investing in our Class A common stock involves a high degree of risk. The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Annual Report on Form 10-K and those we may make from time to time. You should carefully consider the risks described below, in addition to the other information contained in this Report and our other public filings, before you decide to purchase shares of our Class A common stock. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Summary Risk Factors

Our business is subject to a number of risks, including risks that may prevent us from achieving our business objectives or may adversely affect our business, financial condition, results of operations and prospects. These risks are discussed more fully under Part II, Item 1A. "Risk Factors." The following is a summary of some of the principal risks we face:

- clinical drug development involves a lengthy and expensive process, and if our pre-clinical development or clinical trials are prolonged or delayed or do not achieve expected results, we may be unable to commercialize our product candidates;
- we depend on intellectual property licensed from UBI and its affiliates, the termination of which could result in the loss of significant rights;
- even if we obtain regulatory approval of, or commercialize, any of our product candidates in one or more jurisdictions, we may never obtain approval for, or commercialize, our product candidates in other jurisdictions;
- after receipt of regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny and post-marketing requirements, which may include burdensome post-approval trial or risk management requirements that may adversely impact the financial results of any future commercialization efforts or cause us to choose not to commercialize the product candidate;
- if we are able to commercialize any product candidate, the successful commercialization of such product candidate will depend on the extent governmental authorities, private health insurers and other third-party payors provide coverage, adequate reimbursement levels and favorable pricing policies;
- the manufacture of peptide-based medicines is complex and manufacturers often encounter difficulties in production;
- we have no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability;
- the regulatory landscape that will govern our product candidates is uncertain, and changes in regulatory requirements could result in delays or discontinuation of development of our product candidates or unexpected costs;
- developments by competitors may render our products or technologies obsolete or non-competitive or may reduce the size of our markets;
- our capital resources may not be sufficient to successfully complete the development and commercialization of our product candidates, which could delay, limit, reduce or terminate our development or commercialization efforts;
- we have incurred significant losses since inception, and we expect to incur losses for the foreseeable future and may never achieve or maintain profitability;
- conflicts of interest and disputes exist and may further arise between us and UBI and its affiliates, and these conflicts and disputes might ultimately be resolved in a manner unfavorable to us;
- we will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations;
- the dual-class structure of our common stock and the Voting Agreement (as defined below) will have the effect of concentrating voting power, which will significantly limit your ability to influence significant corporate decisions;

- we rely on contract manufacturers for the manufacture of raw materials for our research programs, pre-clinical studies and clinical trials and we do not have long-term contracts with many of these parties, which could impact our ability to develop and commercialize our products;

- undetected errors or defects in our production could harm our reputation or expose us to product liability claims;

- we rely on in-licensed intellectual property and technology, and the loss of such rights, our licensors' inability or refusal to enforce or defend such rights, and any requirement to pay amounts under current or future agreements could harm our business;

- the degree of protection afforded by our intellectual property rights is uncertain because such rights offer only limited protection and may not adequately protect our rights or permit us to gain or keep a competitive advantage;

- we have previously identified and remediated material weaknesses, in our internal control over financial reporting and if we are unable to maintain an effective system of internal control over financial reporting, or if we discover material deficiencies in the future, we may not be able to accurately report our financial results or prevent fraud, and as a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our Class A common stock;

- cyberattacks or other failures in our or our third-party vendors', contractors' or consultants' telecommunications or information technology systems could result in information theft, compromise, or other unauthorized access, data corruption and significant disruption of our business operations, and could harm our reputation and subject us to liability, lawsuits and actions from governmental authorities; and

- we are subject to privacy, tax, anti-corruption and other stringent laws, regulations, policies and contractual obligations across multiple jurisdictions and changes in, or our failure to comply with, such laws, regulations, policies and contractual obligations could adversely affect our business, financial condition, results of operations and prospects.

Risks Related to the Discovery and Development of Product Candidates

Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes, and results of earlier studies and trials may not be predictive of future results. If our pre-clinical development or clinical trials are prolonged or delayed, or if we do not or cannot achieve the results we expect, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our product candidates on a timely basis or at all.

Our business is dependent on the successful development, regulatory approval and commercialization of product candidates based on our Vaxxine Platform. If we and our collaborators are unable to obtain approval for and effectively commercialize our product candidates, our business would be significantly harmed. Even if we complete the necessary pre-clinical studies and clinical trials, the regulatory approval process is expensive, time-consuming and uncertain, and we may not be able to obtain approvals for the commercialization of any product candidates we may develop. Changes in regulatory approval policies, changes in or the enactment of additional statutes or regulations, or changes in regulatory review processes, may cause delays in the approval of a particular product candidate or rejection of an application for a particular product candidate. We have not obtained regulatory approval for any product candidate to date, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. Any regulatory approval we ultimately obtain may be limited or subject to restrictions, including labeling requirements, or post-approval commitments that render the approved product not commercially viable. While our enzyme-linked immunosorbent assay ("ELISA") test has received an EUA from the FDA, there can be no assurance that any of our product candidates will receive an EUA or regulatory approval or that there will not be changes in formulation, whether required by any regulatory authority or at our determination for operational or scientific reasons, affecting the use of our products. Further, some countries may not rely on an EUA or regulatory approval issued by another jurisdiction, and we may be required to seek separate EUAs or regulatory approval from different regulatory authorities in different jurisdictions. See "Risk Factors—Even if we obtain approval of any of our product candidates in one jurisdiction, we may never obtain approval for or commercialize any of our products in other jurisdictions, which would limit our ability to realize their full market potential."

To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate through extensive pre-clinical studies and clinical trials that our products are safe and effective in humans. 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 pre-clinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials and results from post-hoc data analysis may not be predictive of final results and may not support product approval. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through pre-clinical studies and initial clinical trials. For example, an EUA for UB-612 was denied by the TFDA in August 2021 because the neutralizing antibody response generated by UB-612, as compared to a designated adenovirus vectored vaccine, did not meet the TFDA's specified evaluation criteria. If results from our clinical trials differ from previous reports or market expectations, such as a potential

development of market expectations that COVID-19 boosters or vaccines be developed specifically to address certain variants which we fail to satisfy, or if we fail to obtain a required regulatory approval, the price of our Class A common stock could decrease substantially. Several companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our ongoing and future clinical trials may not be successful.

Further, while we have conducted limited head-to-head comparisons in pre-clinical studies of UB-313 and VXX-401, we have not conducted a head-to-head comparison of any competing products to any of our chronic disease product candidates in any clinical trial to date. We have compared the published data for certain of our competitors' products to the clinical trial results of certain of our product candidates. Accordingly, the value of comparisons of our product candidates to any alternative products in this report may be limited because they are not derived from a head-to-head clinical trial, rather they are from trials that were conducted under different protocols, at different sites, with different patient populations, at different times and results were analyzed using non-standardized assays performed internally or by different clinical research organizations ("CROs"). Without head-to-head data, we will be unable to make comparative claims for our product candidates, if any such product candidate is approved. Future clinical trials may not confirm the comparisons or analyses we have made to date.

Clinical trials must be conducted in accordance with applicable regulatory authorities' legal requirements, regulations or guidelines and are subject to oversight by these governmental agencies as well as Institutional Review Boards ("IRBs") at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our product candidates produced in accordance with current good manufacturing practices ("cGMP") and other legal and regulatory requirements. Defects in manufacturing of a clinical trial batch or a failure of a batch to meet all quality control test specifications could result in delays to initiation of our clinical trials. We depend on medical institutions and CROs to conduct our clinical trials in compliance with good clinical practice ("GCP"), and other applicable laws and regulations. Failure to follow and document adherence to such laws and regulations may lead to significant delays in the availability of product for our clinical trials, result in the termination of or a clinical hold being placed on one or more of our clinical trials, or delay or prevent submission or approval of marketing applications for our product candidates.

To the extent our CROs fail to enroll participants for our clinical trials, fail to conduct the trial in accordance with the trial protocol GCP or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business and delay our ability to seek approval for our product candidates. For example, due in part to an error by the CRO responsible for administering blinded placebo and active doses to trial subjects, which reduced the confidence of subsequently collected data, we decided to discontinue a Phase 2a LTE trial for UB-311. In that case, however, we determined that we had collected sufficient data on UB-311's tolerability and immunogenicity.

The completion of clinical trials for our clinical product candidates may be delayed, suspended or terminated because of many factors, including but not limited to:

- the delay or refusal of regulators or IRBs to authorize us to commence a clinical trial at a prospective trial site;
- changes in regulatory requirements, policies and guidelines;
- delays or failure to reach 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;
- delays in patient enrollment and variability in the number and types of patients available for clinical trials;
- negative or inconclusive results, which may require us to conduct additional pre-clinical or clinical trials or to abandon product candidates that we expect to be promising;
- delays in manufacturing and control of clinical trial materials;
- shortages of materials required for the production of our product candidates;
- disruptions from events surrounding the Russia-Ukraine conflict
- the timing, scope and effectiveness of U.S. and international governmental, regulatory, fiscal, monetary and public health responses to the COVID-19 pandemic;
- safety or tolerability concerns causing us to suspend or terminate a trial if it is determined that the participants are being exposed to unacceptable health risks;

- lower than anticipated retention rates of patients and volunteers in clinical trials and difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- failure of us, our CROs or clinical trial sites to comply with regulatory requirements;
- failure of our CROs or clinical trial sites to meet their contractual obligations to us in a timely manner, or at all, deviating from the clinical trial protocol or dropping out of a trial;
- delays relating to adding new clinical trial sites;
- delays in establishing necessary pre-clinical or clinical data;
- the occurrence of unexpected severe or serious product-related adverse events in a clinical trial;
- the quality or stability of the product candidate falling below acceptable standards;
- the inability to produce or obtain sufficient quantities of the product candidate to complete clinical trials on time, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- supply chain constraints and inflationary pressures;
- the lack of adequate funding to continue the clinical trial;
- developments observed in trials conducted by competitors for related technology that raises general concerns from regulatory authorities about risk to patients of similar vaccine technology;
- the determination that a product candidate will not be producible in relevant quantities at the manufacturing stage;
- the failure of regulatory authorities such as the FDA, MHRA or TGA to approve our manufacturing processes or facilities or those of contract manufacturers with which we contract for clinical and commercial supplies; and
- the transfer of manufacturing processes to larger-scale facilities operated by contract manufacturers or by us, and delays or failure by our contract manufacturers or us to make any necessary changes to such manufacturing process.

In addition, pre-clinical and clinical data are often susceptible to varying interpretations and analyses and results from post-hoc data analysis may not be predictive of final results and may not support product approval. Many companies that believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval for their product candidates. Regulatory authorities have substantial discretion in the approval process and in determining when or whether regulatory approval will be obtained for any of our product candidates. Additionally, the FDA typically does not accept post-hoc data analyses as support for regulatory approval. Even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by regulatory authorities. Regulatory authorities may disagree with the design or implementation of our clinical trials and may disagree with our interpretation of data from pre-clinical studies or clinical trials.

In some instances, there can be significant variability in safety or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen and other trial procedures and the rate of dropout among clinical trial participants. Further, none of our trials to date of UB-311 have been large enough to determine whether their assessments of efficacy were statistically significant. Therefore, we are able to report potential trends on such measures, but we will not be able to make more definitive statements about the efficacy of our product candidates until we complete clinical trials that are adequately powered to demonstrate statistical significance of clinically meaningful results.

Moreover, for AD, given the difficulties in assessing whether a product candidate is disease-modifying in terms of interrupting disease pathology and delaying cognitive decline, we plan to include in our trial designs for UB-311 biomarker endpoints and, if our trial results warrant, may apply for regulatory approval based on biomarker data. While the FDA recently approved aducanumab based on biomarker data, there is no assurance that the FDA will accept biomarker data for other product candidates, including UB-311, in the future.

Even if we obtain approval of any of our product candidates in one or more jurisdictions, we may never obtain approval for or commercialize any of our products in other jurisdictions, which would limit our ability to realize the full market potential of our product candidates.

To market any products, we must establish and comply with numerous and varying regulatory requirements in different countries regarding safety and efficacy and obtain relevant approvals to market our product candidates. As discussed in another risk factor above

("*Clinical drug development involves a lengthy and expensive process…*") an EUA for UB-612 was denied by the TFDA in August 2021. Approval by a foreign regulatory authority in any other jurisdiction does not ensure approval by comparable regulatory authorities in other countries or jurisdictions, including approval by the FDA in the United States. The failure to obtain approval in one jurisdiction may delay or otherwise negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Approval procedures vary among countries and even if we have obtained approval in one country, approval in other countries can involve additional product testing and validation and additional administrative review periods.

Seeking regulatory approvals in different countries could result in additional and unexpected costs for us, including as a result of additional required pre-clinical studies or clinical trials which would be costly and time-consuming. Satisfying regulatory requirements is costly, time-consuming, uncertain and may be subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. Apart from our ELISA test, which has been approved for sale by the FDA through an EUA, we do not have any product candidates approved for sale in any jurisdiction, including international markets. We do not have experience in obtaining regulatory approval in international markets, and we will be relying on our collaboration partners such as UBIA to assist us in this process. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our ability to realize the full market potential of our products will be harmed.

Interim, "top-line" 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 also subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or top-line data from our pre-clinical studies and clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also may 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. As a result, the top-line or preliminary 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. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our pre-clinical studies and 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 or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our Class A common stock.

For instance, in the fourth quarter of 2022 we announced conclusions from an end-of-treatment analysis of Part B of our Phase 1 trial of UB-312 in PD patients, and top-line results of our Phase 3 trial of UB-612. These conclusions remain subject to change following a more comprehensive review of the data, or following additional data which from the same respective trials or programs that support different conclusions.

Further, others, including regulatory authorities, 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 product candidate or product and the 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 material or otherwise appropriate information to include in our disclosure.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed and result in increased costs and longer development periods or otherwise be adversely affected.

We will be required to identify and enroll a sufficient number of patients for our planned clinical trials. Trial participant enrollment could be limited in future trials given that many potential participants may be ineligible because of pre-existing conditions, medical treatments or other reasons. For example, the next phase of our UB-311 development could be affected by worldwide effects resulting from the Russia-Ukraine conflict and other geopolitical factors. We may not be able to initiate or continue clinical trials required by applicable regulatory authorities or any of our other product candidates that we pursue if we are unable to locate and enroll enough eligible patients or volunteers to participate in these clinical trials. Patient enrollment is affected by other factors, as well, including the incidence and severity of the disease under investigation; the design of the clinical trial protocol; the size and nature of the patient population; the eligibility criteria for the trial in question; the perceived risks and benefits of the product candidate under trial; the perceived safety and tolerability of the product candidate; the proximity and availability of clinical trial sites for prospective patients; the availability of competing therapies and clinical trials; effects of the COVID-19 pandemic on our clinical trial sites; our ability to

monitor patients adequately during and after treatment; patient referral practices of physicians; clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including standard-of-care and any new drugs that may be approved for the indications we are investigating; and efforts to facilitate timely enrollment in clinical trials.

We also may encounter difficulties in identifying and enrolling such patients with a stage of disease appropriate for our ongoing or future clinical trials. In addition, the process of finding and diagnosing patients may prove costly. Our inability to enroll a sufficient number of patients for any of our clinical trials would result in significant delays or may require us to abandon one or more clinical trials.

Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny and post-marketing requirements.

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and ongoing surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a Risk Evaluation and Mitigation Strategy ("REMS") to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if one of our product candidates is approved in the United States or abroad, it will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post- market information. Manufacturers and manufacturers' facilities are required to comply with extensive requirements by regulatory authorities, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. 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 approved marketing application. 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.

If a regulatory authority such as the FDA discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with product quality or the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory authorities may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory authority or enforcement authority may, among other things: issue warning letters; impose civil or criminal penalties; suspend or withdraw regulatory approval; suspend any of our clinical trials; refuse to approve pending applications or supplements to approved applications submitted by us; impose restrictions on our operations, including closing our contract manufacturers' facilities; or seize or detain products, or require a product recall.

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 adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, our business will be seriously harmed. Further, if a regulatory authority identifies previously unknown problems with our platform, any or all of our product candidates may also be affected.

Furthermore, the burden of these requirements may outweigh any benefit or revenue that we could generate from product sales. Even if we obtain regulatory approval for a product candidate, compliance with the many post-approval regulations may be so costly that it becomes financially prudent to abandon the product or sell ownership of the underlying intellectual property at prices that are not sufficient to recoup our investment in developing the product.

Moreover, the policies of regulatory authorities may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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. 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.

We have no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

We commenced operations through UNS and COVAXX in 2014 and 2020, respectively, and as Vaxxinity in March 2021. Our operations to date have been limited to organizing and staffing Vaxxinity, business planning, raising capital, developing our Vaxxine Platform, identifying and testing potential product candidates and conducting clinical trials. We have a limited track record of successfully conducting late-stage clinical trials, obtaining marketing approvals, manufacturing a commercial-scale product or arranging for a third-party to do so on our behalf, or conducting sales and marketing activities necessary for successful product commercialization. Accordingly, you should consider our prospects considering the costs, uncertainties, delays and difficulties frequently encountered by

companies in the early stages of development, especially clinical-stage biopharmaceutical companies such as ours. Any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will eventually need to transition from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to continue to fluctuate significantly 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.

Our product candidates may cause undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following regulatory approval, if any.

Undesirable side effects that may be caused by our product candidates could cause us, our collaboration partners or the regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of approval by regulatory authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our trials could be suspended or terminated and regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The product-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition, results of operations and prospects significantly.

Clinical trials assess a sample of the potential patient population. With a limited number of patients and duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. If our product candidates receive an EUA or regulatory approval and we or others identify undesirable side effects caused by such product candidates (or any other similar products) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such product candidates and require us to take our approved product(s) off the market;
- regulatory authorities may require the addition of labeling statements, such as a “boxed” warning or a contraindication, or submission of field alerts to physicians and pharmacies;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the product candidates;
- actual or potential drug-related side effects could negatively affect patient recruitment or the ability of enrolled patients to complete a trial for our products or product candidates;
- market acceptance of our products by patients and physicians may be reduced and sales of the product may decrease significantly;
- regulatory authorities may require a REMS plan to mitigate risks, which 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;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide or be required to remove such product candidates from the marketplace;
- we could be sued and potentially held liable for injury caused to individuals exposed to or taking our product candidates;
- sales of the product(s) may decrease substantially; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our product candidates, if approved, and therefore could have a material adverse effect on our business, financial condition, results of operations and prospects.

The regulatory landscape that will govern our product candidates is uncertain. Regulations that impact our product candidates are still developing, and changes in regulatory requirements could result in delays or discontinuation of development of our product candidates or unexpected costs in obtaining regulatory approval.

The regulatory requirements to which our product candidates will be subject are complex and uncertainties exist. Even with respect to more established vaccine products, the regulatory landscape is still evolving, especially as it relates to novel adjuvants in vaccines, such as CpG1, which we use at low concentration in our product candidates. Although regulatory authorities decide whether individual clinical trial protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if another regulatory authority has reviewed the trial and authorizes its initiation. The FDA, for example, can place an IND on clinical hold even if other regulatory agencies have provided a favorable review. In addition, adverse developments in clinical trials involving novel adjuvants in vaccines, such as CpG1, conducted by others may cause regulatory authorities to change the requirements for approval of any of our product candidates.

Complex regulatory environments exist in other jurisdictions in which we might consider seeking regulatory approvals for our product candidates, further complicating the regulatory landscape. For example, in the European Union a special committee called the Committee for Advanced Therapies was established within the European Medicines Authority in accordance with Regulation (EC) No 1394/2007 on advanced-therapy medicinal products ("ATMPs"), to assess the quality, safety and efficacy of ATMPs, and to follow scientific developments in the field.

These various regulatory review committees and advisory groups and new or revised guidelines that they promulgate from time to time may lengthen the regulatory review process, require us to perform additional studies or analyses, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. We may face even more cumbersome and complex regulations than those emerging for novel adjuvants. Furthermore, even if our product candidates obtain required regulatory approvals, such approvals may later be withdrawn because of changes in regulations or the interpretation of regulations by applicable regulatory authorities.

Even if we receive regulatory approval to market any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may materially adversely affect our business, financial condition, results of operations and prospects. Further, other jurisdictions may consider our product candidates to be new drugs, not biologics or medicinal products, and require different marketing applications. Even if a regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, product sampling, adverse event reporting, storage, advertising, marketing, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports and registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such products. There also are continuing, annual program user fees for any marketed products. In the United States, biologic manufacturers and their subcontractors 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, which impose certain procedural and documentation requirements upon us and our contract manufacturers. 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 contract manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the product. For example, the FDA has the authority to require a REMS as part of a BLA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved product, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our contract manufacturers or manufacturing processes, or failure to comply with regulatory requirements may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;

- fines, warning letters, untitled letters or holds on clinical trials;

- refusal by regulatory authorities to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- requirements to conduct additional clinical trials, change our product labeling or submit additional applications or application supplements;
- product seizure or detention, or refusal to permit the import or export of products;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

In addition, regulatory policies may change or additional government regulations or legislation may be enacted that could prevent, limit or delay regulatory approval of our product candidates, particularly in countries where elections may result in changes in government administration. If we fail to comply with existing requirements, 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 regulatory approval that we may have obtained or face regulatory or enforcement actions, which may materially adversely affect our business, financial condition, results of operations and prospects.

The FDA strictly regulates the promotional claims that may be made about prescription products in the United States. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. Federal and state government agencies have levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

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 our product candidates.

A breakthrough therapy designation or fast track designation by the FDA for a product candidate may not lead to a faster development or regulatory review or approval process, and it would not increase the likelihood that the product candidate will receive marketing approval.

In 2022 the FDA granted fast track designation to UB-311. We may in the future seek a fast track designation for other of our product candidates, or a breakthrough therapy designation for any of our product candidates. A breakthrough therapy is defined as a product candidate that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product candidate 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 product candidates 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. Product candidates designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the BLA.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to product candidates considered for approval under conventional FDA procedures and it would not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidate no longer meets the conditions for qualification or it may decide that the time period for FDA review or approval will not be shortened. Further, certain of our product candidates, including UB-612, are not eligible for breakthrough therapy designation, and we will be unable to take advantage of such designation for such product candidates.

Fast track designation is designed to facilitate the development and expedite the review of therapies to treat serious conditions and fill an unmet medical need. Programs with fast track designation may benefit from early and frequent communications with the FDA, potential priority review and the ability to submit a rolling application for regulatory review. Fast track designation applies to both the product candidate and the specific indication for which it is being studied. However, even if one or more of our product candidates qualify for fast track designation, we may not be able to meet the criteria of the fast track designation, or if our clinical trials are delayed, suspended or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply, we will not receive the benefits associated with the fast track program. Furthermore, fast track designation does not change the standards for approval. Fast track designation alone does not guarantee qualification for the FDA's priority review procedures. Fast track designation also does not guarantee our product candidate will be approved in a timely manner, if at all.

We plan to seek approval of certain product candidates through the use of an accelerated approval pathway. If we are unable to obtain such approval, we may be required to conduct additional pre-clinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if our product candidates receive accelerated approval from regulatory authorities, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, such regulatory authorities may seek to withdraw accelerated approval.

We are developing certain product candidates for the treatment of serious or life-threatening conditions, including UB-311, and therefore may decide to seek approval of such product candidates under the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it is designed to treat a serious or life-threatening disease or condition and generally provides a meaningful advantage over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, 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. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit.

The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. If the sponsor fails to conduct such studies in a timely manner, or if such post- approval studies fail to validate the drug's predicted clinical benefit, the FDA may withdraw its approval of the drug on an expedited basis.

If we decide to submit a BLA seeking accelerated approval or receive an expedited regulatory designation for our product candidates, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. Failure to obtain accelerated approval or any other form of expedited development, review or approval for a product candidate would result in a longer time period to commercialization of such product candidate, if any, and could increase the cost of development of such product candidate, which could harm our competitive position in the marketplace.

Because we are developing product candidates for the treatment or prevention of diseases in which there is little clinical experience using new technologies, there is increased risk that the FDA or other foreign regulatory authorities may not consider the endpoints of our clinical trials to provide clinically meaningful results and that these results may be difficult to analyze.

As we are developing novel treatments and preventative measures for diseases in which we believe there is limited clinical experience with new endpoints and methodologies, there is heightened risk that the applicable regulatory authorities may not consider the clinical trial endpoints to provide clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. It is difficult to determine how long it will take, if ever, or how much it will cost to obtain regulatory approvals for our product candidates in the United States or other jurisdictions, if ever. Further, approvals by one regulatory authority may not be indicative of what other regulatory authorities may require for approval.

During the regulatory review process, we will need to identify success criteria and endpoints such that regulatory authorities will be able to determine the clinical efficacy and safety profile of any product candidates we may develop. Because our initial focus is to identify and develop product candidates to treat or prevent diseases in which there is little clinical experience using new technologies, there is heightened risk that regulatory authorities may not consider the clinical trial endpoints that we propose to provide clinically meaningful results. In addition, the resulting clinical data and results may be difficult to analyze.

In the United States, the FDA also weighs the benefits of a product against its risks, and the FDA may view the efficacy results in the context of safety as not being supportive of regulatory approval. Foreign regulatory authorities may make similar comments with respect to these endpoints and data. Any product candidate we may develop will be based on a novel technology that makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval.

We and our collaboration partners have conducted and intend to conduct additional clinical trials for selected product candidates at sites outside the United States, and for any of our product candidates for which we seek approval in the United States, the FDA may not accept data from trials conducted in such locations or may require additional U.S.-based trials.

We and our collaboration partners have conducted, currently are conducting and intend in the future to conduct, clinical trials outside the United States, including but not limited to Australia, Belgium, Netherlands, Panama, Philippines and Taiwan.

Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be conducted by qualified investigators in accordance with GCPs, and the FDA must be able to validate the trial data through an on-site inspection, if necessary. Generally, the patient population for any clinical trial conducted outside of the United States must be representative of the population for which we intend to seek approval in the United States. There can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from any clinical trials that we or our collaboration partners conduct outside the United States, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay or permanently halt our ability to develop and market these or other product candidates in the United States. In other jurisdictions, there is a similar risk regarding the acceptability of clinical trial data conducted outside of that jurisdiction.

In addition, there are risks inherent in conducting clinical trials in multiple jurisdictions, inside and outside of the United States, such as:

- regulatory and administrative requirements of the jurisdiction where the trial is conducted that could burden or limit our ability to conduct our clinical trials;
- foreign exchange fluctuations;
- manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research; and
- the risk that the patient populations in such trials are not considered representative as compared to the patient population in the target markets where approval is being sought.

If any of our product candidates receive EUA or regulatory approval, such products may not achieve broad market acceptance among government agencies, physicians, patients, the medical community and third-party payors, in which case revenue generated from their sales would be limited.

The commercial success of our product candidates and our ability to generate revenues from our products will depend upon their acceptance among government agencies, physicians, patients, the medical community, and third-party payors. The degree of market acceptance of our product candidates will depend on a number of factors, including:

- limitations or warnings contained in the approved labeling for a product candidate and any other product insert requirements of regulatory authorities;
- changes in the standard of care for the targeted indications for any of our product candidates;
- limitations in the approved clinical indications for our product candidates;
- demonstrated clinical safety and efficacy compared to other products;
- the impact of disease variants, such as the Delta or Omicron variant of SARS-CoV-2, on the efficacy and marketability of our product candidates targeting such diseases;
- presence of significant adverse side effects, and the prevalence and severity of any side effects;
- sales, marketing and distribution support;
- availability of coverage and extent of reimbursement from managed care plans and other third-party payors;
- timing of market introduction and perceived effectiveness of our products as well as competitive products;
- continued projected growth of the markets in which our products compete;

- the degree of cost-effectiveness of our product candidates;
- the impact of past product price increases and limitations on future price increases for our products;
- availability of alternative therapies;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second or third-line therapy for particular diseases;
- whether the product can be used effectively with other therapies to achieve higher response rates;
- adverse publicity about our product candidates or favorable publicity about competitive products;
- if and when we are able to obtain regulatory approvals for indications for our products;
- our ability to establish and maintain a continuous supply of our products for commercial sale;
- potential or perceived advantages or disadvantages of our products over alternative treatments;
- convenience and ease of administration of our products; and
- the effect of current and future healthcare laws.

If any of our product candidates are approved, but do not achieve an adequate level of acceptance by government agencies as well as physicians, patients and the medical community, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

We may focus on potential product candidates that may prove to be unsuccessful and such focus may require us to forego opportunities to develop other product candidates that may prove to be more successful.

We may choose to focus our efforts and resources on a potential product candidate that ultimately proves to be unsuccessful, or to license or purchase a marketed product that does not meet our financial expectations. Furthermore, we have limited financial and personnel resources and are placing significant focus on the development of our lead product candidates, and as such, we may forgo or delay pursuit of opportunities with other future product candidates that later prove to have greater commercial potential. Our spending on current and future research and development programs and other future product candidates for specific indications may not yield any commercially viable future product candidates and could result in spending on raw materials that cannot be repurposed. As a result of our resource allocation decisions, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases that may later prove to have greater commercial potential, fail to identify novel product candidates that may be successful, or relinquish valuable rights to such product candidates through collaboration, licensing or other arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights. If we are unable to identify and successfully commercialize additional suitable product candidates, or if the additional product candidates we do identify and develop prove to be ineffective, incapable of being commercialized on a large scale or otherwise fail to achieve market success, this would adversely impact our business strategy and our financial position.

Risks Related to Our Financial Position and Need for Additional Capital

We cannot assure you of the adequacy of our capital resources to successfully complete the development, and if approved, commercialization of our product candidates, and a failure to obtain additional capital, could force us to delay, limit, reduce or terminate one or more of our product development programs or commercialization efforts.

As of December 31, 2022, the Company had $87.9 million of highly liquid assets to fund operations, including $33.5 million of cash and cash equivalents, $53.4 million of short-term investments, and a $1.1 million restricted cash balance of which $1.0 million is restricted for the reimbursement of certain research and development expenses related to our UB-612 COVID-19 vaccine program. We believe that we will continue to expend substantial resources for the foreseeable future developing our proprietary product candidates. These expenditures will include costs associated with research and development, conducting pre-clinical studies and clinical trials, seeking regulatory approvals, as well as launching and commercializing products approved for sale and costs associated with manufacturing products. In addition, other unanticipated costs may arise. Because the outcomes of our anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our proprietary product candidates.

Our future funding requirements will depend on many factors, including but not limited to:

- the numerous risks and uncertainties associated with developing product candidates and maintaining our platform;
- the number and characteristics of product candidates that we pursue;
- the rate of enrollment, progress, cost and outcomes of our clinical trials, which may or may not meet their primary end-points;
- the timing of, and cost involved in, conducting non-clinical studies that are regulatory prerequisites to conducting clinical trials of sufficient duration for successful product registration;
- the cost of manufacturing clinical supply and establishing commercial supply of our product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- tax and other compliance costs associated with operating in foreign jurisdictions (including any withholding requirements);
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates if clinical trials are successful;
- the timing of, and costs involved in, conducting post-approval studies that may be required by regulatory authorities;
- the cost of commercialization activities for our product candidates, including product manufacturing, pharmacovigilance, marketing and distribution of product candidates generated from our platform and any other product opportunity for which we receive marketing approval in the future;
- the terms and timing of any collaborative, licensing and other arrangements that we are currently party to or may establish, including any required milestone and royalty payments thereunder and any non-dilutive funding that we may receive;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs, if any, and the outcome of any such litigation;
- the timing, receipt and amount of sales of, or royalties or milestones on, our future products, if any, including the risk of potential nonpayment by buyers of our future products, if any;
- the costs to recruit and build the organization including key executives needed to transform to a commercial organization; and
- the costs of operating as a public company, including hiring additional personnel.

In addition, our operating plan may change as a result of many factors currently unknown to us. As a result of these factors, we may need additional funds sooner than planned. We expect to finance future cash needs primarily through public or private equity offerings, strategic collaborations and debt financing. If sufficient funds on acceptable terms are not available when needed, or at all, we could be forced to significantly reduce operating expenses and delay, limit, reduce or terminate one or more of our product development programs or commercialization efforts, which would have a negative impact on our business, financial condition, results of operations and prospects.

We have incurred significant losses since our inception, and we expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

We have incurred significant losses since our inception. We had net losses of approximately $75.2 million, $137.2 million and $40.0 million for the years ended December 31, 2022, 2021 and 2020, respectively. As of December 31, 2022, our consolidated accumulated deficit was $304.7 million. Our expectation is that we will continue to incur losses as we continue our research and development of, and seek regulatory approvals for, our product candidates and maintain and develop new platforms, prepare for and begin to commercialize any approved product candidates and add infrastructure and personnel to support our product development efforts and operations as a public company. We have devoted substantially all of our financial resources and efforts to research and development, including pre-clinical studies and clinical trials and we anticipate that our expenses will continue to increase over the next several years as we continue these activities. The net losses and negative cash flows incurred to date, together with expected future losses, have had, and may continue to have, an adverse effect on our working capital. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. For example, our expenses could increase if we are required by regulatory authorities such as the FDA to perform trials in addition to those that we currently expect to perform, or if there are any delays in completing our currently planned clinical trials, the partnering process for our proprietary product candidates or in the development of any of our proprietary product candidates.

Our revenue to date has been generated from the sales of our ELISA test and the sale of an option to negotiate a license with UNS (which option has expired). Our ability to generate revenue and achieve profitability in the future depends in large part on our ability, alone or with our collaborators, to achieve milestones and to successfully complete the development of, obtain the necessary regulatory approvals for, and commercialize, our product candidates and Vaxxine Platform. We may never succeed in these activities and may never generate revenue from product sales that is significant enough to achieve profitability. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become or remain profitable could depress our market value and could impair our ability to raise capital, expand our business, develop other product candidates or continue our operations. A decline in our value could also cause you to lose all or part of your investment.

Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technology or product candidates.

We expect our expenses to continue to increase in connection with our planned operations. To the extent that we raise additional capital through the sale of our Class A common stock, convertible securities or other equity securities, your ownership interest will be diluted, and the terms of these securities could restrict our operations or include liquidation or other preferences and anti-dilution protections that could adversely affect your rights as a stockholder. The issuance of additional equity securities, or the possibility of such issuance, may cause the market price of our Class A common stock to decline. In addition, debt financing, if available, may result in fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming shares or declaring dividends, that could adversely impact our ability to conduct our business. Securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

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

We cannot be certain that additional funding will be available on acceptable terms, or at all. 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 product candidates or other research and development initiatives. Our current or future license agreements may also be terminated if we are unable to meet the payment or other obligations under the agreements.

Changes in or reinterpretations of tax laws and regulations, including their application to us or our customers as reviewed by the relevant tax authorities, may have a material adverse effect on our business, results of operations, financial condition and prospects.

We are subject to complex and evolving tax laws and regulations. New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of any of our future domestic and foreign earnings. Any new taxes could adversely affect our domestic and international business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us or our customers. Future changes in applicable tax laws and regulations, or their interpretation and application, could have an adverse effect on our business, financial conditions, results of operations and prospects.

In addition, our determination of our tax liability is subject to review by applicable tax authorities. Any adverse outcome of such a review could harm our results of operations, cash flow and overall financial condition. The determination of our tax liabilities requires significant judgment and, in the ordinary course of business, there are many transactions and calculations where the ultimate tax determination is complex and uncertain.

Our ability to use our net operating loss carryforwards and other tax attributes to offset future taxable income may be subject to certain limitations.

As of December 31, 2022, we had U.S. federal net operating loss carryforwards ("NOLs") of $165.1 million, which may be available to offset future taxable income, if any, and have no expiration date but are limited in their usage to an annual deduction equal to 80% of annual taxable income. In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), a corporation that undergoes an "ownership change," generally defined as a greater than 50% change by value in its equity ownership over a three-year period, is subject to limitations on its ability to utilize its pre-change NOLs and its research and other tax attributes to offset future taxable income. Our existing NOLs and tax attributes may be subject to limitations arising from previous ownership changes, and if we undergo future ownership changes, our ability to utilize NOLs and research and tax attributes could be further limited by Sections 382 and 383 of the Code. For these reasons, we may not be able to utilize a portion of our existing NOLs or research and tax attributes.

Adverse developments affecting financial institutions, companies in the financial services industry or the financial services industry generally, such as actual events or concerns involving liquidity, defaults or non-performance, could adversely affect our operations and liquidity.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, or SVB, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver. As of March 10, 2023, we had approximately 11% of our cash and cash equivalent balances on deposit with SVB. Since then, we have moved substantially all of our cash and cash equivalent deposits that were at SVB to another major U.S. financial institution.

Although a statement by the U.S. Department of the Treasury, the Federal Reserve and the FDIC stated that all depositors of SVB would have access to all of their money after only one business day following the date of closure and we and other depositors with SVB received such access on March 13, 2023, uncertainty and liquidity concerns in the broader financial services industry remain. Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. The U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments. However, widespread demands for customer withdrawals or other needs of financial institutions for immediate liquidity may exceed the capacity of such program. There is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions in a timely fashion or at all.

Our access to our cash and cash equivalents in amounts adequate to finance our operations could be significantly impaired by the financial institutions with which we have arrangements directly facing liquidity constraints or failures. For example, as we expect to continue to maintain balances at one or more banks and financial institutions that exceed federally insured limits, in the event of a closure of any such banks or institutions we may not be able to recover our uninsured balances. Even if the U.S. Department of the Treasury, the Federal Reserve and the FDIC provide that depositors would have access to all of their balances, there may be a delay in our ability to access such funds. In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any material decline in available funding or our ability to access our cash and cash equivalents could adversely impact our ability to meet our operating expenses, result in breaches of our contractual obligations or result in violations of federal or state wage and hour laws, any of which could have material adverse impacts on our operations and liquidity.

Risks Related to the Manufacturing of Our Product Candidates

The formulation of peptide-based medicines is complex and manufacturers often encounter difficulties in production. If we, UBI or any of our other contract manufacturers encounter difficulties, our ability to provide product candidates for clinical trials or products, if approved, to patients or future customers could be delayed or halted.

The formulation of peptide-based medicines is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and analytics. We are currently dependent on contract manufacturers, including UBI, its affiliates, CSBioa, Pii, and WuXi STA, to conduct the manufacturing and supply activities for our product candidates and the underlying component parts, but may choose to conduct these manufacturing activities ourselves in the future. If our contract manufacturers are unable to manufacture our product candidates in clinical quantities or, when necessary, in commercial quantities and at sufficient yields, then we will need to identify and reach supply arrangements with additional third parties. Further, our product candidates may be in competition with other products for access to these facilities and may be subject to delays in manufacture if our contract manufacturers give other products higher priority. We and our contract manufacturers must comply with cGMP, regulations

and guidelines for the manufacturing of our product candidates used in pre-clinical studies and clinical trials and, if approved, marketed products. If we or our contract manufacturers do not receive any regulatory approvals, or lose existing approvals, required to manufacture our product candidates, production and fulfilment of orders will be delayed, which may materially adversely affect our business. Manufacturers of biotechnology products often encounter difficulties in production, particularly in scaling up and validating initial production. Furthermore, if microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities where our product candidates are made, such manufacturing facilities may be closed for an extended period of time to investigate and remedy the contamination. Shortages of raw materials may also extend the period of time required to develop our product candidates.

Manufacturing these products requires facilities specifically designed for and validated for this purpose and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. Further, delays in our clinical trials or in any regulatory approvals may result in the expiration of manufactured product, which could in turn lead to further delays. When changes are made to the manufacturing process, we may be required to provide pre-clinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. The use of biologically derived ingredients can also lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with cGMP, lot consistency and timely availability of raw materials. Even if we obtain marketing approval for any of our product candidates, there is no assurance that we or our manufacturers will be able to manufacture the approved product to specifications acceptable to regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial launch of the product or to meet potential future demand. If we or our manufacturers are unable to produce sufficient quantities for clinical trials, advance purchase commitments or commercialization, more generally, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and prospects.

We cannot assure you that any disruptions or other issues relating to the manufacture of any of our product candidates will not occur in the future. Any delay or interruption in the supply of clinical trial supplies could delay the completion of planned clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Any adverse developments affecting clinical or commercial manufacturing of our product candidates or products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the supply of our product candidates. We may also have to take inventory write-offs and incur other charges and expenses for product candidates that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could delay or impede the development and commercialization of any of our product candidates and could have an adverse effect on our business, financial condition, results of operations and prospects.

We and our contract manufacturers and suppliers could be subject to liabilities, fines, penalties or other sanctions under federal, state, local and foreign environmental, health and safety laws and regulations if we or they fail to comply with such laws or regulations or otherwise incur costs that could have a material adverse effect on our business.

We currently rely on and expect to continue to rely on contract manufacturers for the manufacturing and supply of our product candidates and custom components. We and these contract manufacturers are subject to various federal, state, local and foreign environmental, health and safety laws and regulations, including those governing laboratory procedures and the generation, handling, labeling, transportation, use, manufacture, storage, treatment and disposal of hazardous materials and wastes and worker health and safety. We do not have control over a manufacturer's or supplier's compliance with environmental, health and safety laws and regulations. Liabilities they incur pursuant to these laws and regulations could result in significant costs or in certain circumstances, an interruption in operations, any of which could adversely affect our business, financial condition, results of operations and prospects.

With respect to any hazardous materials or waste which we are currently, or in the future will be, generating, handling, transporting, using, manufacturing, storing, treating or disposing of, we cannot eliminate the risk of contamination or injury from these materials or waste, including at third-party disposal sites. In the event of such contamination or injury, we could be held liable for any resulting damages and liability. We also could be subject to significant civil or criminal fines and penalties, cessation of operations, investigation or remedial costs or other sanctions for failure to comply with applicable environmental, health and safety laws. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts or otherwise have a material adverse effect on our business.

Undetected errors or defects in our production could harm our reputation or expose us to product liability claims.

Undetected errors and defects in the cGMP materials used in the production of our product candidates could result in a lower quality of any products we produce, and could give rise to reputational harm to us and to the contract manufacturers with whom we work. If any such errors or defects are discovered, we may incur significant costs, the attention of our key personnel could be diverted, or other significant problems may arise. We may also be subject to warranty and liability claims for damages related to errors or defects in products made with our cGMP materials. In addition, if we do not meet industry or quality standards, if applicable, such products may be subject to recall. A material liability claim, recall or other occurrence that harms our reputation or decreases market acceptance of such products could harm our business and operating results.

Risks Related to Our Reliance on UBI, Collaborators and Other Third Parties

Conflicts of interest and disputes have and may arise between us and UBI and its affiliates, and these conflicts and disputes might ultimately be resolved in a manner unfavorable to us.

UBI is our largest stockholder, the licensor of certain of our intellectual property and is a commercial partner for the Company. In addition, Dr. Chang Yi Wang, UBI's founder, holds shares of our common stock. Our co-founders (Mei Mei Hu and Louis Reese), one of their affiliates and UBI (collectively, our "principal stockholders"), are party to a voting agreement (the "Voting Agreement,"), which provides Mei Mei Hu with the authority (and irrevocable proxies) to vote the shares of capital stock held by the stockholders party to the Voting Agreement at her discretion on all matters to be voted upon by stockholders. Our CEO, Mei Mei Hu, our Chairman, Louis Reese and our shareholder and former director James Chui, also serve on and constitute a majority of the board of directors of UBI. UBI's equity interests in the Company, and the overlapping directorships, could give rise to conflicts of interest, in particular when a decision could favor the interests of UBI (or its affiliates) or us over the other. Further, we have historically depended heavily on UBI and its affiliates for our business operations, including the provision of research, development and manufacturing services. While we have taken steps to separate our operations from those of UBI and currently anticipate taking additional steps to lessen our dependence, we still have ongoing relationships with UBI and its affiliates. With respect to our UB-612 program, we have partnered with UBIA for the development of UB-612 in Taiwan, UBIP for the formulation-fill-finish services, and UBP as the sole manufacturer of protein. Relating to our chronic disease pipeline, we continue to work with UBIP and UBIA for the production and testing of clinical material for our UB-312 program.

Conflicts of interest may arise with respect to existing or possible future commercial arrangements between us and UBI or any of its affiliates in which the terms and conditions of the arrangements are subject to negotiation or dispute. For example, conflicts of interest could arise over matters such as:

- disputes over the cost or quality of the manufacturing and testing services provided to us by UBI with respect to our product candidates;
- the allocation of UBI's resources as between our business objectives and UBI's own objectives;
- a decision whether to engage UBI or its affiliates in the future to manufacture, test and supply of additional custom components or product candidates for us;
- decisions as to which particular product candidates we will commit sufficient development efforts to; or
- business opportunities unrelated to our current products that may be attractive both to us and to the other company.

We also cannot guarantee conflicts of interest will not arise in connection with the negotiation or execution of any future agreement with UBI, its affiliates or any other related party.

Further, we have been advised that there is currently an ongoing dispute within UBI between Dr. Wang and the other four members of UBI's board of directors relating to certain corporate governance matters, including the overall management and control of UBI, as well as its relationship with the Company. Specifically, we have been advised that Dr. Wang attempted to replace the UBI board of directors in July and August 2021 and asserted that she is the majority shareholder of UBI, which we understand UBI's other directors dispute as invalid and incorrect, respectively. This dispute has created risks and uncertainties for us, and this dispute or any resolution of it could negatively impact us, including, without limitation, by impairing our ability to work with UBI and its affiliates as a commercial partner in the future and/or otherwise adversely affecting other existing arrangements with or involving UBI or its affiliates. Late in the day on November 9, 2021, counsel to the Company received correspondence on behalf of Dr. Wang (the "Correspondence"). The Correspondence outlined Dr. Wang's concerns that the preliminary prospectus for our initial public offering, subject to completion, dated November 5, 2021 did not accurately describe the relationship between the Company and UBI, namely the Company's ability to operate independently from UBI. The Correspondence also relayed Dr. Wang's concerns that the preliminary prospectus did not fully describe the disruption to the Company's business that could result from the abovementioned dispute, including with respect to intellectual property agreements among the Company and UBI and its affiliates. Various other claims have been made by Dr. Wang

regarding UBI's corporate governance, the operations of the Company and the disclosures for our initial public offering, and the Company cannot predict the course of this dispute. However, the Company has carefully considered Dr. Wang's concerns and, based on the disclosures included in the preliminary prospectus and in the final prospectus for our initial public offering and the Company's diligence efforts, the Company remains confident in the appropriateness and accuracy of its disclosures.

We will rely on contract manufacturers for the manufacture of raw materials for our research programs, pre-clinical studies and clinical trials and we do not have long-term contracts with many of these parties. This reliance on contract manufacturers increases the risk that we will not have sufficient quantities of such materials or product candidates that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost or on an acceptable timeline, which could delay, prevent or impair our development or commercialization efforts.

We rely on contract manufacturers, including UBI and its affiliates, for the manufacture of raw materials for our clinical trials and pre-clinical and clinical development. We do not have a long-term agreement with some of the contract manufacturers we currently use to provide pre-clinical and clinical raw materials. Certain of these manufacturers are critical to our production, and the loss of these manufacturers to one of our competitors or otherwise, or an inability to obtain quantities at an acceptable cost or quality, could delay, prevent or impair our ability to timely conduct pre-clinical studies or clinical trials, and would materially adversely affect our development and commercialization efforts.

We expect to continue to rely on contract manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval, if any. We may be unable to maintain or establish long-term agreements with contract manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with contract manufacturers, reliance on contract manufacturers entails additional risks, including:

- the failure of the contract manufacturer to manufacture our product candidates according to our schedule, or at all, including if our contract manufacturers give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our contract manufacturers at a time that is costly or inconvenient for us;
- the breach by the contract manufacturers of our agreements with them;
- the failure of contract manufacturers to comply with applicable regulatory requirements;
- the failure of the contract manufacturer to manufacture our product candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation or unauthorized disclosure of our intellectual property or other proprietary information, including our trade secrets and know-how.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both custom components and finished products. Contract manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of applicable regulatory authorities, they will not be able to secure and/or maintain authorization for their manufacturing facilities. In addition, we do not have full control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Further, our manufacturing partners may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all, and quality issues may arise during any such scale-up activities. If regulatory authorities do not authorize these facilities for the manufacture of our product candidates or if they withdraw any such authorization in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our contract manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations.

We depend on strategic partnerships, collaborations and license agreements in connection with the research, development and commercialization of our Vaxxine Platform and product candidates. If our existing or future partners, collaborators or licensees do not perform as expected, if we fail to maintain any of these strategic partnerships, collaborations or license agreements, or if they are not successful, our ability to commercialize our product candidates successfully and to generate revenues may be materially adversely affected.

We have established and intend to continue to establish strategic partnerships, collaborations, licensing agreements, or other arrangements with third parties. For our research, development and commercialization activities, we have depended, and will continue to depend, on our partners to design and conduct their own clinical studies. As a result, these activities may not be able to be conducted in the manner or on the time schedule we currently contemplate, which may negatively impact our business operations. While we have certain contractual rights to information about pre-clinical and clinical developments and results under certain of our collaboration and license agreements, including our agreements with UBIA and Aurobindo, we cannot be certain that clinical trials conducted in connection with such collaboration programs will be conducted in a manner consistent with the best interests of our business. In addition, if any of our partners, collaborators or licensees withdraw support for these programs or proposed products or otherwise impair their development, our business could be negatively affected. Also, our inability to find a partner for any of our product candidates may result in our termination of that specific product candidate program or evaluation of a product candidate in a particular indication. Because of contractual restraints and the limited number of contract manufacturers with the expertise, required regulatory approvals and facilities to manufacture our product candidates on a commercial scale, replacement of a contract manufacturer may be expensive and time-consuming and may cause interruptions in the production of our product candidates, which could delay our clinical trials or interrupt our potential future commercial sales. Even if we find or establish a strategic partner, collaborator or licensee for one or more of our product candidates, there is no assurance that upon the approval of one or more of such product candidates that such product candidates will be successfully commercialized.

Furthermore, our licenses and collaboration agreements impose, and any future agreement we enter into may also impose, restrictions on our ability to license certain of our intellectual property to third parties or to develop or commercialize certain product candidates or technologies ourselves.

In the future, we may enter into additional collaborations or license agreements to fund our development programs or to gain access to sales, marketing or distribution capabilities of other parties. While certain of our existing collaboration and license agreements, including our agreements with Aurobindo, impose development or commercialization obligations on our collaborators or licensees, we cannot be certain that our collaboration partners will allocate sufficient resources or attention to our collaboration programs, that they will progress our collaboration programs consistent with the best interests of our business or that they will otherwise meet their obligations under these agreements in a timely manner or at all. Our existing collaborations and licenses, and any future collaborations and licenses we enter into, therefore may pose a number of risks, including the following:

- collaborators or licensees may have significant discretion in determining the efforts and resources that they will apply to developing or commercializing our product candidates, and they may not sufficiently fund the development or commercialization of a product candidate;

- collaborators and licensees may not perform their obligations as expected by us or by health authorities, such as the FDA or comparable foreign regulatory authorities;

- collaborators and licensees may dissolve, merge, be bought or may otherwise become unwilling to fulfill the initial terms of the collaboration with us, or we may be unwilling to continue our arrangement following such an occurrence;

- collaborators and licensees may fail to perform their obligations under their agreements or may be slow in performing their obligations;

- collaborations and licensees may be terminated for the convenience of the collaborator or licensee and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates;

- collaborators and licensees may not pursue commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' or licensees' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities, or due to the actual or perceived competitive situation in a specific indication;

- collaborators and licensees may delay clinical trials, stop a clinical trial or abandon a product candidate, repeat or conduct additional clinical trials or may require a new formulation of a product candidate for clinical testing;

- collaborators and licensees could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;

- disagreements with collaborators or licensees, including disagreements over proprietary rights, contract interpretation and breach of contract claims, payment obligations or the preferred course of development, might cause delays or termination of the research, development or commercialization of products or product candidates, might lead to additional responsibilities, including financial obligations for us with respect to products or product candidates, or delays or withholding of payments due to us or might result in litigation or arbitration, any of which would be time- consuming and expensive, and could limit our ability to execute on our strategies and delay or prevent our ability to devote resources to other product candidates;

- collaborators or licensees may not properly obtain, maintain, enforce or defend our intellectual property or may use our proprietary information in such a way that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation; and

- collaborators may infringe, misappropriate or otherwise violate the intellectual property of third parties, which may expose us to litigation and potential liability.

If our collaborations and licenses related to the research, development and commercialization of product candidates do not result in the successful development and commercialization of our product candidates, or if one of our collaborators or licensees terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration or license, and we may be unable to continue the development and commercialization of the product candidate. Further, even if our collaborations and licenses do result in successful development and commercialization of products, if one of our collaborators breaches its obligations under its agreement with us or enters bankruptcy or insolvency, there may be a material delay in our receipt of payments under such agreements, or we may never receive such payments. If we do not receive the payments we expect under these agreements, our own development and commercialization activities could be delayed or prevented altogether, and we may need to secure additional resources to develop our proprietary product candidates. Moreover, maintaining our relationships with our collaborators and licensees may divert significant time and effort of our scientific staff and management team, which may harm our ability to effectively allocate our resources to multiple internal and other projects. All of the risks relating to product development, regulatory approval and commercialization described in this report also apply to the activities of our collaborators and licensees.

Additionally, subject to its contractual obligations to us, if one of our collaborators or licensors is involved in a business combination, merger, acquisition or other similar transaction, the collaborator or licensor might deprioritize or terminate the development or commercialization of any product candidate licensed to it by us. If one of our collaborators or licensors terminates its agreement with us, we may be unable to attract new collaborators in a timely manner or at all, which may delay or prevent our ability to develop or commercialize one or more of our product candidates.

We rely on third parties to conduct our pre-clinical studies and clinical trials and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or comply with legal and regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon CROs to execute certain of our pre-clinical and clinical trials, and to monitor and manage data for our ongoing pre-clinical and clinical programs and to provide us with significant data and other information related to our projects, pre-clinical studies and clinical trials. If such third parties provide inaccurate, misleading or incomplete data, our business, financial condition and results of operations and prospects could be materially adversely affected. We have control over limited aspects of our CROs' activities; nevertheless, we are responsible for, and our reliance on CROs does not relieve us of our responsibilities for, ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory, scientific and ethical standards. We and our CROs and other vendors are required to comply with cGMP, GCP, Good Laboratory Practice ("GLP") and other laws, regulations and guidelines enforced by applicable regulatory authorities for all of our product candidates during both pre-clinical and clinical development. Regulatory authorities enforce these regulations through periodic inspections of study sponsors, principal investigators, trial sites and other contractors. If we or any of our CROs or vendors fail to comply with applicable regulations, the data generated in our pre-clinical and clinical trials may be deemed unreliable and regulatory authorities may require us to perform additional pre-clinical and clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that all of our clinical trials comply with cGCP regulations or other applicable laws and regulations. Our failure to comply with applicable laws and regulations may require us to repeat clinical trials, which would delay the regulatory approval process and require significant additional expenditures, which we may be unable to meet.

If any of our relationships with these CROs terminates, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms or in a timely manner. We would also incur additional costs and delays while engaging a new CRO, which we may not be able to engage on commercially reasonable terms or at all. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing pre-clinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations, meet expected deadlines, conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements, or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates in a timely manner or at all. For example, due to an error by the CRO responsible for administering blinded placebo and active doses to trial subjects, which reduced the confidence of subsequently collected data, we decided to discontinue a Phase 2a LTE trial for UB-311. In that case, however, we determined that we had collected sufficient data on UB-311's tolerability and immunogenicity. CROs or any of our other collaborators may also generate higher costs than anticipated. As a result, our results of operations and the commercial prospects for our product candidates could be harmed, our costs could increase and our ability to generate revenue could be delayed.

Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, results of operations and prospects.

We do not have multiple sources of commercial supply for some of the components used in our product candidates, nor long-term supply contracts with our existing suppliers, and certain of our suppliers are critical to our production. If we were to lose a critical supplier or if an approved supplier experiences delays due to raw material constraints, it could have a material adverse effect on our ability to complete the development of our product candidates. If we obtain regulatory approval for any of our product candidates, we cannot guarantee that our suppliers will be able to meet our increased demands for supply.

We do not have multiple sources of commercial supply for each of the components used in the manufacturing of our product candidates, nor do we have long-term supply agreements with all of our component suppliers. Manufacturing suppliers are subject to cGMP quality and regulatory requirements, covering manufacturing, testing, quality control and record keeping relating to our product candidates and are subject to ongoing inspections by applicable regulatory authorities. Manufacturing suppliers are also subject to licensing requirements as well as local, state and federal regulations and regulations in foreign jurisdictions in which they operate. Failure by any of our suppliers to comply with all applicable regulations and requirements may result in long delays and interruptions in supply.

The number of suppliers of the raw material components of our product candidates is limited. In the event it is necessary or desirable to acquire supplies from alternative suppliers, we might not be able to obtain such supply on commercially reasonable terms, if at all. It could also require significant time and expense to redesign our manufacturing processes to work with another company and redesign of processes can trigger the need for conducting additional studies such as comparability or bridging studies. Additionally, certain of our suppliers are critical to our production, and the loss of these suppliers to one of our competitors or otherwise would materially adversely affect our development and commercialization efforts. Further, if such critical suppliers experience delays in their ability to supply of components due to limited availability of raw materials or other difficulties which may be beyond our or their control, our manufacturing efforts may be materially adversely affected.

As part of any marketing approval, regulatory authorities conduct inspections that must be successful prior to the approval of a product candidate. Failure of manufacturing suppliers to successfully complete these regulatory inspections will result in delays. If supply from the approved supplier is interrupted, an alternative vendor would need to be qualified through an NDA amendment or supplement, and this could result in significant disruption in commercial supply. Regulatory authorities may also require additional studies if a new supplier is relied upon for commercial production. Switching vendors may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

If we are unable to obtain the supplies we need at a reasonable price or on a timely basis, it could have a material adverse effect on our ability to complete the development of our product candidates or, if we obtain regulatory approval for our product candidates, to commercialize them.

Risks Related to Our Intellectual Property Rights

We depend on intellectual property licensed from UBI and its affiliates, the termination of which could result in the loss of significant rights, which would harm our business.

We are dependent on technology, patents, know-how and proprietary information, both our own and those licensed from UBI and its affiliates. We entered into the Platform License Agreement in August 2021 pursuant to which we obtained a worldwide, sublicensable (subject to certain conditions), perpetual, fully paid-up, royalty-free (i) exclusive license (even as to the Licensors) under all patents owned or otherwise controlled by the Licensors or their affiliates existing as of the effective date of the Platform License Agreement,

(ii) exclusive license (except as to the Licensors) under all patents owned or otherwise controlled by the Licensors or their affiliates arising after the effective date during the term of the Platform License Agreement, and (iii) non-exclusive license under all know-how owned or otherwise controlled by the Licensors or their affiliates existing as of the effective date or arising during the term of the Platform License Agreement, in each of the foregoing cases, to research, develop, make, have made, utilize, import, export, market, distribute, offer for sale, sell, have sold, commercialize or otherwise exploit peptide-based vaccines in the field of all human prophylactic and therapeutic uses, except for such vaccines related to human immunodeficiency virus, herpes simplex virus and Immunoglobulin E. The patents licensed to us under the Platform License Agreement include patents directed to a CpG delivery system, artificial T helper cell epitopes and certain designer peptides and proteins that are used in our product candidates. Any termination of these licenses will result in the loss of significant rights and will restrict our ability to develop and commercialize our product candidates.

Our reliance on in-licensed intellectual property and technology results in a number of risks to the development and commercialization of our product candidates, including the loss of such rights, our licensors' inability or refusal to enforce or defend such rights, and the requirement to pay royalties, milestones, and other amounts.

Agreements under which we license intellectual property or technology to or from UBI, its affiliates and from other third parties may be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. Our business may also suffer if any current or future licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms or at all. In the event of a bankruptcy by one of our licensors, our intellectual property licenses could also be affected. For example, while the U.S. Bankruptcy Code allows a licensee to retain its rights under its license notwithstanding the bankrupt licensor's rejection of such license, such protections may not be available to us in the event a licensor declares bankruptcy in a foreign jurisdiction. Our licensors may also own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensors' rights.

Furthermore, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

We believe the growth of our business may depend in part on our ability to acquire or in-license additional intellectual property rights, including to advance our research or allow commercialization of our product candidates. If we are unable to obtain additional licenses we need to develop and commercialize our product candidates, or if we obtain such licenses and they are terminated, we may be required to expend considerable time and resources in an attempt to develop or license replacement technology. We may also need to cease use of the compositions or methods covered by such third-party intellectual property rights, and our ability to license or develop alternative approaches that do not infringe on such intellectual property rights may entail significant additional costs and development delays, even if we were able to develop or license such alternatives, which may not be feasible.

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire. Even if we are able to obtain a license under such intellectual property rights, any such license may be non-exclusive, which may allow our competitors' access to the same technologies licensed to us.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including those relating to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;

- our compliance with reporting, financial or other obligations under the license agreement;
- the amount and timing of payments owed under license agreements; and
- the allocation of ownership of inventions and know-how resulting from the creation or use of intellectual property by our licensors and by us and our partners.

We may also not be able to fully protect our licensed intellectual property rights or maintain our licenses under our licensing arrangements. Our existing and future licensors could retain the right to prosecute, maintain, defend and enforce the intellectual property rights licensed to us, in which case we would depend on the ability and will of our licensors to do so. Our licensors may take different approaches to prosecuting patents than we would, and it is possible our inability to control such activities could harm our business. Furthermore, our licensors may determine not to pursue litigation against other companies or may pursue such litigation less aggressively than we would. We may also rely upon obtaining the consent of our licensors to settle legal claims. If our licensors do not adequately protect or enforce such licensed intellectual property, competitors may be able to use such intellectual property and erode or negate any competitive advantage we may have, which could materially harm our business, negatively affect our position in the marketplace, limit our ability to commercialize our products and product candidates and delay or render impossible our achievement of profitability.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms or at all, we may be unable to successfully develop and commercialize the affected product candidates. We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to develop or commercialize our products could suffer.

Furthermore, our existing license agreements may impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us and if our licensors, licensees or collaborators conclude that we have failed to comply with our obligations under these agreements, including due to the impact of the COVID-19 pandemic on our business operations or our use of the intellectual property licensed to us in a manner the licensor believe is unauthorized, or we are subject to a bankruptcy, we may be required to pay damages and the licensor may have the right to terminate the license. Any of the foregoing 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. We might not have the necessary rights or the financial resources to develop, manufacture or market our current or future product candidates without the rights granted under our licenses, and the loss of sales or potential sales in such product candidates could have a material adverse effect on our business, financial condition, results of operations and prospects.

Moreover, our rights to our in-licensed patents and patent applications may depend, in part, on inter- institutional or other operating agreements between the joint owners of such in-licensed patents and patent applications or the owners of such in-licensed patents and patent applications and their affiliates. We may not be aware of each party's rights and obligations under such inter-institutional or other operating agreements and, as such, the ownership of our in-licensed patents and patent applications may be uncertain. If one or more of these owners breaches such inter-institutional or other operating agreements, our rights to such in-licensed patents and patent applications may be adversely affected. In addition, the development of certain of our product candidates may be funded by grants that impose certain pricing limitations on such product candidates and limit our ability to commercialize such product candidates and to achieve or maintain profitability. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

We may be required to license or obtain rights to use third party intellectual property or technology in connection with the development and commercialization of our product candidates.

We may not be aware of all technologies developed or under development by third parties, and other pharmaceutical companies or academic institutions may also have filed or may be planning to file patent applications potentially relevant to our business and product candidates. The technologies used in connection with the formulations of our product candidates may also be covered by intellectual property rights held by others. From time to time, in order to avoid infringing these third-party patents, we may be required to license technology from additional third parties to further develop, manufacture, use, sell or commercialize our product candidates, or that we otherwise deem necessary for our business operations. We may fail to obtain any such licenses at a reasonable cost or on reasonable terms, if at all, and as a result we may be unable to develop or commercialize the affected product candidates, and we may have to abandon development of the relevant research programs or product candidates, which would harm our business.

If we are unable to obtain and maintain intellectual property protection for our products or product candidates, or if the duration or scope of our intellectual property protection is not sufficiently broad, our ability to commercialize our product candidates successfully and to compete effectively may be materially adversely affected.

Our success depends on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our current and future proprietary product candidates. We rely upon a combination of patents, trade secret

protection and confidentiality agreements to protect the intellectual property related to our technology, manufacturing processes, products and product candidates. We, UBI and our other collaborators and licensors have primarily sought to protect our proprietary positions by filing patent applications in the United States and abroad related to our proprietary technology, manufacturing processes and product candidates that are important to our business. Despite our or our third party collaborators' or licensors' efforts to protect these proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary. Third parties may also seek to invalidate our patents or those of our licensors. If we are unable to obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our technology, product candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. We could also lose expected revenues under license agreements we maintain with third parties. If we are unable to obtain or maintain our intellectual property, we may be unable to develop or commercialize the affected technology and product candidates or could lose revenue, either of which could harm our business, financial condition, results of operations and prospects significantly.

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 or in all jurisdictions where protection may be commercially advantageous. It is also possible that we may fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

In addition, we, UBI or our other collaborators and licensors, may only pursue, obtain or maintain patent protection in a limited number of countries. Because patent applications in the United States, Europe and many other foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we or our licensors were the first to make the inventions claimed in any of our owned or any in-licensed issued patents or pending patent applications, or that we or our licensors were the first to file for protection of the inventions set forth in our patents or patent applications. As a result, we may not be able to obtain or maintain protection for certain inventions, and there can be no assurance that the patents we file, or those that are issued, will not be vulnerable to claims of invalidity or unenforceability.

Even if patents do successfully issue, our owned or in-licensed patents may not adequately protect our intellectual property, provide exclusivity for our products or product candidates, prevent others from designing around our claims or otherwise provide us with a competitive advantage. Competitors may use our technologies in jurisdictions where we have not obtained or are unable to adequately enforce patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States and Europe. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing with us. We also cannot offer any assurances about which, if any, patents will issue, the breadth of any such patents or whether any issued patents will be found invalid or unenforceable or will be threatened by third parties. In addition, third parties may challenge the validity, enforceability, ownership, inventorship or scope of any of our patents. Any successful challenge to any of our patents or our in-licensed patents could deprive us of rights necessary for the successful commercialization of any product candidate that we may develop and could impair or eliminate our ability to collect future revenues and royalties with respect to such products or product candidates. If any of our patent applications with respect to our product candidates fail to issue as patents, if their breadth or strength of protection is narrowed or threatened, or if they fail to provide meaningful exclusivity or competitive position, it could dissuade companies from collaborating with us or otherwise adversely affect our competitive position.

In addition, patents have a limited lifespan. In the United States, for example, the natural expiration of a patent is generally 20 years after its effective filing date. Various extensions may be available, however, the life of a patent and the protection it affords is limited. Given the amount of time required for the development, testing, regulatory review and approval of new product candidates, our patents protecting such candidates might expire before or shortly after such candidates are commercialized. If we encounter delays in obtaining regulatory approvals, the period of time during which we could market a product under patent protection could be further reduced. Even if patents covering our product candidates are obtained, once such patents expire, or if such patents are waived or suspended, we may be vulnerable to competition from similar or biosimilar products. Any expiration, waiver or suspension of our patent or other intellectual property protection by the U.S. or other foreign governments could lead to the launch of a similar or biosimilar version of one of our products and would likely result in an immediate and substantial reduction in the demand for our product, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may not be able to protect or enforce our intellectual property rights in all jurisdictions, and we cannot guarantee that the patent rights we have will prevent others from competing with us.

The patent position of pharmaceutical companies is generally uncertain because it involves complex legal, scientific and factual considerations for which legal principles remain unsolved. The standards applied by the United States Patent and Trademark Office ("USPTO") and foreign patent offices in granting patents are not always applied uniformly or predictably, and can change. Additionally, the laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant challenges in protecting and defending such rights in foreign jurisdictions. We may face similar challenges. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of

patents and other intellectual property rights, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement, misappropriation or other violation of our patents or other intellectual property, including the unauthorized reproduction of our manufacturing or other know-how or the marketing of competing products in violation of our intellectual property rights generally. Any of these outcomes could impair our ability to prevent competition from third parties, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

Further, the existence of issued patents does not guarantee our right to practice the patented technology or commercialize a patented product candidate. Third parties may design around our patents, or have or obtain rights to patents which they may use to prevent or attempt to prevent us from practicing our patented technology or commercializing any of our patented product candidates. As a result, we could be prevented from selling our products unless we were able to obtain a license under such third-party patents, which may not be available on commercially reasonable terms or at all. In addition, third parties may seek approval to market their own products similar to or otherwise competitive with our products and such products may not violate our patent rights. We may also need to assert our patents against third parties, including by filing lawsuits alleging patent infringement. In any such proceeding, a third party may assert, and a court or agency of competent jurisdiction may find, our asserted patents to be invalid or unenforceable. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights. Proceedings to defend or enforce our patent rights, whether or not successful and whether or not meritorious, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or held unenforceable, or interpreted more narrowly. There can be no assurance that we will have sufficient financial or other resources to file and pursue such claims, which often last for years before they are concluded. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us, especially as we gain greater visibility and market exposure as a public company. In addition, our enforcement of our patent rights could provoke third parties to assert counterclaims against us. Third parties also may raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. We may not prevail in any lawsuits or administrative proceedings that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we could lose part or all of the patent protection on one or more of our product candidates, which could result in our competitors and other third parties using our technology to compete with us. An adverse outcome in a litigation or administrative proceeding involving our patents could limit our ability to assert our patents against competitors, affect our ability to receive royalties or other licensing consideration from our licensees, and may curtail or preclude our ability to exclude third parties from making, using and selling similar or competitive products. Any of these occurrences could have a material adverse effect on our business, financial condition, results of operations and prospects. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop, acquire or license.

Many countries, including certain countries in Asia, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. Our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. For example, the research resulting in certain of our licensors' patents and technology, including patents and technology relating to UB-612, was funded in part by the Taiwanese government. As a result, the Taiwanese government may have certain rights to such patent rights and technology.

Furthermore, certain of our patents and technology, including patents and technology relating to UB-312, were funded in part by grants from nonprofit third parties, including the MJFF and CEPI. We are required to fulfill certain contractual obligations with respect to products created using such grant funding, including certain reporting requirements. If these grant proposals are awarded, or if we receive funding from other nonprofit third parties in the future, we may be required to fulfill other contractual obligations, such as publishing the results of our scientific studies, making certain products available at an affordable price in a list of clearly defined low and lower-middle income countries and ensuring that certain products are available in geographic regions where there has been an outbreak of an infectious disease at certain reduced economic rates.

If we or our licensors infringe, misappropriate, or otherwise violate intellectual property of third parties, we may face increased costs or we may be unable to commercialize our product candidates.

Many of our current and former employees, consultants and independent contractors including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including some which may be competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees, consultants or independent contractors have used or disclosed intellectual property, including trade secrets or other proprietary information, of such individual's current or former employers, or that patents and applications we have filed to protect inventions of these individuals, even

those related to one or more of our current or future product candidates, are rightfully owned by their former or concurrent employer. In addition, while we typically require our employees, consultants and independent contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, or such agreements may be breached or alleged to be ineffective, and the assignment may not be self-executing, which may result in claims by or against us related to the ownership of such intellectual property or may result in such intellectual property becoming assigned to third parties.

Third parties have, and may in the future have, U.S. and non-U.S. issued patents and pending patent applications relating to compounds, methods of manufacturing compounds or methods of use for the treatment of the disease indications for which we are developing our product candidates that may cover our product candidates. For example, we are aware of certain third-party U.S. and non-U.S. patents and patent applications, including those of our competitors, that relate to anti-alpha synuclein binding molecules that may be construed to cover the technology used in our anti-alpha synuclein vaccine product candidate. We are also aware of certain third-party U.S. and non-U.S. patents and patent applications, including those of our competitors, that relate to coronavirus vaccines and treatments and vaccines against other infectious diseases and we expect such third parties to have filed additional patent applications, which have not yet been published and to file additional patent applications in the future.

In the event that any of these patent rights were asserted against us, we believe that we have defenses against any such action, including that such patents would not be infringed by our product candidates and/or that such patents are not valid. However, if any such patent rights were to be asserted against us and our defenses to such assertion were unsuccessful, unless we obtain a license to such patents, we could be liable for damages, which could be significant and include treble damages and attorneys' fees if we are found to willfully infringe such patents. We could also be precluded from commercializing any product candidates that were ultimately held to infringe such patents, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Uncertainties resulting from our participation in patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Furthermore, because of the substantial amount of discovery required in certain jurisdictions 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, the perceived value of our product candidates or intellectual property could be diminished. Accordingly, the market price of our Class A common stock could decline. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business, financial condition, results of operations and prospects.

Changes to the patent law in the United States and other jurisdictions could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, thereby impairing our ability to protect our technologies and product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States or abroad could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. For example, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. Specifically, these decisions stand for the proposition that patent claims that recite laws of nature are not themselves patentable unless those patent claims have sufficient additional features that provide practical assurance that the processes are genuine inventive applications of those laws. What constitutes a "sufficient" additional feature is uncertain. Furthermore, in view of these decisions, since December 2014, the USPTO has published and continues to publish revised guidelines for patent examiners to apply when examining process claims for patent eligibility. This combination of events has created uncertainty with respect to the validity and enforceability of patents, even once they are obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways. In addition, the complexity and uncertainty of European and Asian patent laws have also increased in recent years. Complying with these laws and regulations could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

Obtaining and maintaining our patent protection, including patents licensed from third parties, depends on compliance with various procedural, documentary, 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, renewal fees, annuity fees and various other governmental fees on patents and patent applications will be due to be paid to the USPTO and various government patent agencies outside the United States over the lifetime of our patents and patent applications and any patent rights we may own or license in the future. Additionally, the USPTO and various government patent agencies outside the United States require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, 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. For example, certain of our patents which include claims utilized in our UB-311 anti-Aβ vaccine product candidate recently lapsed in certain European and Asian countries due to non-payment of fees. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official communications 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 or otherwise protecting our technologies or our product candidates, our competitors may be able to enter the market with similar or identical products or technology without infringing our patents, which could have a material adverse effect on our business. In addition, to the extent that we have responsibility for taking any action related to the prosecution or maintenance of patents or patent applications in-licensed from a third party, any failure on our part to maintain the in-licensed intellectual property could jeopardize our rights under the relevant license and may have a material adverse effect on our business, financial condition, results of operations and prospects.

If we do not obtain patent term extensions and data exclusivity for each of our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval in the United States of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984 ("Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. The length of the patent term extension is typically calculated as one half of the clinical trial period plus the entire period of time during the review of the NDA or BLA by the FDA, minus any time of delay by the applicant during these periods. We might not be granted a patent term extension at all, because of, for example, failure to apply within the applicable period, failure to apply prior to the expiration of relevant patents or otherwise failure to satisfy any of the numerous applicable requirements.

In the European Union, a maximum of five and a half years of supplementary protection can be achieved for an active ingredient or combinations of active ingredients of a medicinal product protected by a basic patent, if a valid marketing authorization exists (which must be the first authorization to place the product on the market as a medicinal product) and if the product has not already been the subject of supplementary protection. Although all countries in Europe must provide supplementary protection certificates, there is no unified legislation among European countries and so supplementary protection certificates must be applied for and granted on a country-by-country basis. This can lead to a substantial cost to apply for and receive these certificates, which may vary among countries or not be provided at all. Further, we may not receive an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or if the term of any such extension is less than we request, our competitors may obtain approval of competing products earlier than expected following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

If we are unable to protect the confidentiality of our proprietary information and trade secrets, the value of our technology and products could be materially adversely affected.

In addition to patent protection, we also rely on trade secrets and confidentiality agreements to protect other proprietary information that is not patentable or that we elect not to patent. To maintain the confidentiality of trade secrets and proprietary information, we enter into confidentiality agreements with our employees, consultants, independent contractors, collaborators, contract manufacturers, CROs and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or entity or made known to the individual or entity by us during the course of the individual's or entity's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees as well as our personnel policies also generally provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property or that we may obtain full rights to such inventions at our election. However, we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes and cannot guarantee that individuals with whom we have these agreements will comply with their terms. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets.

We may not have adequate remedies in the event of unauthorized use or disclosure of our proprietary information in the case of a breach of any such agreements and our trade secrets and other proprietary information could be disclosed to third parties, including our competitors. Many of our partners also collaborate with our competitors and other third parties. The disclosure of our trade secrets to our competitors, or more broadly, would impair our competitive position and may materially harm our business, financial condition, results of operations and prospects. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to maintain trade secret protection could adversely affect our competitive business position. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. Courts outside the United States are sometimes

less willing to protect proprietary information, technology and know-how. In addition, others may independently discover or develop substantially equivalent or superior proprietary information and techniques, and the existence of our own trade secrets affords no protection against such independent discovery.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our business, financial condition, results of operations and prospects may be adversely affected.

We rely on our trademarks for name recognition by potential partners and customers in our markets of interest. However, our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names or marks. During trademark registration proceedings, we may receive rejections that we may be unable to overcome. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks or trademark applications may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business, financial condition, results of operations and prospects may be adversely affected.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our proprietary and intellectual property rights is uncertain because such rights offer only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to develop products that are similar to, or better than, our product candidates in a way that is not covered by the claims of the patents we license or may own currently or in the future;
- we, or our licensing partners or current or future collaborators, might not have been the first to make or file patent applications for the inventions covered by issued patents or pending patent applications that we license or may own currently or in the future;
- we may not have the financial or other resources necessary to enforce a patent infringement or other proprietary rights violation action;
- we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property;
- our trade secrets or proprietary know-how may be unlawfully disclosed, thereby losing their trade secret or proprietary status;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents;
- the patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business;
- third parties could design around our patents, or independently develop trade secrets that provide them with an advantage over us;
- any patents that we obtain may not provide us with any competitive advantages or may ultimately be found not to be owned by us, or to be invalid or unenforceable; or
- we may not develop additional proprietary technologies that are patentable.

Should any of these events occur, they could significantly harm our business, financial conditions, results of operations and prospects.

Risks Related to Our Business and Industry

Even if we, or any current or future collaborators, are able to commercialize any product candidate that we or they develop, the successful commercialization of our product candidates will depend in part on the extent to which governmental authorities, private health insurers and other third-party payors provide coverage and adequate reimbursement levels and implement pricing policies favorable for our product candidates. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement. The insurance coverage and reimbursement status of newly approved products is uncertain and failure to obtain or maintain adequate coverage and reimbursement for our product candidates could limit our ability to generate revenue. Our business model is also focused on lowering the cost and increasing the accessibility of healthcare. Even if we are successful in driving down the cost of healthcare, third- party payors may still not view our product candidates, if approved, as cost-effective, and coverage and reimbursement may not be available to our patients or may not be sufficient to allow our products, if any, to be marketed on a competitive basis. If coverage and reimbursement are not available, or reimbursement is available only to limited levels, patient subpopulations of labeled indications, or otherwise restricted, we, or any collaborators, may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us, or any collaborators, to establish or maintain pricing sufficient to realize a sufficient return on our or their investments. Cost-control initiatives could also cause us to decrease any price we might establish for our product candidates, which could result in lower than anticipated product revenues. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including our costs related to research, development, manufacture, sale and distribution. Reimbursement rates may vary, by way of example, according to the use of the product and the clinical setting in which it is used. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be difficult because of the higher costs often associated with administering such drugs. If the prices for our product candidates, if approved, decrease or if governmental and other third-party payors do not provide adequate coverage or reimbursement, our business, financial condition, results of operations and prospects will suffer, perhaps materially.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the CMS, the federal agency responsible for administering the Medicare program, makes the principal decisions about coverage and reimbursement for new treatments under Medicare. Private payors may follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for novel products such as ours. In addition, certain Affordable Care Act marketplace and other private payor plans are required to include coverage for certain preventative services, including vaccinations recommended by the U.S. Centers for Disease Control's Advisory Committee on Immunization Practices ("ACIP") without cost share obligations (i.e., co- payments, deductibles or co-insurance) for plan members. For Medicare beneficiaries, some of our product candidates may be covered for reimbursement under either the Part B program or Part D program depending on several criteria, including the type of vaccine and the beneficiary's coverage eligibility. If our product candidates, once approved, are reimbursed 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 copayments associated with the Part D program. If our product candidates, once approved, are reimbursed only under the Part B program, certain potential drawbacks associated with the Part B program, such as the time and effort required to seek reimbursement after purchase, may make our product candidates less attractive to clinics or other potential customers. Outside of Medicare, private insurance is likely to raise similar claims adjudication and copayment considerations, which may also make our product candidates less attractive to potential customers using private insurance.

Outside the United States, certain countries set prices and reimbursement for pharmaceutical products, with limited participation from the marketing authorization holders. We cannot be sure that such prices and reimbursement will be acceptable to us or our collaborators. If the regulatory authorities in these jurisdictions set prices or reimbursement levels that are not commercially attractive for us or our collaborators, our revenues from sales by us or our collaborators, and the potential profitability of our product candidates, in those countries would be negatively affected. Additionally, some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then may experience delays in the reimbursement approval of our product or be subject to price regulations that would delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country.

Moreover, an increasing number of countries are taking initiatives to attempt to reduce large budget deficits by focusing cost-cutting efforts on pharmaceuticals for their state-run healthcare systems. These international price control efforts have impacted all regions of the world, notably in the European Union. In some countries, in particular in many Member States of the European Union, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. In addition, publication of discounts by third- party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries.

If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, financial condition, results of operations or prospects could be materially adversely affected. Cost-control initiatives could cause us, or

any collaborators, to decrease the price we, or they, might establish for products, which could result in lower than anticipated product revenues. Further, our competitors have more experience dealing with and contracting with payors for preferred coverage, which could potentially put us at a competitive disadvantage. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for any of our product candidates for which we, or any future collaborator, obtain marketing approval could significantly harm our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Our business and current and future relationships with third-party payors, healthcare professionals and customers in the United States and elsewhere will be subject to applicable healthcare laws and regulations, which could expose us to significant 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 product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, third-party payors and customers expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal civil False Claims Act, that may constrain the business or financial arrangements and relationships through which we conduct clinical research, sell, market and distribute any products for which we obtain marketing approval. In addition, we may be subject to physician payment transparency laws and patient privacy regulation by the federal government and by the U.S. states and foreign jurisdictions in which we conduct our business.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, some of whom may recommend, purchase or prescribe our product candidate, if approved, 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, including, without limitation, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government 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 and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business.

Cyberattacks or other failures in our or our third-party vendors', contractors' or consultants' telecommunications or information technology systems could result in information theft, compromise, or other unauthorized access, data corruption and significant disruption of our business operations, and could harm our reputation and subject us to liability, lawsuits and actions from governmental authorities.

The success of our research and development programs depends on data which is stored and transmitted digitally, the corruption or loss of which could cause significant setback to one or all of our programs. We face a number of risks related to our use, processing, storage and security of this critical information, including loss of access, inappropriate use or disclosure, inappropriate modification corruption, unauthorized access or processing. Because we use third-party vendors and subcontractors to manage our sensitive information, we also may not have the ability to adequately monitor, audit or modify the security controls over this critical information. Despite the implementation of security measures, given the size and complexity of our internal information technology ("IT") systems and those of our third-party vendors, contractors and consultants, such IT systems are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war, and telecommunication and electrical failures.

Cyber threats are persistent and constantly evolving. Such threats, which may include ransomware or other malware, phishing attacks, denial of services attacks, man-in-the-middle attacks and others, have increased in frequency, scope and potential impact in recent years, which increase the difficulty of detecting and successfully defending against them. We may not be able to anticipate all types of security threats, and, despite our efforts, we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. There can be no assurance that we or our third-party service providers, contractors or consultants will be successful in preventing cyberattacks or successfully mitigating their effects. Our IT systems and those of our third-party service providers, contractors or consultants are additionally vulnerable to security breaches from inadvertent or intentional actions by our employees, third-party vendors, contractors, consultants, business partners and/or other third parties. These threats pose a risk to the security of our systems and networks, the confidentiality and the availability, security and integrity of our data, and these risks apply both to us and to third parties on whose systems we rely for the conduct of our business. If the IT systems of our third-party vendors and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such

third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of a similar nature from occurring. Any cyberattack or destruction or loss of, unauthorized access to, processing of, or exfiltration of data could have a material adverse effect on our business, financial condition, results of operations and prospects. For example, if such an event were to occur and cause interruptions in our operations, or those of our third-party vendors and other contractors and consultants, it could result in a material disruption or delay of the development of our product candidates. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyberattacks or other data security breaches, particularly those involving personal information or protected health information, and may incur significant additional expense to implement further data protection measures. As cyber threats continue to evolve, we may be required to incur material additional expenses in order to enhance our protective measures or to remediate any information security vulnerability.

We are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies and contractual obligations could adversely affect our business, financial condition, results of operations and prospects.

We are subject to data privacy and security laws and regulations that apply to the collection, transmission, storage, use, processing, destruction, retention and security of personal information, which among other things, including additional laws or regulations relating to health information. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and these laws may at times be conflicting. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices and our efforts to comply with the evolving data protection rules may be unsuccessful. We must devote significant resources to understanding and complying with this changing landscape. Failure to comply with federal, state and international laws regarding privacy and security of personal information could expose us to penalties under such laws, orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which have a material adverse effect on our business, financial condition, results of operations and prospects. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, criminal prosecution of employees, claims for damages by affected individuals and damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Additionally, if we are unable to properly protect the privacy and security of personal information, including protected health information, we could be found to have breached our contracts with certain third parties.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. In particular, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") and their respective implementing regulations, establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. If we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face civil and criminal penalties. The HHS has the discretion to impose penalties without attempting to first resolve violations. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. Even when HIPAA does not apply, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce and be construed as a violation of Section 5(a) of the Federal Trade Commission Act (the "FTCA"), 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards and the FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

Internationally, laws, regulations and standards in many jurisdictions apply broadly to the collection, transmission, storage, use, processing, destruction, retention and security of personal information. For example, in the European Union, the collection, transmission, storage, use, processing, destruction, retention and security of personal data is governed by the provisions of the General Data Protection Regulation (the "GDPR") in addition to other applicable laws and regulations. The GDPR came into effect in May 2018, repealing and replacing the European Union Data Protection Directive, and imposing revised data privacy and security requirements on companies in relation to the processing of personal data of European Union data subjects. The GDPR, together with national legislation, regulations and guidelines of the European Union Member States governing the collection, transmission, storage, use, processing, destruction, retention and security of personal data, impose strict obligations with respect to, and restrictions on, the collection, use, retention, protection, disclosure, transfer and processing of personal data. The GDPR also imposes strict rules on the transfer of personal data to

countries outside the European Union that are not deemed to have protections for personal information, including the United States. The GDPR authorizes fines for certain violations of up to 4% of the total global annual turnover of the preceding financial year or €20 million, whichever is greater. Such fines are in addition to any civil litigation claims by data subjects. Separately, Brexit has led and could also lead to legislative and regulatory changes and may increase our compliance costs. As of January 1, 2021, and the expiry of transitional arrangements agreed to between the United Kingdom and the European Union, data processing in the United Kingdom is governed by a United Kingdom version of the GDPR (combining the GDPR and the Data Protection Act 2018), exposing us to two parallel regimes, each of which authorizes similar fines and other potentially divergent enforcement actions for certain violations. On June 28, 2021, the European Commission adopted an adequacy decision for the United Kingdom, allowing for the relatively free exchange of personal information between the European Union and the United Kingdom. Other jurisdictions outside the European Union are similarly introducing or enhancing privacy and data security laws, rules and regulations, which could increase our compliance costs and the risks associated with noncompliance. We cannot guarantee that we are, or will be, in compliance with all applicable international regulations as they are enforced now or as they evolve.

We face potential liability related to the privacy of health information we obtain from clinical trials sponsored by us.

Most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act. We do not believe that we are currently classified as a covered entity or business associate under HIPAA and thus are not directly subject to its requirements or penalties. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. Even when HIPAA does not apply, according to the FTC failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of the FTCA. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

In addition, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations. As such, we may be subject to state laws, including the CCPA, requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Our clinical trial programs outside the United States may implicate international data protection laws, including the GDPR and legislation of the EU member states implementing it.

Our activities outside the United States impose additional compliance requirements and generate additional risks of enforcement for noncompliance. Failure by our CROs and other contractors to comply with the strict rules on the transfer of personal data outside of the EU into the United States may result in the imposition of criminal and administrative sanctions on such collaborators, which could adversely affect our business. Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information.

Moreover, patients about whom we or our collaborators obtain health information, as well as the providers who share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

If we or our contract manufacturers, CROs or other contractors or consultants fail to comply with applicable federal, state or local regulatory privacy requirements, we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our product candidates and could harm or prevent sales of any affected products that we are able to commercialize, or could substantially increase the costs and expenses of developing, commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. Increasing use of social media could give rise to liability, breaches of data security or reputational damage. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face and will continue to face competition from third parties that use similar platforms and from third parties focused on developing and commercializing other peptide and peptide-based product candidates. The competition is likely

to come from multiple sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions, government agencies and public and private research institutions.

Many of our potential competitors, alone or with their strategic partners, have substantially greater financial, technical and other resources than we do, such as larger research and development, clinical, marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even greater concentration of resources among a smaller number of competitors. Our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approvals for their products faster or earlier than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. For example, some of our competitors have already received approval from regulatory authorities for their COVID-19 vaccines and boosters to address variants of SARS-CoV-2. Additionally, technologies developed by our competitors may render our product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors' products. In addition, the availability of our competitors' products and the lack of complementary products offered by our sales and distribution team as compared to competitors with more extensive product lines, could limit the demand and the prices we are able to charge for any products that we may develop and commercialize.

Developments by competitors may render our products or technologies obsolete or non-competitive or may reduce the size of our markets.

Our industry has been characterized by extensive research and development efforts, rapid developments in technologies, intense competition and a strong emphasis on proprietary products. We expect our product candidates to face intense and increasing competition as new products enter the relevant markets and advanced technologies become available. We face potential competition from many different sources, including pharmaceutical, biotechnology and specialty pharmaceutical companies. Academic research institutions, governmental agencies and public and private institutions are also potential sources of competitive products and technologies. Our competitors may have or may develop superior technologies or approaches and have different business models from us which do not focus on democratizing healthcare and on lower cost, all of which may provide them with competitive advantages. Many of these competitors may also have compounds already approved or in development in the therapeutic categories that we are targeting with our product candidates. The global vaccine market is highly concentrated among a small number of multinational pharmaceutical companies: Pfizer, Merck, GlaxoSmithKline and Sanofi together control most of the global vaccine market. While we are not aware of all of our competitors' efforts, there are approximately fifty COVID-19 vaccines currently approved for use in one or more countries around the world. We also face substantial competition in therapeutic areas outside of COVID-19. For example, the FDA approved aducanumab in June 2021 as the first FDA-approved immunotherapy for AD, and lecanemab in January 2023, and multiple approved products exist in the fields of migraine and hypercholesterolemia, including products that act on the same therapeutic targets as our vaccine candidates. In addition, many of our competitors, either alone or together with their collaborative partners, may operate larger research and development programs or have substantially greater financial resources than we do, as well as greater experience in:

- developing product candidates;
- undertaking pre-clinical testing and clinical trials;
- obtaining BLA approval by the FDA;
- obtaining comparable foreign regulatory approvals of product candidates;
- formulating and manufacturing products;
- launching, marketing and selling products; and
- competing for market share, obtaining reimbursement and securing payor contractors for preferential coverage.

If these competitors access the marketplace with safer, more effective, or less expensive therapeutics, our product candidates, if approved for commercialization, may not be profitable to sell or worthwhile to continue to develop. Technology in the pharmaceutical industry has undergone rapid and significant change, and we expect that it will continue to do so. Any compounds, products or processes that we develop may become obsolete or uneconomical before we recover any expenses incurred in connection with their development. The success of our product candidates will depend upon factors such as product efficacy, safety, reliability, availability, timing, scope of regulatory approval, acceptance and price, among other things. Other important factors to our success include speed in developing product candidates, completing clinical development and laboratory testing, obtaining regulatory approvals and manufacturing and selling commercial quantities of potential products.

Our product candidates are intended to compete directly or indirectly with existing products and products currently in development. Even if approved and commercialized, our product candidates may fail to achieve market acceptance with hospitals, physicians, patients

or third-party payors. Hospitals, physicians or patients may conclude that our products are less safe or effective or otherwise less attractive than existing drugs. If our product candidates do not receive market acceptance for any reason, our revenue potential would be diminished, which would materially adversely affect our ability to become profitable.

Many of our competitors have substantially greater capital resources, robust product candidate pipelines, established presence in the market and expertise in research and development, manufacturing, pre-clinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. As a result, our competitors may achieve product commercialization or patent or other intellectual property protection earlier than we can. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified clinical, regulatory, scientific, sales, marketing and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop or that would render any products that we may develop obsolete or noncompetitive.

We are subject to anti-corruption laws, including the U.S. Foreign Corrupt Practices Act ("FCPA"), and similar laws of non-U.S. jurisdictions where we conduct business. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures, and legal expenses, which could adversely affect our business, financial condition, results of operations and prospects.

We are currently subject to anti-corruption laws, including the FCPA. The FCPA, the U.K. Bribery Act 2010 and other applicable anti-bribery and anti-corruption laws generally prohibit us, our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain other business advantages. In furtherance of our goal to democratize healthcare, we intend to distribute any product candidates that are approved or receive an EUA in various countries around the world, including countries with a heightened corruption risk. This may raise the risk of non-compliance with anti-corruption laws and other rules and regulations prohibiting bribery and other crimes. We also participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA or other jurisdictions' anti-corruption laws, which in turn could result in internal and external investigations, associated legal costs and even civil fines and criminal charges, any of which would divert time and resources away from our core business operations even if we and our employees and agents do not violate laws and regulations. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are (directly or indirectly) employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under, but not limited to, the FCPA. In recent years, the SEC and Department of Justice have also increased their FCPA enforcement activities with respect to pharmaceutical companies.

We are in the process of establishing a program to govern the compliance of any potential sales or marketing operations of our products, should any of them be approved or receive an EUA. To date, we have not had a robust compliance program. We cannot ensure that our operations to date have complied, and that our future operations will comply, with our compliance program or laws, rules and regulations governing the sales and marketing of pharmaceutical products, government contracting and other aspects of our business. We have used, and plan to use, a network of agents in countries around the world to conduct our sales and marketing operations. These agents will not be our employees, and while we intend to have a robust diligence program in connection with engaging agents, our diligence program and compliance program may not be sufficient to prevent wrong-doing.

There is also no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA, particularly given the high level of complexity of these laws. We have adopted a code of conduct applicable to all of our employees and contractors, but it is not always possible to identify and deter misconduct by these parties 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 governmental investigations or other actions, claims or lawsuits stemming from a failure to comply with such laws or regulations. If we are not in compliance with the FCPA or other anti-corruption laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and prospects. Similarly, any investigation of any potential violations of the FCPA or other anti-corruption laws by authorities in the United States or other jurisdictions where we conduct business could also have an adverse impact on our reputation, business, financial condition, results of operations and prospects.

As a result of our geographically diverse operations, we are more susceptible to certain risks.

We have operation in multiple countries. We have also used, and plan to use, a network of agents in countries around the world to conduct our sales and marketing operations. If we are unable to manage the risks of our global operations, including fluctuations in foreign exchange and inflation rates, international hostilities such as the Russia-Ukraine conflict, natural disasters, security breaches, our ability to supply our product candidates on a timely and large scale basis in local markets, lead times for shipping, accounts receivable

collection times, import or export licensing requirements, language barriers, failure to maintain compliance with our clients' control requirements and multiple legal and regulatory systems, our results of operations and ability to grow could be materially adversely affected. In particular, our business and stock price may be affected by fluctuations in foreign exchange rates between currencies in different jurisdictions in which operate or in which we may have sales in the future.

Certain legal and political risks are also inherent in foreign operations. Foreign sales of our product candidates could be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs. In many countries, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. There is a risk that foreign governments may nationalize private enterprises in certain countries where we may operate. In certain countries or regions, terrorist activities and the response to such activities may threaten our operations more than in the United States. Social and cultural norms in certain countries may not support compliance with our corporate policies, including those that require compliance with substantive laws and regulations. Also, changes in general economic and political conditions in countries where we may operate are a risk to our financial performance and future growth. Additionally, the need to identify financially and commercially strong partners for commercialization outside the United States who will comply with the high manufacturing and legal and regulatory compliance standards we require is a risk to our financial performance. As we operate our business globally, our success will depend, in part, on our ability to anticipate and effectively manage these and other related risks. There can be no assurance that the consequences of these and other factors relating to our international operations will not have an adverse effect on our business, financial condition, results of operations and prospects.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products.

The use of our investigational medicinal products in clinical trials, past sales of our ELISA test and the sale of any approved products in the future may expose us to liability claims. These claims might be made by patients who use the product, health care providers, pharmaceutical companies or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our product candidates or any prospects for commercialization of our product candidates.

In addition, regulations vary significantly across jurisdictions regarding the clinical trial sponsor's responsibility to provide free medical care and compensation to clinical trial participants who experience an injury or illness during the trial. For example, there is no legal requirement in the United States for sponsors to provide free medical treatment or compensation to a participant injured during a study; as a result, sponsors usually agree to pay for the medical care to diagnose and treat participant injuries to the extent related to the clinical trial and typically do not pay unless the injury is determined to be related to participation in the trial. In contrast, India requires free medical care until it is established that the injury is not related to the study and compensation for any injury that is determined to be related to the study. In 2019, India's Ministry of Health and Family Welfare published the "New Drugs and Clinical Trials Rules," which increased a clinical trial sponsor's liability for injuries related to clinical trial trials. Under the regulation, sponsors are required to (i) provide "free medical management" to participants that experience an injury that, in the investigator's opinion, is related to the study or until it is established that the injury is not related to the study and (ii) "compensate" clinical trial participants for trial-related injuries. Clinical trials conducted in jurisdictions with broad compensation and medical care requirements could result in increased overall research costs and adversely affect our ability to conduct clinical trials.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a product, even after regulatory approval, may exhibit unforeseen side effects, including rare side effects more likely to be seen in commercial use than in clinical studies. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates.

To cover such liability claims, we purchase clinical trial insurances in the conduct of each of our clinical trials (typically conducted through our CROs). It is possible that our liabilities could exceed our insurance coverage or that our insurance will not cover all situations in which a claim against us could be made. We also intend to expand our insurance coverage to include the sale of commercial products if we receive marketing approval for any of our proprietary products. However, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired. Should any of the events described above occur, this could have a material adverse effect on our business, financial condition, results of operations and prospects, including, but not limited to:

- decreased demand for our future product candidates;
- adverse publicity and 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;
- compensation in response to a liability claim;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources; and
- the inability to commercialize our products or product candidates.

We could be adversely affected if we are subject to negative publicity. We could also be adversely affected if any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to patients. Any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies could have a material adverse impact on our business, financial condition, results of operations or prospects.

If we need to expand our organization, we may experience difficulties in managing this growth, which could disrupt our operations.

If we expand our organization, we may encounter difficulties in managing our growth, which could disrupt our operations. We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development and regulatory affairs, as well as to support our public company operations. For example, we may build our own focused sales, distribution and marketing infrastructure to market our product candidates, if approved, in markets around the world, which involves significant expenses and risks. To manage these growth activities, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Our management may need to devote a significant amount of its attention to managing these growth activities. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations, retain key employees or identify, recruit and train additional qualified personnel. Our inability to manage the expansion or relocation of our operations effectively may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy, including the successful development and commercialization of our product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. Future growth would impose significant additional responsibilities on our management, including:

- the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors;
- managing our internal development efforts effectively, including the clinical and regulatory review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures. We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain related parties, independent organizations, advisors and consultants to provide certain services, including substantially all aspects of regulatory approval, clinical trial management and manufacturing. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, or we are not able to effectively build out new facilities to accommodate this expansion, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Many of the biotechnology and pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than we do. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can discover and develop product candidates and operate our business will be limited.

We only have a limited number of employees to manage and operate our business, which may lead to certain operational issues.

As of March 15, 2023 we had 76 full-time employees and 1 part-time employee. Our focus on the development of UB-612, UB-312, UB-313, VXX-401 and other product candidates requires us to manage and operate our business in a highly efficient manner. We have a limited number of employees upon which we rely to effectively manage and operate our business and we cannot assure you that operational issues will not arise.

While we intend to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors to support our growth, we cannot assure you that we will be able to hire and/or retain adequate staffing levels to develop our product candidates or run our operations and/or to accomplish all of the objectives that we otherwise would seek to accomplish.

If we lose key management or scientific personnel, cannot recruit qualified employees, directors, officers or other significant personnel or experience increases in our compensation costs, our business may materially suffer.

We are highly dependent on our management and directors. Due to the specialized knowledge each of our officers and key employees possesses with respect to our product candidates and our operations, the loss of service of any of our officers or directors could delay or prevent the successful enrollment and completion of our clinical trials. We do not carry key person life insurance on any officers or directors. In general, the employment arrangements that we have with our executive officers do not prevent them from terminating their employment with us at any time. Our agreements with our employees generally provide for at-will employment.

In addition, our future success and growth will depend in part on the continued service of our directors, employees and management personnel and our ability to identify, hire and retain additional personnel. If we lose one or more of our executive officers or key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers and key employees may be difficult or costly and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize product candidates successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or effectively incentivize these additional key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research, development and commercialization strategy. Our consultants and advisors may be engaged by entities other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to develop and commercialize product candidates will be limited.

Many of our employees have become or will soon become vested in a substantial amount of our Class A common stock or a number of common stock options. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of Class A our common stock. Our future success also depends on our ability to continue to attract and retain additional executive officers and other key employees.

If we engage in future acquisitions, joint ventures or strategic collaborations, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

We may evaluate various acquisitions and collaborations, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any potential acquisition, joint venture, or collaboration may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;

- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or investigational medicines and regulatory approvals; and

- our inability to generate revenue from acquired technology or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may utilize our cash, issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

Moreover, we may not be able to locate suitable acquisition or strategic collaboration opportunities, and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

We or the third parties upon whom we depend may be adversely affected by natural disasters or pandemics and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters or pandemics, other than or in addition to COVID-19 and including any potential future waves of COVID-19, could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. For example, our headquarters and main laboratory is located on the Eastern coast of Florida, a location that is at a higher risk of exposure to hurricanes. If a hurricane or natural disaster causes us to sustain significant damage to our Florida headquarters and main laboratory, or if we must shut down our operations there for an extended period of time, our business and financial results would be adversely impacted.

If a natural disaster, power outage, pandemic, such as the COVID-19 pandemic, or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities on which we rely, 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.

Unstable market and economic conditions have had and may have further serious adverse consequences on our business, financial condition and share price.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. For example, the COVID-19 pandemic has resulted in widespread unemployment, an economic slowdown and extreme volatility in the capital markets. While these effects of COVID-19 have abated as countries, including the United States, have re-opened and the rate of vaccinations have increased, COVID-19 may cause further disruptions globally. If the equity and credit markets further deteriorate, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. In addition, there is a risk that one or more of our CROs, suppliers, contract manufacturers or other third-party providers may not survive an economic downturn, or that industry trends with respect to pricing models, supply chains and delivery mechanisms, among other things, deviate from our expectations. As a result, our business, results of operations and price of our Class A common stock may be adversely affected.

Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

Though we have insurance coverage for clinical trial product liability, we do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, auto, renters', workers' compensation and directors' and officers' insurance.

Any additional product liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for any of our product candidates, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the development and commercialization of any product candidates we develop. We do not carry specific biological or hazardous waste insurance coverage, and our renters' and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

Operations as a public company have made it more difficult and more expensive for us to obtain director and officer liability insurance, and we and have incurred substantially higher costs since becoming a public company. As a result, it has become more expensive for us to obtain the coverage needed to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash and cash equivalents position and results of operations.

The coronavirus pandemic has caused interruptions or delays of our business plan and could continue to adversely affect our business.

The COVID-19 pandemic and related federal, state and local government responses to COVID-19 and our responses to the pandemic and such restrictions has and may continue to have a material adverse effect on our business, results of operations, liquidity and financial condition. Our business has been disrupted and could be further disrupted to the extent our business partners are adversely impacted by the COVID-19 pandemic.

The full extent to which the COVID-19 pandemic will continue to impact our business, development plans, business partners and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted. To the extent the pandemic continues to adversely affect our business and financial condition, it may also have the effect of exacerbating many of the other risk factors discussed herein, which could have a material adverse effect on us.

Due to the vaccination rate, the demand for our COVID-19 product candidate may decrease significantly or disappear entirely.

We are pursuing a path to conditional and provisional approval of UB-612 as a heterologous boost (boosting the immunity of a subject who has already received a different vaccine) in the United Kingdom and Australia, respectively. Other companies have also responded to the pandemic at a faster pace, and to date approximately fifty COVID-19 vaccines are currently in use around the world. As our competitors continue to develop, receive regulatory approval for and commercialize their own COVID-19 vaccines and boosters, demand for our COVID-19 product candidate may materially decrease or disappear entirely, along with a corresponding decrease in our potential revenues. Further, the existence and significance of the opportunity to provide COVID-19 boosters in the future is highly uncertain, and there can be no assurance that we will commercially benefit from the development of a COVID-19 booster vaccine.

Risks Related to Our Class A Common Stock

An active trading market for our Class A common stock may not continue to be developed or sustained.

Prior to our initial public offering, there was no public market for our Class A common stock. Although our Class A common stock is now listed on The Nasdaq Global Market, an active trading market for our shares of Class A common stock may never develop or be sustained. If an active market for our Class A common stock does not develop or is not sustained, it may be difficult for you to sell shares of our Class A common stock at an attractive price or at all. An inactive market may also impair our ability to raise capital by selling shares of our common stock, our ability to motivate our employees through equity incentive awards, and our ability to acquire other companies, products or technologies by using our common stock as consideration for such acquisitions.

The price of our Class A common stock has been volatile and may be further affected by market conditions beyond our control, and purchasers of our Class A common stock could incur substantial losses.

Our results of operations have fluctuated and are likely to continue to fluctuate in the future. In addition, securities markets worldwide have experienced, and are likely to continue to experience, significant price and volume fluctuations. This market volatility, as well as general economic, market or political conditions, could subject the market price of our shares of Class A common stock to wide price fluctuations regardless of our operating performance, which has caused and could further cause a decline in the market price of our common stock. Price volatility may be greater if the public float and trading volume of shares of our Class A common stock is low. Some factors that may cause the market price of our Class A common stock to fluctuate, in addition to the other risks mentioned in this Report, include:

- our operating and financial performance and prospects;
- our announcements or our competitors' announcements regarding new products or services, enhancements, significant contracts, acquisitions or strategic investments;
- any delay in our development or regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings;

- if any of our product candidates receives an EUA or regulatory approval, the terms of such approval and market acceptance and demand for such product candidates;
- the success of any efforts to acquire or in-license additional technologies, products or product candidates;
- changes in earnings estimates or recommendations by securities analysts who cover our Class A common stock;
- fluctuations in our financial results or, in the event we provide it from time to time, earnings guidance, or the financial results or earnings guidance of companies perceived by investors to be similar to us;
- changes in our capital structure, such as future issuances of securities, sales of large blocks of common stock by our stockholders, including our principal stockholders, or the incurrence of additional debt;
- additions and departure of key personnel;
- any disputes relating to our intellectual property, including any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- reputational issues, including reputational issues involving our competitors and their products;
- actions by institutional stockholders;
- changes in general economic and market conditions, including related to the COVID-19 pandemic;
- changes in industry conditions or perceptions or changes in the market outlook for the industry in which we compete, including changes in the structure of healthcare payment systems; and
- changes in applicable laws, rules or regulations or regulatory actions affecting us or our clients and other dynamics.

These and other factors have caused and may further cause the market price for shares of our Class A common stock to fluctuate substantially, which may further limit or prevent investors from readily selling their shares of our Class A common stock and negatively affect the liquidity of our Class A common stock. In addition, in the past, when the market price of a stock has been volatile, holders of that stock sometimes have instituted securities class action litigation against the company that issued the stock. Securities litigation against us, regardless of the merits or outcome, could result in substantial costs and divert the time and attention of our management from the business, which could significantly harm our business, results of operation, financial condition or reputation.

The dual-class structure of our common stock and the Voting Agreement will have the effect of concentrating voting power, which will significantly limit stockholders' ability to influence the outcome of matters submitted to our stockholders for approval, including the election of our board of directors, the adoption of amendments to our Charter and Bylaws and the approval of any merger, consolidation, sale of all or substantially all of our assets or other major corporate transaction.

Our Class A common stock has one vote per share, and our Class B common stock has ten votes per share. Our principal stockholders have entered into the Voting Agreement. As of March 15, 2023 on a fully diluted basis, Mei Mei Hu, as proxyholder under the Voting Agreement, controls approximately 65.8% of the total voting power of our outstanding capital stock. The Voting Agreement provides Mei Mei Hu with the authority (and irrevocable proxies) to direct the vote and vote the shares of capital stock held by the parties to the voting agreement at her discretion on all matters to be voted upon by stockholders. The voting power covered by the Voting Agreement may increase over time as the UBI Warrant is exercised and as our principal stockholders exercise or vest equity awards that were outstanding at the time of the completion of our initial public offering. If all such equity awards held by our principal stockholders had been exercised or vested and exchanged for shares of common stock and the UBI Warrant had been exercised in full for shares of Class A common stock as of March 15, 2023, assuming no other equity awards had been exercised or vested, the Voting Agreement would have covered, in the aggregate as of the completion of our initial public offering, approximately 68.2% of the total voting power of our outstanding capital stock. As a result, if our principal stockholders retain all or a large portion their common stock, including the common stock issuable upon the exercise or vesting of such principal stockholders' outstanding equity awards or upon the exercise of the UBI Warrant, our principal stockholders will be able to significantly influence (if not control) any action requiring the approval of our stockholders, including the election of our board of directors, the adoption of amendments to our amended and restated certificate of incorporation (the "Charter") and our amended and restated bylaws (the "Bylaws") and the approval of any merger, consolidation, sale of all or substantially all of our assets or other major corporate transaction. Assuming our principal stockholders retain their equity interests and the Voting Agreement remains in effect, our principal stockholders will effectively control all such matters submitted to the stockholders for the foreseeable future. Our principal stockholders will also have the voting power to determine the composition of our board of directors, which in turn will be able to determine matters affecting us, including, among others:

- any determination with respect to our business direction and policies, including the appointment and removal of officers;

- the adoption of amendments to our Charter and Bylaws;
- determinations with respect to mergers, business combinations or disposition of assets;
- compensation and benefit programs and other human resources policy decisions;
- the payment of dividends on our common stock; and
- determinations with respect to tax matters.

Our principal stockholders may have interests that differ from yours and may vote in a way with which you disagree and which may be adverse to your interests. This concentrated control may have the effect of delaying, preventing or deterring a change in control of the Company, could deprive our stockholders of an opportunity to receive a premium for their capital stock as part of a sale in the Company and might ultimately affect the market price of our Class A common stock. In addition, each share of Class B common stock will automatically convert into one share of Class A common stock upon any transfer, whether or not for value and whether voluntary or involuntary or by operation of law, except for certain transfers described in our Charter, including, without limitation, certain transfers for tax and estate planning purposes. Such issuances will be dilutive to holders of our Class A common stock.

We are an "emerging growth company" and a "smaller reporting company" and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies, which could make our Class A common stock less attractive to investors and adversely affect the market price of our Class A common stock.

We are an "emerging growth company," as defined in the JOBS Act. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which we have annual gross revenues of $1.235 billion or more; (ii) the date on which we have issued more than $1.0 billion in non-convertible debt in the previous three years; (iii) the date we qualify as a "large accelerated filer" under the Exchange Act, which would occur at the end of a given fiscal year if the market value of our common stock that is held by non-affiliates is $700 million or more as of the last business day of the second fiscal quarter of such year (and we have been a public company for at least 12 months and have filed one annual report on Form 10-K); and (iv) the last day of the fiscal year ending after the fifth anniversary of our initial public offering. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- being required to provide only two years of audited financial statements in addition to any required unaudited interim financial statements;
- permitting an extended transition period for complying with new or revised accounting standards, which allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies;
- reduced disclosure obligations regarding executive compensation; 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.

We may choose to take advantage of some, but not all, of the available exemptions. We have elected to use the extended transition period for new or revised accounting standards during the period in which we remain an emerging growth company. To the extent that we continue to qualify as a "smaller reporting company," as such term is defined in Rule 12b-2 under the Exchange Act, after we cease to qualify as an emerging growth company, we will continue to be permitted to make certain reduced disclosures in our periodic reports and other documents that we file with the SEC. We cannot predict whether investors will find our Class A common stock less attractive as a result of our reliance on these exemptions. If some investors find our Class A common stock less attractive as a result, there may be a less active trading market for our Class A common stock and our stock price may be more volatile.

As long as our principal stockholders hold a majority of the voting power of our capital stock, we may rely on certain exemptions from the corporate governance requirements of the Nasdaq available for "controlled companies."

We are a "controlled company" within the meaning of the corporate governance requirements of the Nasdaq because our principal stockholders will continue to hold more than 50% of the voting power of our outstanding shares of capital stock as a result of our dual-class common stock structure and the Voting Agreement. A controlled company may elect not to comply with certain corporate governance requirements of the Nasdaq. Accordingly, our board of directors will not be required to have a majority of independent directors and our Compensation Committee and Nominating and Governance Committee will not be required to meet the director independence requirements to which we would otherwise be subject until such time as we cease to be a "controlled company." Accordingly, you will not have certain of the protections afforded to stockholders of companies that are subject to all of the corporate governance requirements of the Nasdaq.

Your percentage ownership in us may be diluted by future issuances of capital stock, which could reduce your influence over matters on which stockholders vote.

Pursuant to our Charter and Bylaws, our board of directors has the authority, without action or vote of our stockholders, to issue all or any part of our authorized but unissued shares of common stock, including shares issuable upon the exercise of options, or shares of our authorized but unissued preferred stock. Issuances of shares of common stock or shares of voting preferred stock would reduce your influence over matters on which our stockholders vote and, in the case of issuances of shares of preferred stock, would likely result in your interest in us being subject to the prior rights of holders of that preferred stock.

Future sales of a substantial number of shares of our Class A common stock may depress the price of our shares.

If our stockholders sell a large number of shares of our Class A common stock, or if we issue a large number of shares of our Class A common stock in connection with future acquisitions, financings or other circumstances, the market price of shares of our Class A common stock could decline significantly. Moreover, the perception in the public market that our stockholders might sell shares of our Class A common stock could depress the market price of those shares. In addition, sales of a substantial number of shares of our common stock by our principal stockholders could adversely affect the market price of our Class A common stock.

We do not anticipate declaring or paying regular dividends on our Class A common stock in the near term, and any indebtedness could limit our ability to pay dividends on our Class A common stock.

We have never declared and do not anticipate declaring or paying regular cash dividends on our Class A common stock in the near term. We currently intend to use our future earnings, if any, to pay any debt obligations, to fund our growth and develop our business and for general corporate purposes. Therefore, you are not likely to receive any cash dividends on your Class A common stock in the near term, and the success of an investment in shares of our Class A common stock will depend upon any future appreciation in their value, which is not certain to occur. There is no guarantee that shares of our Class A common stock will appreciate in value or even maintain the price at which they are initially offered. Any future declaration and payment of cash dividends or other distributions of capital will be at the discretion of our board of directors and the payment of any future cash dividends or other distributions of capital will depend on many factors, including our financial condition, earnings, cash needs, regulatory constraints, capital requirements (including requirements of our subsidiaries) and any other factors that our board of directors deems relevant in making such a determination. We cannot assure you that we will establish a dividend policy or pay cash dividends in the future or continue to pay any cash dividend if we do commence paying cash dividends pursuant to a dividend policy or otherwise.

Our Charter designates courts in the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, and also provide that the federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, each of which could limit our stockholders' ability to choose the judicial forum for disputes with us or our directors, officers, stockholders or employees.

Our Charter provides that, subject to limited exceptions, the Court of Chancery for the State of Delaware or other specified courts in the State of Delaware will be the sole and exclusive forum to the fullest extent of the law for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders;
- any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law (the "DGCL"), our Charter or our Bylaws;
- any action to interpret, apply, enforce or determine the validity of our Charter or Bylaws; and

- any other action asserting a claim against us that is governed by the internal affairs doctrine.

Our Charter also provides that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action against us or any of our directors, officers, employees or agents and arising under the Securities Act. However, Section 22 of the Securities Act provides that federal and state courts have concurrent jurisdiction over lawsuits brought pursuant to the Securities Act or the rules and regulations thereunder. To the extent the exclusive forum provision restricts the courts in which claims arising under the Securities Act may be brought, there is uncertainty as to whether a court would enforce such a provision. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. This provision does not apply to claims brought under the Exchange Act.

Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to these provisions. These 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 such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our Charter inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business or financial condition.

Delaware law and provisions in our Charter and Bylaws might discourage, delay or prevent a change in control of the Company or changes in our management and, therefore, depress the trading price of our Class A common stock.

Provisions of our Charter and Bylaws and of state law may delay, deter, prevent or render more difficult a takeover attempt that our stockholders might consider in their best interests, including the following provisions:

- our dual-class common stock structure and the Voting Agreement, which provide our principal stockholders with a majority of the voting power of our capital stock will enable our principal stockholders to influence the outcome of matters submitted to our stockholders for approval even if they own significantly less than a majority of the number of shares of our outstanding common stock;

- our Charter does not provide for cumulative voting in the election of directors;

- vacancies on our board of directors may be filled only by our board of directors and not by stockholders;

- our stockholders may act by written consent only so long as the Voting Agreement is in effect and our principal stockholders hold a majority of the voting power of then-outstanding shares of our capital stock;

- a special meeting of our stockholders may only be called by the chairperson of our board of directors, our Chief Executive Officer, our President, a majority of our board of directors or, so long as the Voting Agreement is in effect and our principal stockholders hold a majority of the voting power of then-outstanding shares of our capital stock, our stockholders;

- amendments to certain provisions of our Charter and stockholder-proposed amendments to our Bylaws require the affirmative vote of the holders of at least 66 2/3% in voting power of all the then outstanding shares of our capital stock entitled to vote thereon at any time the Voting Agreement is not in effect or our principal stockholders do not hold, in the aggregate, a majority of the voting power of then-outstanding shares of our capital stock;

- our Charter authorizes our board of directors, subject to the limitations imposed by Delaware law or the Nasdaq's listing rules, without any further vote or action by our stockholders, to issue preferred stock in one or more series and to fix the designations, powers, preferences, limitations and rights of the shares of each series; and

- advance notice procedures apply for stockholders to nominate candidates for election as directors or to bring matters before an annual meeting of stockholders.

Such provisions or laws may prevent our stockholders from receiving the benefit from any premium to the market price of our Class A common stock offered by a bidder in a takeover context. Even in the absence of a takeover attempt, the existence of these provisions may adversely affect the prevailing market price of our Class A common stock if they are viewed as discouraging takeover attempts in the future.

Provisions in our Charter and Bylaws, including the dual-class structure of our common stock, might discourage or prevent institutional investors from purchasing or holding our Class A common stock, and, therefore, depress the trading price of our Class A common stock.

Our governance structure and our Charter may negatively affect the decision by certain institutional investors to purchase or hold shares of our Class A common stock. The holding of low-voting stock, such as our Class A common stock, may not be permitted by the

investment policies of certain institutional investors or may be less attractive to the portfolio managers of certain institutional investors. In addition, in July 2017, FTSE Russell and Standard & Poor's announced that they would cease to allow most newly public companies utilizing dual- or multi-class capital structures to be included in their indices. Affected indices include the Russell 2000 and the S&P 500, S&P MidCap 400 and S&P SmallCap 600, which together make up the S&P Composite 1500. Our dual-class common stock capital structure may make us ineligible for inclusion in any of these and certain other indices, and as a result, mutual funds, exchange-traded funds and other investment vehicles that attempt to passively track these indices would not invest in our stock. These policies may depress our valuation compared to those of other similar companies that are included in such indices.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about us, our business or our market, or if they change their recommendation regarding our Class A common stock adversely, the trading price and trading volume of our Class A common stock could decline.

The trading market for our Class A common stock will depend in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. If no or few securities or industry analysts cover us, the price and trading volume of our Class A common stock likely would be negatively impacted. If one or more of the securities or industry analysts who cover us downgrade our Class A common stock or publish inaccurate or unfavorable research about us, the trading price of our Class A common stock would likely decline. If analysts publish target prices for our Class A common stock that are below our then-current public price of our Class A common stock, it could cause the trading price of our Class A common stock to decline significantly. Further, if one or more of these analysts cease coverage of the Company or fail to publish reports on us regularly, demand for our Class A common stock could decrease, which might cause our Class A common stock trading price and trading volume to decline.

General Risk Factors

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

As a public company, and particularly after we are no longer an "emerging growth company" or "smaller reporting company," we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act and rules subsequently implemented by the SEC and the Nasdaq impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and will make some activities more time- consuming and costly. For example, these rules and regulations have made it more difficult and more expensive for us to obtain director and officer liability insurance.

Pursuant to Section 404, we are 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. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. Further, despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. In addition, if we are not able to continue to meet these requirements, we may not be able to remain listed on the Nasdaq.

Our independent registered public accounting firm may not be able to certify as to the effectiveness of our internal controls over financial reporting, which could have a significant and adverse effect on our business and reputation.

As a public company, we are now 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 control over financial reporting. However, we are not 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 have identified and may identify further 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. In addition, we may be required to incur additional costs in improving our internal control system and the hiring of additional personnel. 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.

Further, 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 facts that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. 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 in the past identified material weaknesses in our internal control over financial reporting, which have since been remediated. If we are unable to develop and maintain an effective system of internal control over financial reporting, or if we discover material deficiencies in the future, we may not be able to accurately report our financial results or prevent fraud, and as a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our Class A common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. 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 financial statements will not be prevented or detected on a timely basis.

During the preparation of our audited consolidated financial statements for the year ended December 31, 2021, we identified certain errors in our previously issued financial statements that were determined not to be material. Further, as disclosed in Item 4 of our Quarterly Reports on Form 10-Q during 2022, we identified material weaknesses in the design and operation of our internal control over financial reporting relating to maintaining and performing our financial close process, ensuring that formal processes exist for identifying, analyzing and accounting for complex, non-routine transactions and proper segregation of duties and responsibilities within our finance department. We have invested resources and taken measures to improve internal control over financial reporting to remediate the control deficiencies that led to these material weaknesses. Although we have successfully remediated these material weaknesses, we cannot assure you that we will be able to successfully remediate other material weaknesses that we may discover additional weaknesses in the future. If we are unable to successfully prevent or remediate any future issues or if the design and operation of our internal controls fails, it could result in material misstatements or omissions in our financial statements and potentially require us to restate our financial statements, which may result in the trading value of our Class A common stock being materially adversely affected.

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our operating results could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our Class A common stock.

The preparation of financial statements in conformity with U.S. generally accepted accounting principles ("GAAP") requires management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. If our assumptions change or if actual circumstances differ from our assumptions, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our Class A common stock.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Facilities

Our principal executive offices are located in Merritt Island, Florida, where we sublease approximately 9,900 square feet of office and lab space from Space Florida. In April 2022, we entered into a facility lease agreement for 4,419 square feet of office space in New York, New York, which will expire in March 2029. We do not currently own any real property. We believe that our current facilities are adequate to meet our immediate needs and believe that we should be able to renew each of our leases and subleases without an adverse impact on our operations. In addition, we believe that if we require additional office space or manufacturing facilities, we will be able to obtain additional facilities on commercially reasonable terms.

Item 3. Legal Proceedings.

From time to time we are a party to various litigation matters incidental to the conduct of our business. We are not presently party to any legal proceedings the resolution of which we believe would have a material adverse effect on our business, prospects, financial condition, liquidity, results of operation, cash flows or capital levels.

Item 4. Mine Safety Disclosures.

The disclosure required by this item is not applicable.

PART II

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

Market Price for the Common Stock

Our Class A common stock is listed on the Nasdaq Global Market under the symbol "VAXX." As of March 15, 2023, the number of shares of our Class A common stock outstanding was 112,188,911 held by approximately 81 shareholders of record, not including shareholders whose shares are held in securities position listings.

Our Class B common stock is not listed on any exchange nor traded on any public market. As of March 15, 2023, the number of shares of our Class B common stock outstanding was 13,874,132 held by approximately 4 shareholders of record.

Dividends

We have never declared or paid, and do not anticipate declaring or paying in the foreseeable future, any cash dividends on our capital stock. Any future determination to declare and pay cash dividends will be at the discretion of our board of directors in accordance with applicable laws and will depend on, among other things, our financial condition, results of operations, cash requirements, contractual restrictions and such other factors as our board of directors deems relevant. Our ability to pay dividends may also be limited by covenants of any future outstanding indebtedness we or our subsidiaries incur.

Issuer Purchases of Equity Securities

We did not repurchase any shares during the years ended December 31, 2022 and 2021.

Unregistered Sales of Equity Securities

There were no unregistered sales of equity securities during the fourth quarter of 2022.

Use of Proceeds

On November 15, 2021, the Company closed its IPO, as discussed in Note 1 of our consolidated financial statements for the year ended December 31, 2022. The aggregate net proceeds to us from the offering, after deducting underwriting discounts and commissions and other offering expenses payable by us, were approximately $71.1 million. The proceeds from our IPO have been invested primarily in U.S. Treasury securities and money market accounts. There has been no material change in the expected use of the net proceeds from our IPO as described in our prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on November 12, 2021.

Item 6. [Reserved].

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

The following discussion and analysis of our financial condition and results of operations should be read together with our consolidated financial statements and related notes and other financial information appearing elsewhere in this Report. We intend for this discussion to provide you with information that will assist you in understanding our consolidated financial statements, the changes in key items in those consolidated financial statements from year to year and the primary factors that accounted for those changes. Some of the information contained in this discussion and analysis or set forth elsewhere in this Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks, uncertainties and assumptions. See the section of this Report titled "Special Note Regarding Forward-Looking Statements" for a discussion of forward-looking statements. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Report, our actual results could differ materially from management's expectations and the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

Vaxxinity is engaged in the development of rationally designed prophylactic and therapeutic vaccines to combat chronic disorders and infectious diseases with large patient populations and unmet medical needs. While vaccines have traditionally been unable to effectively and safely combat such disorders, we believe our platform could overcome the traditional hurdles facing vaccines in this area. Our Vaxxine Platform relies on a synthetic peptide vaccine technology first developed by UBI and subsequently refined over the last two decades. We believe our vaccines have the potential to combat conditions that have not yet been successfully treated, or which have primarily been addressed with monoclonal antibodies (mAbs) which, while generally effective, are extremely costly and cumbersome, and thus have limited accessibility. Our pipeline primarily consists of five programs focused on chronic disease, spanning

neurodegenerative disorders in addition to other neurology and cardiovascular indications. Given the global COVID-19 pandemic and our Vaxxine Platform's applicability to infectious disease, we are also opportunistically advancing a product candidate that addresses SARS-CoV-2.

We separated our business from UBI through two separate transactions: a spin-out from UBI in 2014 of operations focused on developing chronic disease product candidates that resulted in UNS, and a second spin-out from UBI in 2020 of operations focused on the development of a COVID-19 vaccine that resulted in COVAXX. On February 2, 2021, Vaxxinity was incorporated for the purpose of reorganizing and combining UNS and COVAXX and did so on March 2, 2021 through the Reorganization. In connection with the Reorganization, (i) all outstanding shares of UNS and COVAXX preferred stock and common stock were contributed to Vaxxinity and exchanged for an aggregate of 57,702,458 shares of our Class A common stock, 10,999,149 shares of our Class B common stock and 58,175,751 shares of our Series A preferred stock, (ii) the outstanding options to purchase shares of UNS and COVAXX common stock were terminated and substituted with options to purchase an aggregate of 19,712,504 shares of our Class A common stock, (iii) the outstanding warrant to purchase shares of COVAXX common stock was cancelled and exchanged for a warrant that is exercisable for 112,373 shares of our Class A common stock, and (iv) the outstanding Convertible Notes and the Related Note were contributed to Vaxxinity and the former holders of such notes received an aggregate of 4,047,344 shares of our Series A preferred stock. As a result of the Reorganization, COVAXX and UNS became our wholly-owned subsidiaries. All shares of our Series A preferred stock converted into shares of our Class A common stock concurrently with the closing of our initial public offering. The Reorganization was determined to be a common control transaction, so the carrying values of all contributed assets and assumed liabilities remained unchanged and the financial information for all periods in this section of the financial statements presented prior to the Reorganization are presented on consolidated basis. Unless the context requires otherwise, in this section we use the terms "Vaxxinity," "we," "us" and "our" to refer to our operations (including through UNS and COVAXX) both prior to and after the Reorganization.

Since our spin-out transactions from UBI, we have focused on organizing and staffing our business, business planning, raising capital, developing our Vaxxine Platform, identifying and testing potential product candidates and conducting clinical trials. We have also developed a SARS CoV-2 antibody ELISA test, which received an EUA from the FDA in January 2021.

Our current pipeline consists of six programs from early to late-stage development, including five programs focused on chronic disease: UB-311, our leading neurology product candidate, which targets AD; UB-312, which targets PD and other synucleinopathies; VXX-301, an anti-tau product candidate which has the potential to address multiple neurodegenerative conditions, including AD; UB-313, which targets CGRP to prevent migraines; and VXX-401, which targets PCSK9 to reduce LDL cholesterol, a risk factor for atherosclerotic heart disease. Through our Vaxxine Platform, we believe we may be able to address a wide range of other chronic diseases, including chronic diseases that are or could potentially be successfully treated by mAbs, which increasingly dominate the treatment paradigm but remain accessible only to a small proportion of patients who could potentially benefit from them.

In addition to our chronic disease pipeline, given our Vaxxine Platform's applicability to infectious disease and the ongoing need for vaccines to address SARS-CoV-2, we are advancing an infectious disease product candidate, UB-612, as a heterologous booster against COVID-19. We have reported topline results of a pivotal Phase 3 trial of UB-612, and have completed rolling submissions for conditional/provisional authorization with regulatory authorities in the United Kingdom and Australia, respectively, in March of 2023.

To date, our revenue has been generated from the modest sales of our ELISA test and the sale of an option to negotiate a license with UNS (which option has expired). As a result, our ability to generate revenue sufficient to achieve profitability will depend on the eventual regulatory approval, and commercialization of one or more of our product candidates. We have not yet obtained any regulatory approvals for our product candidates or conducted sales and marketing activities for our product candidates.

We have principally funded our operations through financing transactions. Through December 31, 2022, we received gross proceeds of $306.4 million in connection with various financial instruments, including the sale of preferred and common stock, the issuance of promissory notes (including convertible promissory notes ("Convertible Notes")), and the entry into simple agreements for future equity ("SAFEs").

Costs associated with research and development are the most significant component of our expenses. These costs can vary greatly from period to period depending on the timing of various trials for our product candidates. We expect our allocated research and development costs and general and administrative expenses could increase over time if we expand the number of product candidates that we are advancing and incur increased costs as a result of operating as a public company. Further, we anticipate incurring greater selling and marketing expenses if we commercialize any of our product candidates in the future. Our product candidates are in clinical stage or pre-clinical stage development. We have generated limited revenue to date, and have incurred significant operating losses since inception. Net losses were $75.2 million and $137.2 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $304.7 million. We anticipate our expenses and capital requirements may increase over time in connection with expanding our operations, which could include:

- continuing pre-clinical studies, existing clinical trials, or initiating new clinical trials for product candidates UB-312, UB-313, VXX-401, UB-612, and other product candidates;

- hiring additional clinical, quality control, medical, scientific and other technical personnel to support additional clinical and research and development programs;
- expanding operational, financial and management systems and infrastructure, expanding our facilities and increasing personnel to support operations;
- undertaking actions to meet the requirements and demands of being a public company;
- maintaining, expanding and protecting our intellectual property portfolio;
- seeking regulatory approvals for any product candidates that successfully complete clinical trials, including UB-612; and
- undertaking pre-commercialization activities to establish sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we elect to commercialize products on our own or jointly with third parties.

As of the date of this Report, we expect our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 12 months. We also believe that cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into mid-2024. Thereafter, our viability will be dependent on our ability to raise additional capital to finance operations, to successfully commercialize our product candidates, or to enter into collaborations with third parties for the development of our product candidates. If we are unable to do any of the foregoing, we would be forced to delay, limit, reduce or terminate our product candidate development or future commercialization efforts. Our estimates are based on a variety of assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than expected. See "— Liquidity and Capital Resources."

Business Update Regarding COVID-19 Pandemic

In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. The onset of the pandemic led to our institutional prioritization of COVID-19 vaccine development efforts, which correlated with a relative decline in research and development expenditures for our chronic disease product candidates. To date, our operations have not been negatively impacted by the COVID-19 pandemic in a material manner. While the pandemic has subsided around the world since 2020, we cannot predict the specific extent, duration or full impact that future outbreaks associated with new variants of the COVID-19 virus may have on our financial condition and operations. Potential impacts could include delays of the development of clinical supply materials, and enrollment of patients in our studies may be delayed or suspended, as hospitals and clinics in areas where we are conducting trials may need to shift resources to cope with COVID-19 and may limit access or close clinical facilities. Additionally, if our trial participants are unable to travel to our clinical study sites as a result of quarantines or other restrictions resulting from COVID-19 outbreaks, we may experience higher drop-out rates or delays in our clinical studies. The impact of the COVID-19 pandemic on our financial performance will depend on future developments, including the duration and spread of future outbreaks and related governmental advisories and restrictions. The impact of future outbreaks on the financial markets and the overall economy are also highly uncertain and cannot be predicted. If the financial markets and/or the overall economy are impacted for an extended period, our results may be materially adversely affected. See "Risk Factors—Risks Related to Our Business and Industry—The ongoing coronavirus pandemic has caused interruptions or delays of our business plan. Delays caused by the coronavirus pandemic may have a significant adverse effect on our business."

Components of Our Consolidated Results of Operations

Revenue

We recorded no revenues for the year ended December 31, 2022. Revenue for the year ended December 31, 2021 was $0.1 million, and consisted of commercial sales of our ELISA tests. We do not expect to generate any meaningful revenue unless and until we obtain regulatory approval of and commercialize or out-license our product candidates, and we do not know when, or if, this will occur. If our development efforts for our product candidates are successful and result in commercialization, we may generate additional revenue in the future from a combination of product sales or payments from collaboration or license agreements that we have entered into or may enter into with third parties. See Risk Factors—Risks Related to the Discovery and Development of Product Candidates. We have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

Cost of Revenue

We recorded no cost of revenue for the year ended December 31, 2022. Cost of revenue for the year ended December 31, 2021 consists of kit production costs consisting of materials, labor and overhead expenses directly related to ELISA tests sold and the costs of expired ELISA tests, which are not available for commercial sale.

If our development efforts in respect of our current pipeline of product candidates are successful and result in regulatory approval, we expect our cost of revenue will increase in relative proportion to the level of our revenue as we commercialize the applicable product candidate. We expect that cost of revenue will increase in absolute dollars as and if our revenue grows and will vary from period to period as a percentage of revenue.

Research and Development Expenses

The design, initiation and execution of candidate discovery and development programs of our potential future product candidates is key to our success and involves significant expenses. Prior to initiating these programs, project teams incorporating individuals from the essential disciplines within Vaxxinity scope out the activities, timing, requirements, inclusion and exclusion criteria and the primary and secondary endpoints. Once we have decided to proceed, our Vaxxine Platform enables the iteration of drug candidates in the discovery phase through rapid, rational design and formulation. After we have identified drug candidates, the costs of scaling the formulation from research grade to clinical grade, then to commercial grade, typically consumes significant resources. In addition, to internal research and development, we utilize service providers, including related parties, to complete activities we lack the internal resources to handle.

Research and development expenses consist primarily of costs incurred for research activities, including drug discovery efforts and the development of our product candidates. We expense research and development costs as incurred, which include:

- expenses incurred to conduct the necessary preclinical studies and clinical trials required to obtain regulatory approval;
- expenses incurred under agreements with CROs that are primarily engaged in the oversight and conduct of our clinical trials, preclinical studies and drug discovery efforts and contract manufacturers that are primarily engaged to provide preclinical and clinical drug substance and product for our research and development programs;
- other costs related to acquiring and manufacturing materials in connection with our drug discovery efforts and preclinical studies and clinical trial materials, including manufacturing validation batches;
- costs related to investigative sites and consultants that conduct our clinical trials, preclinical studies and other scientific development services;
- employee-related expenses, including salaries and benefits, travel and stock-based compensation expense for employees engaged in research and development functions;
- costs related to compliance with regulatory requirements; and
- facilities-related costs, depreciation and other expenses, which include rent and utilities.

We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by service providers. This process involves reviewing open contracts and purchase orders, communicating with personnel 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 actual costs. Any nonrefundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are expensed as the related goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered, or the services rendered, at which point the net remainder is expensed.

We continue to work with related parties for the advancement of our research and development programs, including for manufacturing, quality control, testing, validation, supply services, as well as the winding down of some previously initiated clinical initiatives. While this related party work has significantly diminished over the last year, and we expect this trend to continue, we are still reliant on UBIA to provide certain manufacturing-related data that will be needed for inclusion in our regulatory applications for UB-612. During the years ended December 31, 2022 and 2021, related party expenses were approximately 6% and 29% of our operating expenses, respectively.

Where appropriate, we allocate our third-party research and development expenses on a program-by-program basis. These expenses primarily relate to outside consultants, CROs, contract manufacturers and research laboratories in connection with pre-clinical development, process development, manufacturing and clinical development activities. We do not allocate our internal costs, such as employee costs, costs associated with our discovery efforts, laboratory supplies and facilities, including depreciation or other indirect costs, to specific programs because these costs often relate to platform development, to multiple programs simultaneously or to discovery of new programs, and any such allocation would necessarily involve significant estimates and judgments and, accordingly, would be imprecise. When we refer to the research and development expenses associated with a specific program, these refer exclusively to the allocated third-party expenses associated with that product candidate. All other research and development costs are referred to as unallocated costs.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. Additionally, greater research and development overhead is required to support broader and more rapid development of our Vaxxine Platform and new product candidates. As a result, we expect that our research and development expenses could increase if we continue our existing and planned clinical trials and conduct increased pre-clinical and clinical development activities, including submitting regulatory filings for product candidates, and focus more generally on the development of our chronic disease product candidates.

At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the pre-clinical and clinical development of any of our product candidates or when, if ever, material net cash inflows may commence from any of our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and benefits, travel and stock-based compensation expense for personnel in executive, business development, finance, human resources, legal, information technology, public relations, communications and administrative functions. General and administrative expenses also include insurance costs and professional fees for legal, patent, consulting, investor and public relations, accounting and audit services and other general operating expenses not otherwise classified as research and development expenses. We expense general and administrative costs as incurred.

In the event UB-612 obtains regulatory approval and we subsequently commence commercialization of this product, we expect general and administrative expenses will increase. We will continue to incur public company-related expenses, including services associated with maintaining compliance with Nasdaq listing and SEC requirements, director and officer liability insurance and investor and public relations costs.

Other Expense (Income)

Interest Expense

Interest expense consists of (i) interest expense recognized on the note payable entered into during June 2020 for the acquisition of an airplane (the "2025 Note"), (ii) interest expense accrued on the related party promissory note, (iii) interest expense recognized on the Convertible Notes and (iv) interest expense recognized on other promissory notes, including $0.1 million borrowed from our Chief Executive Officer (the "Executive Note") and a related party Convertible Note payable for $2.0 million in aggregate proceeds that was received in three tranches (the "2018 Related Notes"). The Executive Note was repaid in full in August 2021 and the 2018 Related Notes were converted into Series A preferred stock concurrently with the Reorganization.

Interest Income

Interest income consists of income earned on our cash and cash equivalents, money market holdings, and short-term investments.

Change in Fair Value of Convertible Notes, SAFEs and Series A-1 Warrant Liability

We issued a series of Convertible Notes during the years ended December 31, 2018 through 2021, a series of SAFEs during the years ended December 31, 2020 and 2021, and warrants to purchase shares of our Series A-1 preferred stock ("Series A-1 Warrants") during the year ended December 31, 2020, each of which were measured and accounted for at fair value. We remeasured the fair value of each of the Convertible Notes, SAFEs and Series A-1 Warrants at each reporting date and recognize changes in the fair value in our consolidated statements of operations. Inputs to the calculation of fair value generally include market and acquisition comparable(s) as well as other variables. In connection with the Reorganization, all outstanding Convertible Notes, SAFEs, and Series A-1 Warrants were exchanged for shares of Series A preferred stock, which were subsequently exchanged into shares of Class A common stock upon closing of the IPO in November 2021.

Loss on Foreign Currency Translation, Net

Our foreign subsidiaries, which are wholly-owned by Vaxxinity, use the U.S. dollar as their functional currency and maintain records in the local currency. Nonmonetary assets and liabilities are remeasured at historical rates and monetary assets and liabilities are remeasured at exchange rates in effect at the end of the reporting period. Income statement accounts are remeasured at average exchange rates for the reporting period. The resulting gains or losses are included in foreign currency (losses) gains in the consolidated financial statements.

Provision for Income Taxes

We have not recorded any significant amounts related to income tax but have reserved $0.7 million of unrecognized tax benefits against NOLs. We have not recorded any income tax benefits for the majority of our net losses we incurred to date.

We account for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements or our tax returns.

Deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax basis of existing assets and liabilities and for loss and credit carryforwards, which are measured using the enacted tax rates and laws in effect in the years in which the differences are expected to reverse. The realization of our deferred tax assets is dependent upon the generation of future taxable income, the amount and timing of which are uncertain. Valuation allowances are provided, if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. As of December 31, 2022, we continue to maintain a full valuation allowance against all of our deferred tax assets based on evaluation of all available evidence. We file income tax returns in the U.S. federal and state jurisdictions and may become subject to income tax audit and adjustments by related tax authorities. Our tax return periods (for entities then in existence) for U.S. federal income taxes for the tax years since 2017 remain open to examination under the statute of limitations by the Internal Revenue Service and state jurisdictions. We record reserves for potential tax payments to various tax authorities related to uncertain tax positions, if any. The nature of uncertain tax positions is subject to significant judgment by management and subject to change, which may be substantial. These reserves are based on a determination of whether and how much a tax benefit taken by us in our tax filings or positions is more likely than not to be realized following the resolution of any potential contingencies related to the tax benefit. We develop our assessment of uncertain tax positions, and the associated cumulative probabilities, using internal expertise and assistance from third-party experts. As additional information becomes available, estimates are revised and refined. Differences between estimates and final settlement may occur resulting in additional tax expense. Potential interest and penalties associated with such uncertain tax positions is recorded as a component of our provision for income taxes.

Factors Affecting the Comparability of Our Consolidated Results of Operations

On March 2, 2021, Vaxxinity entered into the Contribution and Exchange Agreement, pursuant to which the outstanding equity interests of UNS and COVAXX were contributed to Vaxxinity in return for equity interests in Vaxxinity, resulting in UNS and COVAXX becoming wholly owned subsidiaries of Vaxxinity. Accordingly, all share and per share amounts prior to the Reorganization have been adjusted to reflect the Reorganization. In addition, we formed COVAXX, and commenced our COVAXX business, on March 23, 2020. As a result, the historical financial information between March 23, 2020 and March 2, 2021 described in this Annual Report refers to the combined historical financial information of UNS and COVAXX. Our operations for the year ended December 31, 2022 reflects the operations of Vaxxinity and its subsidiaries. Our operations for the year ended December 31, 2021 reflects the operations of UNS and COVAXX businesses on a consolidated basis for the period from January 1, 2021 to March 1, 2021 and of Vaxxinity and its subsidiaries for the remainder of that twelve-month period. See Note 1 to our consolidated financial statements included elsewhere in this Form 10-K filing.

Consolidated Results of Operations

The following is a summary of our consolidated results of operations:

	Years Ended December 31,		2022 vs. 2021	
(In thousands)	**2022**	**2021**	**Change $**	**Change %**
Revenue	$ —	$ 66	$ (66)	(100)%
Cost of revenue	—	1,937	(1,937)	(100)%
Gross (loss) profit	—	(1,871)	1,871	(100)%
Operating expenses:				
Research and development	47,627	71,379	(23,752)	(33)%
General and administrative	28,352	51,825	(23,473)	(45)%
Total operating expenses	75,979	123,204	(47,225)	(38)%
Loss from operations	(75,979)	(125,075)	49,096	(39)%
Other (income) expense:				
Interest and other expense	514	840	(326)	(39)%
Interest and other income	(1,259)	(9)	(1,250)	13,889 %
Change in fair value of convertible notes	—	2,667	(2,667)	(100)%
Change in fair value of simple agreement for future equity	—	8,365	(8,365)	(100)%
Change in fair value of warrant liability	—	214	(214)	(100)%
(Gain) loss on foreign currency translation, net	(12)	23	(35)	(152)%
Other (income) expense	(757)	12,100	(12,857)	(106)%
Net loss	$ (75,222)	$ (137,175)	$ 61,953	(45)%

Comparison of the Years Ended December 31, 2022 and 2021

Revenue

We did not record any revenues for the year ended December 31, 2022. Total revenue was $0.1 million for the year ended December 31, 2021. All revenues were due to sales of our ELISA tests. We are not actively pursuing commercialization of our ELISA tests at this time.

Gross Margin

All gross margin and comparable decreases were due to sales of our ELISA tests. Gross margin was zero for the year ended December 31, 2022. The gross margin for the year ended December 31, 2021 was negative, however the sales volume was de minimis. During the year ended December 31, 2021, we wrote off, to cost of revenue, $1.9 million in expired ELISA tests that had no commercial value.

Research and Development Expenses

Research and development expenses were $47.6 million and $71.4 million for the years ended December 31, 2022 and 2021, respectively.

The $23.8 million decrease was comprised of a $38.3 million decrease in allocated costs (i.e., costs that can be directly attributed to a specific clinical program), offset by a $14.6 million increase in unallocated costs. The decrease in allocated costs was primarily due to a decrease of $47.7 million in costs related to our UB-612 Covid vaccine program, including a $1.8 million expense in 2022 for raw materials acquired by UBP, a related party contract manufacturer. See Note 17, "Commitments and Contingencies", for more information about this expense. The decrease in allocated costs was offset by increases in spend of $4.7 million on our VXX-401 hypercholesterolemia program, $2.1 million on our UB-313 CGRP program, and $0.5 million on our UB-312 PD program. The $14.6 million increase in unallocated costs was driven by increased salaries and personnel-related costs of $9.6 million, including stock-based compensation expense of $1.8 million, a $3.2 million increase in rent, lab supplies, logistics and travel costs, and a $1.8 million increase in external professional services supporting research and development activities across the pipeline.

General and Administrative Expenses

General and administrative expenses were $28.4 million and $51.8 million for the years ended December 31, 2022 and 2021, respectively. The $23.5 million decrease was primarily due to a decrease of $23.6 million in stock-based compensation expense; we recorded a $23.1 million expense in 2021 related to performance-based grants that vested upon the successful completion of our IPO in November 2021. There were also decreases of $0.7 million in legal spend, and $1.0 million in consulting spend versus the prior year when we were preparing for our initial public offering, and $0.8 million in spending on external recruiters. These cost decreases were partially offset by an increase in director and officer insurance expense of $3.0 million in 2022 versus 2021.

Interest and Other Expense

Interest and other expense was $0.5 million and $0.8 million for the years ended December 31, 2022 and 2021, respectively. The decrease was due to the conversion of Convertible Notes for Series A preferred stock in connection with the Reorganization.

Interest and Other Income

Interest and other income on cash and short-term investments was $1.3 million and less than $0.1 million for the years ended December 31, 2022 and 2021, respectively.

Change in Fair Value of Convertible Notes, SAFEs and Series A-1 Warrant Liability

The $2.7 million change in fair value of the Convertible Notes recognized during the year ended December 31, 2021 related to the revaluation of the Convertible Notes upon conversion to equity. The $8.6 million change in fair value of SAFEs recognized during the year ended December 31, 2021 related to insight into the pricing of Vaxxinity's next stock issuance at a higher valuation. The $0.2 million change in fair value of Series A-1 Warrants recognized during the year ended December 31, 2021 related to an increase in value of the Series A-1 preferred stock.

In connection with the Reorganization, all outstanding Convertible Notes, SAFEs and Series A-1 Warrants were exchanged into shares of Series A preferred stock, which were subsequently exchanged into shares of Class A common stock upon the closing of the IPO in November 2021 as described in Note 9 to our consolidated financial statements included elsewhere in this Report.

(Gain) Loss on Foreign Currency Translation, Net

The net gain (loss) of foreign currency translation reflects de minimis fluctuations in the foreign exchange rate for the year ended December 31, 2022 compared to the year ended December 31, 2021.

Liquidity and Capital Resources

Sources of Liquidity

We have generated limited revenue from sales of our ELISA tests and have not yet obtained regulatory approval for or commercialized any of our product candidates, which are in various phases of pre-clinical and clinical development. We have financed operations primarily through the issuance of common stock, convertible preferred stock, borrowings under promissory notes (including Convertible Notes) and the execution of SAFEs. Through December 31, 2022, we received gross proceeds of $306.4 million in connection with the issuance of various financial instruments, including the sale of preferred and common stock, the issuance of promissory notes (including Convertible Notes), and the execution of SAFEs. In addition, we also generated revenue from the sale of an option to negotiate a license with UNS (which option has expired) and the sales of ELISA tests in 2020 and 2021. At December 31, 2022, we had $33.5 million in cash and cash equivalents, $53.4 million of short-term investments, and a $1.1 million restricted cash balance, compared to $145.1 million as of December 31, 2021. The decrease in cash and cash equivalents balances for the periods reported are primarily due to the factors described under “Cash Flows” below.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2022 and 2021 (in thousands):

	December 31,	
	2022	**2021**
Balance Sheet Data:		
Cash and cash equivalents	$ 33,475	$ 144,885
Short-term investments, net	53,352	—
Restricted cash	1,095	172
Total assets	106,399	166,673
Total liabilities	44,222	38,054
Total stockholders' equity	$ 62,177	$ 128,619

	Years Ended December 31,	
	2022	**2021**
Statement of Cash Flow Data:		
Net cash used in operating activities	$ (55,928)	$ (80,990)
Net cash used in investing activities	(54,392)	(1,318)
Net cash used in financing activities	(167)	196,167
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (110,487)	$ 113,859

Operating Activities

Net cash used in operating activities for the year ended December 31, 2022 was $55.9 million, primarily due to a $75.2 million net loss, offset by a favorable $9.8 million change in operating assets and liabilities and total non-cash items of $9.5 million. The favorable cash flow impact from changes in net operating assets and liabilities was primarily due to $9.0 million related to accrued expense, accounts payable and other liabilities and $3.3 million in prepaid expenses for UB-612 production, partially offset by $2.4 million in amounts due to related parties. The primary non-cash adjustments to net loss included addbacks of $8.7 million of stock-based compensation and $1.7 million in depreciation, offset by a reduction of $1.0 million for amortization of discounts on short-term investments.

Net cash used in operating activities for the year ended December 31, 2021 was $81.0 million, primarily due to a $137.2 million net loss, offset by a favorable $12.9 million change in operating assets and liabilities and total non-cash items of $43.3 million. The cash flow impact from changes in net operating assets and liabilities were primarily due to $11.4 million in amounts due to related parties as well as $3.9 million related to accrued expense, accounts payable and other liabilities. These increases were offset by $4.7 million in prepaid expenses for UB-612 production. The primary non-cash adjustments to net loss included an $11.2 million change in the fair market value of financial instruments as well as $30.4 million of stock-based compensation and $1.1 million in depreciation.

Investing Activities

Net cash used in investing activities totaled $54.4 million for the year ended December 31, 2022. The cash used in investing activities consisted primarily of the net impact of the acquisition and redemption of short-term investments, and the acquisition of laboratory and computer equipment, and leasehold improvements.

Net cash used in investing activities totaled $1.3 million for the year ended December 31, 2021. The cash used in investing activities consisted primarily of the acquisition of equipment.

Financing Activities

Net cash used by financing activities was $0.2 million for the year ended December 31, 2022. We repaid $0.4 million in relation to a note payable and received $0.3 million from the exercise of stock options.

Net cash provided by financing activities totaled $196.2 million for the year ended December 31, 2021. We raised capital to support our operations through the issuance of Class A common stock in the IPO, with net proceeds of $71.1 million, the issuance prior to the Reorganization of SAFEs and Convertible Notes, with net proceeds of $2.9 million and $2.0 million, respectively, as well as the issuance of Series B convertible preferred stock, with net proceeds of $122.8 million. We also repaid $2.0 million in relation to a Convertible Note, $0.1 million in relation to a note payable with related party, $0.3 million in repayment for Paycheck Protection Program, and $0.4 million in relation to a note payable entered into for the acquisition of an airplane.

Funding Requirements

We have generated approximately $3.7 million in revenue since inception and have incurred net losses in each reporting period since inception. We do not expect to generate any meaningful revenue unless and until we obtain regulatory approval of and commercialize our product candidates, or enter into collaboration or licensing deals with one or more third-party strategic partners. We do not know when, or if, this will occur. If we do not receive regulatory approval for any of our product candidates, or if we receive approval but our commercialization results fall short of our expectations, we will continue to incur significant losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates and begin to commercialize any approved products.

As of the date of this Annual Report, we expect our existing cash and cash equivalents will be sufficient to fund our operating expenses over the next 12 months. As of December 31, 2022, other than our 2025 Note and the 2022 Promissory Note, we have no material debt obligations.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect, and we may use all of our available capital resources sooner than we expect. Our future capital requirements will depend on many factors, which include:

- the scope, number, progress, initiation, duration, cost, results and timing of pre-clinical programs and nonclinical studies of our current or future product candidates;
- the outcomes and timing of regulatory reviews, approvals or other actions;
- the timing and manner in which we manufacture our pre-clinical and clinical drug material, the terms on which we can have such manufacturing completed, and the extent to which we undertake commercialization of any drug products, if approved;
- the extent to which we establish sales, marketing, medical affairs and distribution infrastructure to commercialize any product candidates;
- the timing and extent to which we expand our operational, financial and management systems and infrastructure, and facilities;
- the timing and extent to which we increase our personnel to support operations, including necessary increases in headcount to conduct and expand our clinical trials, commercialize any approved products and support our operations as a public company;
- the number of patent applications we must file and claims we must defend in order to maintain, expand and protect our intellectual property portfolio, and the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights;
- our ability to obtain marketing approval for our product candidates;

- our ability to establish and maintain additional licensing, collaboration or similar arrangements on favorable terms and whether and to what extent we retain development or commercialization responsibilities under any new licensing, collaboration or similar arrangement;

- the success of any other business, product or technology that we acquire or in which we invest;

- our ability to maintain, expand and defend the scope of our intellectual property portfolio;
- the current and potential impacts of the COVID-19 pandemic on our business;

- the costs of acquiring, licensing or investing in businesses, product candidates and technologies;

- market acceptance of our product candidates, to the extent any are approved for commercial sale; and

- the effect of competing technological and market developments.

Until such time, if ever, as we can generate positive cash flows from operations, we expect to finance our cash needs through public or private equity offerings, strategic collaborations and debt financing. To the extent that we raise additional capital through the sale of our Class A common stock, convertible securities or other equity securities, shareholders' ownership interest will be diluted and the terms of these securities could include liquidation or other preferences and anti-dilution protections. In addition, debt financing, if available, may result in fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming shares or declaring dividends.

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

Contract Research and Manufacturing Organizations

We recorded accrued expenses of $4.3 million and $4.5 million in our balance sheet for expenditures incurred by CROs and contract manufacturers as of December 31, 2022 and 2021, respectively.

Tax-Related Obligations

We have reserved $0.7 million of unrecognized tax benefits against NOLs. Additionally, as of December 31, 2022 and 2021, we accrued $0.2 million and $0.2 million, respectively, in interest and penalties related to prior year tax filings.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Critical Accounting Policies and Estimates

The preparation of financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. Management bases its estimates on historical experience, market and other conditions, and various other assumptions it believes to be reasonable. Although these estimates are based on management's best knowledge of current events and actions that may impact us in the future, the estimation process is, by its nature, uncertain given that estimates depend on events over which we may not have control. In addition, if our assumptions change, we may need to revise our estimates, or take other corrective actions, either of which may also have a material effect on our consolidated financial statements. Significant estimates contained within these consolidated financial statements include, but are not limited to, the estimated fair value of our common stock, convertible notes payable and SAFEs, stock-based compensation, warrant liabilities, income tax valuation allowance and the accruals of research and development expenses. We base our estimates on historical experience, known trends and other market-specific or other relevant factors that we believe to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates, as there are changes in facts and circumstances. If market and other conditions change from those that we anticipate, our consolidated financial statements may be materially affected.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this Annual Report, we believe that the following critical accounting policies and estimates have a higher degree of inherent uncertainty and require our most significant judgments.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate accrued research and development expenses. As we advance our programs, we anticipate more complex clinical studies resulting in greater research and development expenses, which will place even greater emphasis on the accrual. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel 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 actual costs. In the past years, UBI and its affiliated companies performed and administered a significant amount of research and development work on our behalf. Having UBI and its affiliated company act as intermediaries added to the complexity of determining appropriate accruals, and we have largely moved away from this model. Certain accruals and amounts owed to the UBI entities are still under review, and these amounts may change as a result of this review.

The majority of our service providers invoice in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. We make estimates of accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of the estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- vendors, including research laboratories, in connection with pre-clinical development activities;
- CROs and investigative sites in connection with pre-clinical studies and clinical trials; and
- contract manufacturers in connection with drug substance and drug product formulation of pre-clinical studies and clinical trial materials.

We base our expenses related to pre-clinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple research institutions and CROs that supply, conduct and manage pre-clinical studies and clinical trials 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 expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, it adjusts the accrual or the prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, our estimated accruals have not differed materially from actual costs incurred.

Stock-Based Compensation

We measure all stock-based awards granted to employees, directors and non-employees based on their fair value on the date of the grant and recognize the corresponding compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. Forfeitures are accounted for as they occur. We grant stock options and restricted stock awards that are subject to service vesting conditions.

We classify stock-based compensation expense in our consolidated statements of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

We estimate the fair value of each stock option grant using the Black-Scholes option-pricing model, which requires the use of subjective assumptions that could materially impact the estimation of fair value and related compensation expense to be recognized. These assumptions include (i) the expected volatility of our stock price, (ii) the periods of time over which recipients are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on our common stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Developing these assumptions requires the use of judgment. Both prior to and after the IPO, we lacked company-specific historical and implied volatility information. Therefore, we estimate our expected stock volatility based on the historical volatility of a publicly traded set of peer companies. The expected term of the Company's options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of options granted to non-employees is equal to the contractual term of the option award. The expected dividend yield is zero as we have never paid dividends and do not currently anticipate paying any in the foreseeable future.

Determination of the Fair Value of Common Stock

Before there was a public market for our common stock, the estimated fair value of common stock was determined by its most recently available third-party valuations of common stock. These third-party valuations were performed in accordance with the guidance outlined

in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. Our common stock valuations were prepared using an option pricing method ("OPM"). The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceeded the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock.

In addition to considering the results of these third-party valuations, our board of directors considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, including:

- the prices at which we sold shares of preferred stock and the superior rights and preferences of the preferred stock relative to our common stock at the time of each grant;
- the progress of our research and development programs, including the status and results of pre-clinical studies and clinical trials for our product candidates;
- our stage of development and commercialization and our business strategy;
- external market conditions affecting the biopharmaceutical industry and trends within the biopharmaceutical industry;
- our financial position, including cash on hand, and our historical and forecasted performance and results of operations;
- the lack of an active public market for our common stock and our preferred stock;
- the likelihood of achieving a liquidity event, such as an initial public offering or our sale in light of prevailing market conditions; and
- the analysis of initial public offerings and the market performance of similar companies in the biopharmaceutical industry.

The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used significantly different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could have been materially different.

Once a public trading market for our common stock has been established for a sufficient period of time, it will no longer be necessary to estimate the fair value of our common stock in connection with our accounting for granted stock options and other such awards we may grant, as the fair value of our common stock will be determined based on the quoted market price of our common stock.

Awards Granted

The following table sets forth information on stock options awarded to employees and board members since January 1, 2019:

Grant Date	Number of shares subject to award	Per share exercise price of options	Per share fair value of common stock on grant date	Per share estimated fair value of award on grant date
December 30, 2019	1,139,717	$0.57	$0.64	$0.40
August 22, 2020	1,984,553	$1.21	$1.65	$0.75
August 24, 2020	521,406	$1.21	$1.65	$0.75
September 2, 2020	160,161	$0.57	$1.43	$1.18
January 26, 2021	9,043,916	$4.12	$4.12	$2.26
February 11, 2021	1,404,291	$4.01	$4.01	$2.53
June 16, 2021	690,266	$4.81	$4.81	$3.59
July 16, 2021	282,776	$4.81	$4.81	$3.63
July 28, 2021	562,605	$10.07	$10.07	$7.47
November 11, 2021	1,499,085	$13.00	$13.00	$9.77
January 3, 2022	183,238	$5.96	$5.96	$4.47
March 1, 2022	25,662	$4.99	$4.99	$3.73
March 31, 2022	94,186	$4.30	$4.30	$3.22
April 1, 2022	32,900	$4.30	$4.30	$3.24
May 1, 2022	14,600	$6.95	$6.95	$5.26
June 1, 2022	27,700	$4.22	$4.22	$3.21
June 21, 2022	645,935	$2.09	$2.09	$1.54
July 1, 2022	2,300	$1.57	$1.57	$1.36
August 1, 2022	3,900	$1.92	$1.92	$1.46
August 8, 2022	20,000	$2.27	$2.27	$1.73
September 1, 2022	54,500	$2.48	$2.48	$1.90
October 3, 2022	254,600	$2.04	$2.04	$1.57
November 1, 2022	12,300	$1.40	$1.40	$1.10
December 1, 2022	15,400	$2.38	$2.38	$1.90

Simple Agreement for Future Equity

During the year ended December 31, 2021, we entered into SAFEs. The SAFEs were not mandatorily redeemable, nor did they require us to repurchase a fixed number of shares. We determined that the SAFEs contained a liquidity event provision that embodied an obligation indexed to the fair value of the equity shares and could require us to settle the SAFE obligation by transferring assets or cash. Our SAFEs represented a recurring measurement that is classified within Level 3, discussed and defined in Note 2 to our consolidated financial statements included elsewhere in this Report, of the fair value hierarchy wherein fair value is estimated using significant unobservable inputs, including an estimate of the number of months to a liquidity event, volatility rates and the estimation of the most likely conversion feature for converting the SAFE.

The fair value of the SAFEs on the date of issuance was determined to equal the proceeds we received. The value of the SAFEs on the date of conversion into Series A preferred stock was determined to be equal to the fair value of the Series A preferred stock issued in connection with the Reorganization.

Convertible Notes

Beginning in 2018, we issued Convertible Notes that bore simple interest at annual rates ranging from 4.8% to 6%. All unpaid principal, together with the accrued interest thereon, for the Convertible Notes were payable upon the event of default or upon maturity, which ranged from one to three years. The Convertible Notes contained a number of provisions addressing automatic and optional conversion, events of default and prepayment provisions. We determined that a portion of the Convertible Notes contained a liquidity event provision, requiring them to be measured and accounted for at fair value at each reporting date. We determined the Convertible Notes requiring a measurement to fair value represented a recurring measurement that was classified within Level 3, disclosed and defined in Note 4 to our consolidated financial statements included elsewhere in this Annual Report, of the fair value hierarchy wherein fair value is estimated using significant unobservable inputs.

Coalition for Epidemic Preparedness ("CEPI") Grant

In April 2022, we entered into an agreement with the Coalition for Epidemic Preparedness Innovations ("CEPI") whereby CEPI agreed to provide funding of up to $9.3 million to co-fund a Phase 3 clinical trial of our UB-612 COVID-19 vaccine candidate as a heterologous – or 'mix-and-match' – booster dose. The Phase 3 trial, which began in early 2022, is evaluating the ability of UB-612 to boost COVID-19 immunity against the original strain and multiple variants of concern including Omicron - in people aged 16 years or older, who have been previously immunized with an authorized COVID-19 vaccine.

We will also be performing further manufacturing scale-up work to enable readiness for potential commercialization. Under the terms of the agreement with CEPI, if successful, a portion of the released doses of the commercial product will be delivered to the COVID-19 Vaccines Global Access ("COVAX") consortium for distribution to developing countries at low cost.

Cash payments received in advance under the CEPI Funding Agreement are restricted as to their use until expenditures contemplated in the funding agreement are incurred. As funds are received they are included within restricted cash offset by a corresponding short-term accrued liability. We recognize payments from CEPI as a reduction of research and development expenses, in the same period as the expenses that the grant is intended to reimburse are incurred.

Taiwan Centers for Disease Control Grant

UBIA, which is responsible for applying for and managing grants on our behalf, was awarded a grant by the Taiwan Centers for Disease Control ("TCDC") for COVID-19 vaccine development. The grant provides that costs incurred to complete the two phases of the clinical trial will be reimbursed based on the achievement of certain milestones as defined in the agreement. We are entitled to reimbursement under the TCDC grant. At each reporting date, we assess the status of all of the activities involved in completing the clinical study in relation to the milestones. We account for the amounts that have been received from the TCDC to reimburse costs incurred on the clinical study and not expected to be refunded back to the TCDC as contra research and development expenses in the accompanying consolidated statements of operations.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk in the ordinary course of our business. These risks primarily relate to foreign currency, inflation and changes in interest rates.

Inflation Risk

Inflation generally may affect us by increasing our cost of labor, clinical trial costs, and other outsourced activities. To date, inflation has not had a material impact on our business, but if the global inflationary trends continue, we expect appreciable increases in clinical trial, selling, labor, and other operating costs. If our costs were to become subject to significant inflationary pressures, this would adversely affect our business, financial condition and results of operations.

Foreign Currency Exchange Risk

We have limited exposure to foreign currency exchange risk as most of our operating activities are primarily denominated in U.S. dollars. We believe actual foreign exchange gains and losses did not have a significant impact on our results of operations for any periods presented herein. The results of the analysis based on our financial position as of December 31, 2022, indicated that a hypothetical 10% increase or decrease in applicable foreign currency exchange rates would not have a material effect on our financial results.

Interest Rate Risk

We are exposed to market risk related to changes in interest rates. As of December 31, 2022 and 2021, our cash equivalents consisted of interest-bearing checking accounts and money market accounts. We issued Convertible Notes, which Convertible Notes were exchanged for Series A preferred stock in connection with the Reorganization. The Convertible Notes bore simple interest at the annual rates ranging from 4.8% to 6%, with redemption terms payable at the earlier of one year, or upon the event of default. In addition, the Convertible Notes contained provisions addressing automatic and optional conversion. Given the redemption of the Convertible Notes, and the short-term nature and fixed interest rate, we believe there is no material exposure to interest rate risk. The 2025 Note we entered into for the year ended December 31, 2020 bears a fixed annual interest rate of 3.4% and matures in June 2025. Additionally, the 2022 Promissory Note we entered into for the year ended December 31, 2022 bears a fixed annual interest rate of 7.0% and matures in October 2026. Given that the 2025 Note and the 2022 Promissory Note bear fixed rates of interest, we believe there is no material exposure to interest rate risk. The results of the analysis based on our financial position as of December 31, 2022, indicated that a hypothetical 100 basis point increase or decrease in risk-free rates would not have a material effect on our financial results.

Our measurement of interest rate risk involves assumptions that are inherently uncertain and, as a result, cannot precisely estimate the impact of changes in interest rates on net interest revenues. Actual results may differ from simulated results due to balance growth or decline and the timing, magnitude, and frequency of interest rate changes, as well as changes in market conditions and management strategies, including changes in asset and liability mix.

Item 8. Financial Statements and Supplementary Data

VAXXINITY, INC.
INDEX TO FINANCIAL STATEMENTS

Audited Consolidated Financial Statements as of and for the years ended December 31, 2022 and 2021

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders

Vaxxinity, Inc. Merritt Island, Florida

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Vaxxinity, Inc. and Subsidiaries (collectively the "Company") as of December 31, 2022 and 2021, the related consolidated statements of operations, convertible preferred stock and stockholders' equity (deficit), and cash flows, for each of the two years in the period ended December 31, 2022, and the related notes (collectively referred to as the "financial statements").

In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

The Company's management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on the Company's consolidated financial statements. 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 consolidated 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 of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinion.

We have served as the Company's auditor since 2018.

/s/ Armanino LLP

San Ramon, California

March 27, 2023

VAXXINITY, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)

	December 31,	
	2022	**2021**
Assets		
Current assets:		
Cash and cash equivalents	$ 33,475	$ 144,885
Short-term investments	53,352	—
Restricted cash	1,095	172
Amounts due from related parties	414	393
Prepaid expenses and other current assets	5,551	8,851
Total current assets	93,887	154,301
Property and equipment, net	12,512	12,372
Total assets	$ 106,399	$ 166,673
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,295	3,192
Amounts due to related parties	12,772	19,407
Accrued expenses and other current liabilities	11,370	4,519
Notes payable	391	376
Notes payable to related party	1,113	—
Total current liabilities	30,941	27,494
Other liabilities:		
Notes payable, net of current portion	9,933	10,323
Notes payable to related party, net of current portion	3,112	—
Other long-term liabilities	236	237
Total liabilities	44,222	38,054
Commitments and contingencies (Note 17)		
Preferred stock: $0.0001 par value, 50,000,000 shares authorized at December 31, 2022 and 2021	—	—
Stockholders' equity:		
Class A common stock, $0.0001 par value; 1,000,000,000 shares authorized, 112,182,750 and 111,518,094 shares issued and outstanding at December 31, 2022 and 2021, respectively	278	278
Class B common stock, $0.0001 par value; 100,000,000 shares authorized, 13,874,132 and 13,874,132 shares issued and outstanding at December 31, 2022 and 2021, respectively	—	—
Additional paid-in capital	366,799	357,822
Accumulated other comprehensive income (loss)	(197)	—
Accumulated deficit	(304,703)	(229,481)
Total stockholders' equity	62,177	128,619
Total liabilities and stockholders' equity	$ 106,399	$ 166,673

The accompanying notes are an integral part of the consolidated financial statements.

VAXXINITY, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)

	Years Ended December 31,	
	2022	**2021**
Revenue	$ —	$ 66
Cost of revenue	—	1,937
Gross (loss) profit	—	(1,871)
Operating expenses:		
Research and development	47,627	71,379
General and administrative	28,352	51,825
Total operating expenses	75,979	123,204
Loss from operations	(75,979)	(125,075)
Other (income) expense:		
Interest and other expense	514	840
Interest and other income	(1,259)	(9)
Change in fair value of convertible notes	—	2,667
Change in fair value of simple agreement for future equity	—	8,365
Change in fair value of warrant liability	—	214
(Gain) loss on foreign currency translation, net	(12)	23
Other (income) expense	(757)	12,100
Loss before income taxes	(75,222)	(137,175)
Provision for income taxes	—	—
Net loss	$ (75,222)	$ (137,175)
Net loss per share, basic and diluted	$ (0.60)	$ (1.79)
Weighted average common shares outstanding, basic and diluted	125,939,050	76,586,842
Other comprehensive loss:		
Unrealized loss (gain) on investments	197	—
Other comprehensive loss	$ 197	$ —

The accompanying notes are an integral part of the consolidated financial statements.

VAXXINITY, INC.
CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK
(in thousands, except share amounts)

	Convertible Preferred Stock														
	Series Seed		Series Seed-1		Series Seed-2		Series A-1		Series A-2		Series A		Series B		
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Total
Balance at December 31, 2020	**7,831,528**	**$ 10,383**	**22,876,457**	**$ 20,903**	**14,615,399**	**$ 11,315**	**1,871,511**	**$ 4,640**	**6,307,690**	**$ 15,234**	**—**	**$ —**	**—**	**$ —**	**$ 62,475**
Exchange of Series Seed, Series Seed-1, Series Seed-2, Series A-1 and Series A-2 for Series A	(7,831,528)	(10,383)	(22,876,457)	(20,903)	(14,615,399)	(11,315)	(1,871,511)	(4,640)	(6,307,690)	(15,234)	53,502,585	62,475	—	—	—
Conversion of convertible notes to Series A preferred stock, net of debt issuance costs	—	—	—	—	—	—	—	—	—	—	3,624,114	27,545	—	—	27,545
Conversion of notes payable with related parties to Series A convertible preferred	—	—	—	—	—	—	—	—	—	—	423,230	2,205	—	—	2,205
Conversion of Simple Agreement for Future Equity to Series A convertible preferred	—	—	—	—	—	—	—	—	—	—	4,539,060	35,600	—	—	35,600
Conversion of warrant liability to Series A convertible preferred	—	—	—	—	—	—	—	—	—	—	134,106	614	—	—	614
Issuance of Series B convertible preferred stock, net of issuance costs of $133	—	—	—	—	—	—	—	—	—	—	—	—	15,365,574	122,791	122,791
Conversion of Series A and Series B to Class A common stock concurrently with initial public offering	—	—	—	—	—	—	—	—	—	—	(62,223,095)	(128,439)	(15,365,574)	(122,791)	(251,230)
Balance at December 31, 2021	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**$ —**

The accompanying notes are an integral part of the consolidated financial statements.

VAXXINITY, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except share amounts)

	Stockholders' Deficit											
	Common Stock		Common Stock-Class A		Common Stock-Class B		Treasury Stock					
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Stockholders' Equity (Deficit)
Balance at December 31, 2020	**—**	**$ —**	**60,360,523**	**$ 272**	**10,999,149**	**$ —**	**(3,169,093)**	**$ (23)**	**$ 4,682**	**$ —**	**$ (92,306)**	**$ (87,375)**
Issuance of common stock upon exercise of stock options	—	—	186,202	—	—	—	—	—	170	—	—	170
Vesting of restricted stock	—	—	15,405	—	—	—	—	—	—	—	—	—
Reclassification of Class A common stock to Class B common stock	—	—	(2,874,983)	—	2,874,983	—	—	—	—	—	—	—
Issuance of common stock upon stock grant	—	—	485,836	—	—	—	—	—	103	—	—	103
Retirement of treasury stock upon reorganization	—	—	(3,169,093)	—	—	—	3,169,093	23	(23)	—	—	—
Proceeds from initial public offering, net of offering expenses of $13913	—	—	6,537,711	1	—	—	—	—	71,076	—	—	71,077
Exercise of warrants concurrently with initial public offering	—	—	112,373	—	—	—	—	—	177	—	—	177
Conversion of Series A and Series B to Class A common stock concurrently with initial public offering	—	—	49,864,120	5	—	—	—	—	251,225	—	—	251,230
Stock-based compensation expense	—	—	—	—	—	—	—	—	30,412	—	—	30,412
Net loss	—	—	—	—	—	—	—	—	—	—	(137,175)	(137,175)
Balance at December 31, 2021	**—**	**$ —**	**111,518,094**	**$ 278**	**13,874,132**	**$ —**	**—**	**$ —**	**$ 357,822**	**$ —**	**$ (229,481)**	**$ 128,619**
Issuance of common stock upon exercise of stock options	—	—	664,656	—	—	—	—	—	263	—	—	263
Stock-based compensation expense	—	—	—	—	—	—	—	—	8,714	—	—	8,714
Unrealized loss on investments	—	—	—	—	—	—	—	—	—	(197)	—	(197)
Net loss	—	—	—	—	—	—	—	—	—	—	(75,222)	(75,222)
Balance at December 31, 2022	**—**	**$ —**	**112,182,750**	**$ 278**	**13,874,132**	**$ —**	**—**	**$ —**	**$ 366,799**	**$ (197)**	**$ (304,703)**	**$ 62,177**

The accompanying notes are an integral part of the consolidated financial statements.

VAXXINITY, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Years Ended December 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (75,222)	$ (137,175)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	1,684	1,102
Amortization of debt issuance costs	53	261
Amortization of discount on short-term investments	(1,022)	—
Stock-based compensation expense	8,714	30,412
Non-cash consulting expense	—	280
Non-cash loss on disposal	43	
Change in fair value of convertible notes	—	2,667
Change in fair value of warrant liability	—	214
Change in fair value of simple agreement for future equity	—	8,365
Change in operating assets and liabilities:		
Accounts receivable	—	26
Amounts due from related parties	(21)	(31)
Prepaid expenses and other current assets	3,300	(4,704)
Deferred offering costs	—	2,254
Accounts payable	2,103	2,174
Amounts due to related parties	(2,410)	11,402
Accrued expenses and other current liabilities	6,851	1,775
Other long-term liabilities	(1)	(12)
Net cash used in operating activities	(55,928)	(80,990)
Cash flows from investing activities:		
Purchase of short-term investments	(107,526)	—
Redemption of short-term investments	55,000	—
Purchase of property and equipment	(1,866)	(1,318)
Net cash used in investing activities	(54,392)	(1,318)
Cash flows from financing activities:		
Proceeds from initial public offering, net of offering expenses of $13,913	—	71,077
Proceeds from issuance of convertible note payable	—	2,000
Repayment of convertible notes payable	—	(2,000)
Repayment of notes payable	(430)	(414)
Repayment of note payable with related party	—	(100)
Proceeds from issuance of Series B convertible preferred stock, net of issuance costs	—	122,791
Proceeds from issuance of simple agreement for future equity	—	2,900
Repayment of Paycheck Protection Program	—	(257)
Proceeds from exercise of stock options	263	170
Net cash (used in) provided by financing activities	$ (167)	$ 196,167
Change in cash, cash equivalents and restricted cash	(110,487)	113,859
Cash, cash equivalents and restricted cash at beginning of period	145,057	31,198
Cash, cash equivalents and restricted cash at end of period	34,570	145,057
Supplemental Disclosure		
Cash paid for interest	$ 367	$ 581
Noncash Financing Activities		
Conversion of amounts due to related party into note payable	$ 4,225	$ —
Conversion of Series A and Series B to Class A common stock concurrently with initial public offering	$ —	$ 251,230
Exchange of Series Seed, Series Seed-1, Series Seed-2, Series A-1 and Series A-2 for Series A	$ —	$ 62,475
Conversion of simple agreement for future equity into Series A preferred stock	$ —	$ 35,600
Conversion of convertible notes into Series A preferred stock	$ —	$ 27,545
Conversion of notes payable with related party to Series A convertible preferred	$ —	$ 2,205
Conversion of warrant liability into Series A preferred stock	$ —	$ 614
Cashless exercise of warrant into Class A common stock concurrently with initial public offering	$ —	$ 177
Retirement of treasury stock upon reorganization	$ —	$ 23

The accompanying notes are an integral part of the consolidated financial statements.

1. Nature of the Business

Vaxxinity, Inc., a Delaware corporation ("Vaxxinity," and together with its subsidiaries, the "Company"), was formed through the combination of two separate businesses that originated from United Biomedical, Inc. ("UBI") in two separate transactions: a spin-out from UBI in 2014 of operations focused on developing chronic disease product candidates that resulted in United Neuroscience ("UNS"), and a second spin-out from UBI in 2020 of operations focused on the development of a COVID-19 vaccine that resulted in C19 Corp. ("COVAXX"). On February 2, 2021, Vaxxinity was incorporated for the purpose of reorganizing and combining UNS and COVAXX and on March 2, 2021, did so by acquiring all of the outstanding equity interests of UNS and COVAXX pursuant to a contribution and exchange agreement (the "Contribution and Exchange Agreement") whereby the existing equity holders of UNS and COVAXX contributed their equity interests in each of UNS and COVAXX in exchange for equity in Vaxxinity (the "Reorganization").

The Company is a biotechnology company currently focused on developing product candidates for human use in the fields of neurology, pain, cardiovascular diseases and coronaviruses utilizing its "Vaxxine Platform"—a synthetic peptide vaccine technology first developed by UBI and subsequently refined over the last two decades. The Company is engaged in the development of rationally designed prophylactic and therapeutic vaccines to combat common chronic diseases with large global unmet medical need. The Company is also developing a heterologous booster vaccine for SARS-Cov-2. UBI is a significant shareholder of the Company and, therefore, considered a related party.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry including, but not limited to, uncertainty of product development and commercialization, lack of marketing and sales history, development by its competitors of new technological innovations, dependence on key personnel, market acceptance of products, product liability, protection of proprietary technology, ability to raise additional financing, and compliance with government regulations. If the Company does not successfully commercialize any of its product candidates, it will be unable to generate recurring product revenue or achieve profitability.

The Company's product candidates are in development and will require significant additional research and development efforts, including extensive pre-clinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and is dependent upon the services of its employees and consultants.

Contribution and Exchange Agreement

On March 2, 2021, in accordance with the Contribution and Exchange Agreement, (i) all outstanding shares of UNS and COVAXX preferred stock and common stock were contributed to Vaxxinity and exchanged for like shares of stock in Vaxxinity, (ii) the outstanding options to purchase shares of UNS and COVAXX common stock were terminated and substituted with options to purchase shares of common stock in Vaxxinity, (iii) the outstanding warrant to purchase shares of COVAXX common stock was cancelled and exchanged for a warrant to acquire common stock in Vaxxinity and (iv) each outstanding Reorganization Convertible Note (as defined below) was contributed to Vaxxinity and the holders of such notes received Series A preferred stock in Vaxxinity. In particular:

- Each UNS common share and convertible preferred share was exchanged for 0.2191 shares of Vaxxinity common stock or Series A preferred stock, as applicable;
- Each share of COVAXX common and convertible preferred stock was exchanged for 3.4233 shares of Vaxxinity common stock or Series A preferred stock, as applicable (and prior to the closing of the Reorganization, all the holders of outstanding COVAXX SAFEs agreed to convert such SAFEs into shares of Series A-3 preferred stock of COVAXX, which shares were then exchanged for shares of Vaxxinity's Series A preferred stock);
- The Reorganization Convertible Notes were exchanged for an aggregate of 4,047,344 shares of Vaxxinity's Series A preferred stock; and
- Each outstanding option of both UNS and COVAXX to purchase common shares of UNS or COVAXX was terminated and substituted with an option to purchase shares of Class A common stock of Vaxxinity. Each outstanding UNS option was exchanged based on a conversion ratio of 0.2191. Each outstanding COVAXX option was exchanged based on a conversion ratio of 3.4233.

All parties to the Contribution and Exchange Agreement intend that the contribution of outstanding equity interests to Vaxxinity in exchange for Vaxxinity's common stock and preferred stock will be treated as an integrated transaction for U.S. federal income tax purposes that is governed by Section 351(a) of the Internal Revenue Code of 1986, as amended.

The Reorganization was determined to be a common control transaction, so the carrying values of all contributed assets and assumed liabilities remained unchanged and the financial information for all periods in the financial statements presented prior to the Reorganization are presented on a consolidated basis.

Reverse Stock Split

On October 29, 2021, the Company effectuated a reverse stock split of 1-for-1.556 (the "Stock Split") of the Company's Class A and Class B common stock pursuant to an amendment to the Company's Amended and Restated Certificate of Incorporation approved by the Company's board of directors and stockholders. As a result of the Stock Split, the Company also adjusted the share and per share amounts associated with its options and warrants to purchase shares of its common stock. These consolidated financial statements including the notes have been retroactively adjusted to reflect the Stock Split for all periods presented. Any fractional shares that would have resulted from the Stock Split have been rounded down to the nearest whole share.

Initial Public Offering

On November 15, 2021, the Company closed its IPO of 6,000,000 shares of Class A common stock at a public offering price of $13.00 per share. On November 18, 2021 the Company held a subsequent closing for the issuance of an additional 537,711 shares of Class A common stock pursuant to a 30-day option granted to the underwriters to purchase up to an additional 900,000 shares of Class A common stock at the IPO price, less underwriting discounts and commissions. The aggregate net proceeds to the Company from the offering, after deducting underwriting discounts and commissions and other offering expenses payable by the Company, was approximately $71.1 million. Upon the closing of the IPO, all previously outstanding shares of the Company's redeemable convertible preferred stock were automatically converted at the same ratio used for the Stock Split (1-for-1.556) into shares of its Class A common stock.

Liquidity

As of December 31, 2022, the Company had $87.9 million of highly liquid assets to fund operations, including $33.5 million of cash and cash equivalents, $53.4 million of short-term investments, and a $1.1 million restricted cash balance of which $1.0 million is restricted for the reimbursement of certain research and development expenses related to our UB-612 COVID-19 vaccine program. To date, the Company has primarily financed its operations through the sale of convertible preferred stock and common stock, borrowings under promissory notes (including Convertible Notes), a portion of which has been raised from related party entities, and grants from foundations such as the Coalition of Epidemic Preparedness Innovations (CEPI) and the Michael J. Fox Foundation (MJFF). The Company has experienced significant negative cash flows from operations since inception, and incurred a net loss of $75.2 million for the year ended December 31, 2022. Net cash used in operating activities for the year ended December 31, 2022 was $55.9 million. In addition, as of December 31, 2022, the Company has an accumulated deficit of $304.7 million. The Company expects to incur substantial operating losses and negative cash flows from operations for the foreseeable future. As of the date these financial statements were available to be issued, the Company expects its existing cash and cash equivalents to be sufficient to fund its operating expenses and capital expenditure requirements for at least the next 12 months.

Unless and until the Company is able to obtain regulatory approval for, and generate significant revenues from commercialization of our product candidates, the Company will need to seek additional capital in order to continue to fund future research and development activities. This may occur through strategic alliances, licensing arrangements, grants and/or future public or private debt or equity financings. Additional funding may not be available on terms the Company finds acceptable or at all. If the Company is unable to obtain sufficient capital to continue to advance its programs, the Company would be forced to delay, limit, reduce or terminate its product development or future commercialization efforts or grant rights to third parties to develop and market product candidates that the Company would otherwise prefer to develop and market itself.

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

Impact of COVID-19 Pandemic

In March 2020, the World Health Organization declared the outbreak of a COVID-19 pandemic. The COVID-19 pandemic is evolving, and to date, has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures.

While the pandemic has significantly subsided since 2020, the Company continues to monitor how COVID-19 outbreaks associated with new variants impact all aspects of its business, including our operations and the operations of its customers, suppliers, vendors and business partners. The extent to which COVID-19 impacts the Company's business, results of operation and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, new information that may emerge concerning the severity of COVID-19 or the effectiveness of actions to contain COVID-19 or treat its impact, among others. If the Company or any of the third parties with whom the Company engages, however, were to experience shutdowns or other business disruptions, its ability to conduct its business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on its business, results of operation and financial condition.

The Company has not incurred impairment losses in the carrying values of its assets as a result of the COVID-19 pandemic and the Company is not aware of any specific related event or circumstance that would require it to revise estimates reflected in these consolidated financial statements.

2. Summary of Significant Accounting Policies

Basis of presentation

The accompanying consolidated financial statements have been prepared using generally accepted accounting principles in the United States of America (GAAP) and pursuant to the rules and regulations of the United States Securities and Exchange Commission ("SEC") for financial reporting. The consolidated financial statements for the periods presented include the accounts of UNS and COVAXX that were parties to the Contribution and Exchange Agreement. All share and per share amounts, as originally recorded by each entity, have been converted to a number of shares and per share amounts using the conversion ratios determined under the Contribution and Exchange Agreement and the Stock Split ratio.

Foreign currency translation

The Company's consolidated financial statements are prepared in U.S. dollars. Its foreign subsidiaries use the U.S. dollar as their functional currency and maintain their records in the local currency. Nonmonetary assets and liabilities are re-measured at historical rates and monetary assets and liabilities are re-measured at exchange rates in effect at the end of the reporting period. Income statement accounts are re-measured at average exchange rates for the reporting period. The resulting gains or losses are included in foreign currency (losses) gains in the consolidated statements of operations.

Segment information

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker ("CODM") in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its Chief Executive Officer ("CEO"). The Company has determined that it operates as a single operating segment and has one reportable segment.

Use of estimates

The preparation of consolidated financial statements in accordance with GAAP requires the Company's management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. Significant estimates contained within these consolidated financial statements include, but are not limited to, the estimated fair value of the Company's common stock and convertible notes payable, simple agreements for future equity, warrant liabilities, stock-based compensation, prepaid expense recognition, income tax valuation allowance and the accruals of research and development expenses. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates, as there are changes in facts and circumstances. Actual results may differ materially from those estimates or assumptions.

Related party transactions

The Company has a policy governing related party transactions that defines related parties, and assigns oversight responsibility for related party transactions to the Company's Audit Committee. The Audit Committee reviews in advance related party transactions, and considers multiple factors, including the proposed aggregate value of the transaction, or, in the case of indebtedness, the amount of principal that would be involved, the benefits to the Company of the proposed transaction, the availability of other sources of comparable products or services, and an assessment of whether the proposed transaction is on terms that are comparable to the terms available to or from, as the case may be, unrelated third parties. Under the policy, related party transactions are approved only if the Audit Committee determines in good faith that the transaction is not inconsistent with the interests of the Company and its shareholders.

Cash and cash equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the time of initial purchase to be cash equivalents, including balances held in the Company's money market accounts. The Company maintains its cash and cash equivalents with financial institutions, in which balances from time to time may exceed the U.S. federally insured limits. The objectives of the Company's cash management policy are to safeguard and preserve funds to maintain liquidity sufficient to meet the Company's cash flow requirements, and to attain a market rate of return.

Restricted cash

As of December 31, 2022 and 2021 a deposit of $1.1 million and $0.2 million, respectively, was restricted from withdrawal. These restrictions related to cash payments received in advance under the CEPI Funding Agreement and securing credit card obligations as of December 31, 2022 and securing credit card obligations as of December 31, 2021. These balances are included in restricted cash on the accompanying consolidated balance sheets.

Short Term Investments

The Company determines the appropriate classification of its investments at the time of purchase. Currently, all of the Company's investments are classified as available-for-sale in accordance with ASC Topic 320. The Company classifies investments available to fund current operations as current assets on its consolidated balance sheets. Investments are classified as long-term assets on the consolidated balance sheets if (i) the Company has the intent and ability to hold the investments for a period of at least one year and (ii) the contractual maturity date of the investments is greater than one year.

Available-for-sale investments are recorded at fair value, with unrealized gains or losses included in accumulated other comprehensive income or loss. Realized gains and losses, interest income earned on the Company's cash, cash equivalents and investments, and amortization or accretion of discounts and premiums on investments are included within other income (expense) on the accompanying consolidated statements of operations.

Available-for-sale debt securities are reviewed for possible impairment at least quarterly, or more frequently if circumstances arise that may indicate impairment. When the fair value of the securities declines below the amortized cost basis, impairment is indicated and it must be determined whether it is other than temporary. Impairment is considered to be other than temporary if the Company: (i) intends to sell the security, (ii) will more likely than not be forced to sell the security before recovering its cost, or (iii) does not expect to recover the security's amortized cost basis. If the decline in fair value is considered other than temporary, the cost basis of the security is adjusted to its fair market value and the realized loss is reported in earnings. Subsequent increases or decreases in fair value are reported within equity as accumulated other comprehensive income on the accompanying consolidated statement of stockholder's equity (deficit).

The Company did not record any such impairments during the year ended December 31, 2022 and 2021.

Concentration of credit risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. Cash equivalents are occasionally invested in money market accounts. The Company maintains each of its cash balances with high-quality and accredited financial institutions and accordingly, such funds are not exposed to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. The Company maintains a portion of its cash and cash equivalent balances in the form of a money market account with a financial institution that management believes to be creditworthy.

The Company is dependent on contract manufacturers, several of whom are considered to be related parties, for manufacturing, quality control, testing, validation and supply services, including production, research and development and clinical activities. The Company's future revenue as well as research and development programs could be adversely affected by a significant supply interruption by one or more of its contract manufacturers.

Leases

At inception of a contract, the Company determines whether an arrangement is or contains a lease. For all leases, the Company determines the classification as either operating leases or financing leases. Operating leases are included in Operating lease right-of-use assets and Operating lease liabilities in our consolidated balance sheets.

Lease recognition occurs at the commencement date and lease liability amounts are based on the present value of lease payments over the lease term. The lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. If a lease does not provide information to determine an implicit interest rate, the Company uses its incremental borrowing rate in determining the present value of lease payments. Right-of-use (ROU) assets represent the Company's right to use an underlying asset for the lease term, and lease liabilities represent the Company's obligation to make lease payments under the lease. ROU assets also include any lease payments made prior to the commencement date and exclude lease incentives received. Operating lease expense is recognized on a straight-line basis over the lease term. The depreciable life of assets and leasehold improvements are limited by the expected lease term, unless there is a transfer of title or purchase option reasonably certain of exercise. Lease agreements with both lease and non-lease components, are generally accounted for together as a single lease component. The Company has elected to apply the practical short-term expedient to leases with a lease term of 12 months or less, which does not subject the leases to capitalization.

Property and equipment

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is computed on the straight-line basis over the estimated useful life of the assets.

The estimated useful life of property and equipment is as follows:

	Estimated Useful Life
Airplane	15 years
Facilities	5 years
Furniture and fixtures	5 years
Vehicles	5 years
Laboratory and computer equipment	3 years
Software	3 years
Leasehold improvements	Shorter of the useful life of improvement or the remaining lease term

Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in gain or loss from operations. Expenditures for repairs and maintenance are charged to expense as incurred.

Impairment of long-lived assets

Long-lived assets, comprised of property and equipment, are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows. To date, the Company has not recorded any impairment losses or disposals on long-lived assets.

Deferred offering costs

The Company capitalizes certain legal, audit, accounting and other third-party fees that are directly associated with an in-process capital financing effort as deferred offering costs until such financing is consummated. After consummation of the financing, these costs are recorded as a reduction of additional paid-in capital generated as a result of the financing. Should the financing be abandoned, the

deferred offering costs are expensed immediately as a charge to operating expenses in the accompanying consolidated statements of operations.

Fair value measurements

Certain assets and liabilities are carried at fair value under U.S. GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

Level 1—Quoted prices in active markets that are identical assets or liabilities.

Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

Prior to the conversion in accordance with the Contribution and Exchange Agreement, the majority of the Company's convertible notes and all of the simple agreement for future equity ("SAFE") and warrant liabilities were carried at fair value and were classified as Level 3 liabilities.

Convertible notes payable

The Company issued convertible notes payable at various times from 2014 to 2021. The Company accounts for the convertible notes payable at fair value in accordance with ASC 480, Distinguishing Liabilities from Equity ("ASC 480"). The notes payable with related parties are accounted for as straight debt under ASC 470, Debt ("ASC 470"). The Company has elected to separate interest expense from the full change in fair value of the convertible notes. Debt issuance costs incurred by the Company are amortized to interest expense over the term of the convertible notes using the effective interest method in the accompanying consolidated statements of operations.

On March 2, 2021, each convertible note that was outstanding was exchanged for shares of Series A preferred stock (see Note 9).

Debt issuance costs

The Company records debt issuance costs as a reduction to the carrying value of the debt. The debt discounts are amortized over the term of the debt using the effective interest method and recognized as interest expense in the accompanying consolidated statements of operations.

Simple Agreement for Future Equity—SAFE

The Company accounts for SAFEs at fair value in accordance with ASC 480. The SAFEs are subject to revaluation at the end of each reporting period, with changes in fair value recognized in the accompanying consolidated statements of operations.

On March 2, 2021, each SAFE that was outstanding was converted into shares of the Company's Series A preferred stock (see Note 12).

Classification of convertible preferred stock

The Company records all convertible preferred stock at its original issuance price, less direct and incremental issuance costs, as stipulated by its terms. The Company's convertible preferred stock is classified outside of stockholders' deficit because the holders of such shares have liquidation rights in the event of a deemed liquidation that, in certain situations, are not solely within the control of the Company.

All shares of the Company's Series A and Series B preferred stock converted into shares of the Company's Class A common stock concurrently with the closing of the initial public offering (see Note 11).

Revenue recognition

The Company accounts for revenue in accordance with ASC Topic 606, Revenue from Contracts With Customers ("ASC 606"). Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to be entitled to in exchange for those goods or services. The Company applies ASC 606 to contracts with customers only when it is probable that the entity will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

The Company assesses the goods or services promised within each contract and determines those that are performance obligations by evaluating whether each promised good or service is distinct. This assessment involves subjective determinations and requires management to make judgments about the individual promised goods or services, the intended benefit of the contract and whether each good or service is separately identifiable from the other aspects of the contractual relationship. If a promised good or service is not distinct, an entity is required to combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct.

If the consideration promised in a contract includes a variable amount, the Company estimates the amount of consideration to which it will be entitled in exchange for transferring the promised goods or services to a customer. The Company determines the amount of variable consideration by using the most likely amount method and applies the constraint on variable consideration, which requires the amount included in the transaction price to be constrained to the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, the Company re-evaluates the estimated variable consideration included in the transaction price and any related constraint, and if necessary, adjusts its estimate of the overall transaction price.

The Company recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied, either at a point in time or over time, and, if over time, recognition is based on the use of an output or input method.

For its sales of ELISA tests, the Company recognizes revenue once control is transferred upon delivery to the customer.

Coalition for Epidemic Preparedness ("CEPI") grant

In April 2022, the Company entered into an agreement with the Coalition for Epidemic Preparedness Innovations ("CEPI") whereby CEPI has agreed to provide funding of up to $9.3 million to co-fund a Phase 3 clinical trial of Vaxxinity's next generation UB-612 COVID-19 vaccine candidate as a heterologous – or 'mix-and-match' – booster dose. The Phase 3 trial, which began in early 2022, is evaluating the ability of UB-612 to boost COVID-19 immunity against the original strain and multiple variants of concern including Omicron - in people aged 16 years or older, who have been previously immunized with an authorized COVID-19 vaccine.

Cash payments received in advance under the CEPI Funding Agreement are restricted as to their use until expenditures contemplated in the funding agreement are incurred. As funds are received they are included within restricted cash offset by a corresponding short-term accrued liability. The Company recognizes payments from CEPI as a reduction of research and development expenses, in the same period as the expenses that the grant is intended to reimburse are incurred.

Taiwan Centers for Disease Control grant

United Biomedical, Inc., Asia ("UBI-Asia"), a related party through common ownership which is responsible for applying for and managing grants on the Company's behalf, was awarded a grant by the Taiwan Centers for Disease Control ("Taiwan CDC") for COVID-19 vaccine development. UBI-Asia contracted with the Company to conduct a two-phase clinical trial of a COVID-19 vaccine candidate in Taiwan. The grant provides that costs incurred to complete the two phases of the clinical trial will be reimbursed based on the achievement of certain milestones as defined in the agreement. At each reporting date, the Company assesses the status of all the activities involved in completing the clinical trials in relation to the milestones. The Company accounts for the amounts that have been received from the Taiwan CDC to reimburse costs incurred on the clinical trials and not expected to be refunded back to the Taiwan CDC as contra research and development expenses in the accompanying consolidated statements of operations.

Research and development

Research and development expenses include employee related costs, consulting, contract research, depreciation, rent, stock-based compensation and other corporate costs attributable to research and development activities and are expensed as incurred.

The Company has entered into various research, development and manufacturing contracts, some of which are with related parties (see Note 19). These agreements are generally cancelable by either party, and related payments are recorded as research and development

expenses as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or trials, including the phase or completion of events, invoices received and contracted costs. The Company's historical accrual estimates have not been materially different from the actual costs.

Patent costs

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

Stock-based compensation

The Company measures all stock-based awards granted to employees, directors and non-employees based on the fair value on the date of grant and recognizes compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. Forfeitures are accounted for as they occur.

The Company classifies stock-based compensation expense in its consolidated statements of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Prior to the Company's IPO in November 2021, there was no public market for the Company's common stock and the estimated fair value of its common stock was determined by its most recently available third-party valuations of common stock. There are significant judgments and estimates inherent in the determination of the fair value of the Company's common stock. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, the prices at which the Company sold shares of preferred securities, the superior rights and preferences of securities senior to the common securities at the time of, and the likelihood of, achieving a liquidity event, such as an IPO or sale. Significant changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

The fair value of each restricted stock award is estimated on the date of grant based on the fair value of the Company's common stock on that same date. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model ("Black-Scholes"), which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the award, the risk-free interest rate and expected dividends. The Company, both prior to and after the IPO in November 2021, lacks sufficient company-specific historical and implied volatility information for its stock, and therefore estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

Performance-based options

The Company accounts for performance-based options according to the ASC 718, Compensation – Stock Compensation ("ASC 718"), which are subject to different accounting depending on whether they meet the definition of performance conditions, market conditions, or other conditions. The conditions present in the Company's grants contain both performance and market conditions. The effect of each condition is reflected in the grant-date fair value and the performance-based options are measured considering the probability of satisfying the performance and market conditions. The Company has used a Monte Carlo Simulation Model to calculate the fair value of the performance condition (the completion of the IPO) and market condition (the 25% higher value after the IPO condition). The performance condition was determined to not be probable at the time of the grant date, and the recognition of compensation cost was deferred until the IPO was consummated in November 2021. The recognition of expense for the portion of the grant-date fair value assigned to the market condition will be recognized as expense according to the derived service period in the valuation model.

Income taxes

The Company accounts for income taxes according to the ASC 740, Income Taxes ("ASC 740") using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be realized and, to the extent it believes, based upon the weight of available evidence, 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 established through a charge to income tax expense. In evaluating its ability to recover its deferred tax assets, the Company considers all available positive and negative evidence, including projected future taxable income, prudent and feasible tax planning strategies and recent financial operations.

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. To the extent the Company determines that such tax positions will not be sustained, the provision for income taxes would include the effects of any resulting income tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Net loss per share

Basic earnings per common share is computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings per common share is computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding during the period, plus the potential dilutive effect of other securities if those securities were converted or exercised. During periods in which the Company incurs net losses, both basic and diluted loss per common share is calculated by dividing the net loss by the weighted-average shares of common stock outstanding and potentially dilutive securities are excluded from the calculation because their effect would be antidilutive. For purpose of this calculation, outstanding options, unvested restricted stock and convertible preferred stock are considered potential dilutive common stock and are excluded from the computation of net loss per share if their effect is anti-dilutive.

The Company's convertible preferred stock contractually entitles the holders of such shares to participate in dividends but does not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such participating securities. In periods in which the Company reports a net loss, diluted net loss per share is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to be outstanding if their effect is anti-dilutive.

Emerging growth company status

The Company is an "emerging growth company" ("EGC"), as defined in the Jumpstart Our Business Startups Act ("JOBS Act") and is permitted to and plans to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not EGCs. The Company may take advantage of these exemptions until it is no longer an EGC under Section 107 of the JOBS Act, which provides that an EGC can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. The Company has elected to avail itself of the extended transition period and, therefore, as long as the Company remains an EGC, it will not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not EGCs.

Reclassifications

The Company reclassified certain prepaid expenses from prepaid materials and supplies to clinical prepayments within the consolidated balance sheet to provide more current information on the components of this account. Prior year amounts have been reclassified to conform to the current year presentation. Additionally, certain expenses were reclassified between the research and development and general and administrative expenses within the consolidated statements of operations. These changes have no impact on our previously reported consolidated net loss, financial position or net increase in cash, cash equivalents, and restricted cash. Prior year amounts were not reclassified to conform to the current year presentation in the consolidated statements of operations.

Recently issued accounting pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

Recently adopted accounting standards

In July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842): Targeted Improvements ("ASU 2018-11"). ASU 2018-11provided an alternative method in addition to the modified retrospective transition method for ASU No. 2016-02, Leases: Amendments to the FASB Accounting Standards Codification ("ASU 2016-02"), issued in February 2016. Under ASU 2018-11, an

entity may elect to initially apply the new lease standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Under ASU 2016-02, a lease is required to recognize assets and liabilities with lease terms of more than twelve months. ASU 2016-02 is effective for nonpublic business entities and public entities eligible to be smaller reporting companies for fiscal years beginning after December 15, 2021.

The Company adopted the new standard on January 1, 2022 using the modified retrospective approach. The Company has elected to apply the transition method that allows companies to continue applying the guidance under the lease standard in effect at that time in the comparative periods presented in the financial statements and recognize a cumulative-effect adjustment to the opening balance of accumulated deficit on the date of adoption. The Company has elected to combine lease components (for example fixed rent payments) with non-lease components (for example, common-area maintenance costs) on our facility, lab equipment and CRO embedded lease asset classes. The Company also elected the "package of practical expedients", which permits the Company not to reassess under the new standard the Company's prior conclusions about lease identification, lease classification and initial direct costs. In addition, the Company also elected the short-term lease practical expedients allowed under the standard. Lastly, the Company did not elect the practical expedient allowing the use-of-hindsight which would require the Company to reassess the lease term of its leases based on all facts and circumstances through the effective date.

Results for reporting period beginning after January 1, 2022 are presented under the new standard, while prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for the prior period. Upon adoption of the new lease standard, on January 1, 2022, the Company did not enter into any leases subject to ASC 842 and did not capitalize a ROU asset or lease liability.

3. Short Term Investments

As of December 31, 2022, the Company's short-term investments consist of the following (in thousands):

	As of December 31, 2022		
	Amortized Cost	Unrealized Gains (Losses), Net	Recorded Basis
U.S. Treasury Securities	$ 53,549	$ (197)	$ 53,352
Total	$ 53,549	$ (197)	$ 53,352

4. Fair Value Measurements

The Company's money market accounts and short-term investments are shown at fair value based on unadjusted quoted market prices in active markets for identical assets.

The value for the Convertible Notes, SAFE and warrant liability balances during 2021 were based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. In accordance with the Contribution and Exchange Agreement, on March 2, 2021 the Convertible Notes, SAFEs and warrants were all converted into Series A preferred stock.

The following table presents information about the Company's financial instruments measured at fair value on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values (in thousands):

December 31, 2022	Level 1	Level 2	Level 3	Total
Assets:				
Short-term investments	$ 53,352	$ —	$ —	$ 53,352
Money market account	27,724	—	—	27,724
Total assets	$ 81,076	$ —	$ —	$ 81,076

December 31, 2021	Level 1	Level 2	Level 3	Total
Assets:				
Money market account	$ 139,794	$ —	$ —	$ 139,794
Total assets	$ 139,794	$ —	$ —	$ 139,794

During the years ended December 31, 2022 and 2021, there were no transfers between Level 1, Level 2 and Level 3.

Convertible Notes

During the year ended December 31, 2021, the Company issued Convertible Notes. In accordance with ASC 480, a portion of the Convertible Notes were required to be measured and accounted for at fair value at each reporting date. The Company determined the Convertible Notes requiring a measurement to fair value represent a recurring measurement that is classified within Level 3 of the fair value hierarchy wherein fair value is estimated using significant unobservable inputs.

Convertible Notes requiring a measurement to fair value are as follows (in thousands):

	Convertible Notes
Balance at December 31, 2020	$ 24,680
Issuance of convertible notes	2,000
Repayments	(2,000)
Change in fair value	2,667
Amortization of issuance costs	217
Accrued interest	168
Interest paid	(187)
Conversion to Series A preferred stock	(27,545)
Balance at December 31, 2021	$ —

The fair value of the Convertible Notes was estimated using a straight debt and conversion feature valuation model consisting of probability assumptions on multiple conversion scenarios, discount rates and interest rates.

In accordance with the Contribution and Exchange Agreement, on March 2, 2021, the Convertible Notes were converted into Series A preferred stock.

Simple Agreement for Future Equity—SAFE

During the year ended December 31, 2021, the Company executed SAFE arrangements. The fair value of the SAFEs on the date of issuance was determined to equal the proceeds received by the Company. The value of the SAFEs on the date of conversion into preferred stock was determined to be equal to the fair value of the preferred stock issued, or $35.6 million during the year ended December 31, 2021.

The following table sets forth a summary of the activities of the SAFE arrangements, which represents a recurring measurement that is classified within Level 3 of the fair value hierarchy wherein fair value is estimated using significant unobservable inputs (in thousands):

	SAFE Liability
Balance at December 31, 2020	$ 24,335
Change in fair value	8,365
Issuance of SAFEs	2,900
Conversion to Series A preferred stock	(35,600)
Balance at December 31, 2021	$ —

In accordance with the Contribution and Exchange Agreement, on March 2, 2021, the SAFEs were converted into Series A preferred stock.

Warrants to Purchase Series A-1 Convertible Preferred Stock & Common Stock

In connection with the 2020 Series A-1 convertible preferred stock (“Series A-1 preferred”) financing transactions, the Company issued fully vested warrants to purchase 205,970 shares of Series A-1 preferred. The warrants were issued to advisors as consideration for assistance with the sale and issuance of the Series A-1 preferred. The warrants were determined to represent issuance costs and were recorded as a reduction in the proceeds received from the sale.

The warrants were issued to advisors of the company and represented non-variable contingently redeemable instruments. As such, the warrants were accounted for as liabilities and adjusted to fair value at each reporting period.

The warrants are exercisable on the date of issuance and have an exercise price of $0.003 per share and a contractual term of ten years. In December 2020, warrants were exercised for 71,862 shares of Series A-1 at $0.003 per share, resulting in cash proceeds of less than $1,000. As of December 31, 2020, warrants to purchase 134,106 shares of Series A-1 preferred were outstanding. The Company continued to re-measure the fair value of the liability associated with the warrant to purchase shares of Series A-1 preferred at the end of each reporting period until the Reorganization, when the warrant converted into Series A preferred stock and subsequently, in connection with the IPO, converted into Class A common stock.

The following table sets forth a summary of the activity of the warrant liability which represented a recurring measurement that is classified within Level 3 of the fair value hierarchy wherein fair value is estimated using significant unobservable inputs (in thousands):

	Warrant Liability
Balance at December 31, 2020	$ 400
Change in fair value	214
Conversion to warrants for shares of Series A preferred stock	(614)
Balance at December 31, 2021	$ —

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	December 31,	
	2022	2021
Clinical prepayments	$ 2,679	$ 612
Prepaid insurance	1,870	3,510
Prepaid materials and supplies	248	3,517
Deposits	232	869
Other	522	343
	$ 5,551	$ 8,851

Clinical prepayments consisted of amounts paid in advance to clinical research organizations (“CROs”) for expenses related to our clinical trials, primarily UB-612, and included $1.9 million on deposit as of December 31, 2022 that will be credited against final UB-612 trial expenses. The remaining clinical prepayment amounts are amortized to expense as earned by the CRO and clinical trial sites.

Prepaid insurance consisted primarily of $1.6 million and $3.3 million for the unamortized portion of the Company’s annual D&O insurance fee as of December 31, 2022 and 2021, respectively.

Prepaid materials and supplies consisted of amounts paid in advance related to the procurement and/or production of materials for use in the Company’s clinical trials, primarily UB-612. Amounts held by related parties totaled $0.2 million at December 31, 2022 and $3.5 million at December 31, 2021.

Deposits consist of amounts held by the Company’s aircraft management company and the leaseholder for the Florida lab. Other prepaid expenses and current assets consist of various sales tax credits and receivables totaling $0.3 million and $0.3 million, as of December 31, 2022 and 2021, respectively and other prepaid expenses incurred in the normal course of business.

6. Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	December 31,	
	2022	2021
Airplane	$ 11,983	$ 11,983
Laboratory and computer equipment	3,146	1,831
Leasehold improvements	403	—
Software	415	168
Facilities, furniture and fixtures	37	85
Vehicles	87	87
Construction in progress	65	199
Total property and equipment	16,136	14,353
Less: accumulated depreciation	(3,624)	(1,981)
Property and equipment, net	$ 12,512	$ 12,372

Depreciation expense for the years ended December 31, 2022 and 2021 was $1.7 million and $1.1 million, respectively.

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31,	
	2022	2021
Accrued external research and development	$ 6,904	$ 1,501
Accrued bonuses	2,568	2,294
Accrued professional fees and other	1,722	692
Accrued interest	176	32
	$ 11,370	$ 4,519

8. Other Long-Term Liabilities

Other long-term liabilities consisted of the following (in thousands):

	December 31,	
	2022	2021
Accrued tax provision	$ 236	$ 236
Accrued rent	—	1
	$ 236	$ 237

As of December 31, 2022 and 2021, approximately $0.2 million of the accrued tax provision relates to penalties and interest the Company may be subject to paying for late filing fees related to a foreign subsidiary. The Company expects these amounts to be forgiven but has accrued for them until the statute of limitations expires and it is appropriate to write them off.

9. Convertible Notes Payable

Beginning in April 2018, the Company issued several Convertible Notes, some of which were issued to related parties. The Convertible Notes bore simple interest at annual rates ranging from 4.8% to 6%. All unpaid principal, together with the accrued interest thereon, were payable upon an event of default or upon maturity, which ranged from one to three years. The Convertible Notes contained a number of provisions addressing automatic and optional conversion, events of default, and prepayment provisions.

The Company accounted for the Convertible Notes at fair value, in accordance with ASC 480, with any changes in fair value being included in other (income) expense, net in the accompanying statements of operations.

In accordance with the Contribution and Exchange Agreement, on March 2, 2021 each Reorganization Convertible Note that was outstanding was exchanged for shares of Series A preferred stock, as set forth in the applicable Convertible Note agreements and the Contribution and Exchange Agreement.

During the year ended December 31, 2021, the Company recognized interest expense of $0.2 million related to the Convertible Notes. In addition, during the year ended December 31, 2021, the Company recognized a change in fair value of $2.7 million in the accompanying consolidated statements of operations related to the Convertible Notes.

The following table shows the activity of the Convertible Notes (in thousands):

	Convertible Notes								
	Principal Amount Payable		Change in Fair Value		Accrued Interest		Issuance	Conversion to	
	Standard	Related Party	Standard	Related Party	Standard	Related Party	Costs	Series A	Balance
December 31, 2020	$ 7,710	$ 10,510	$ 1,972	$ 3,848	$ 674	$ 183	$ (217)	$ —	$ 24,680
Additions	—	2,000	812	1,855	58	110	—	—	4,835
Settlements	(2,000)	—	—	—	(187)	—	—	—	(2,187)
Amortization	—	—	—	—	—	—	217	—	217
Conversion of Convertible Notes to Series A preferred stock	(5,710)	(12,510)	(2,784)	(5,703)	(545)	(293)	—	(27,545)	(27,545)
December 31, 2021	$ —	$ —	$ —	$ —	$ —	$ —	$ —	$ (27,545)	$ —

10. Notes Payable

Notes Payable with Related Parties

In December 2018, the Company entered into related party convertible notes payable (the "2018 Related Notes" and together with the Convertible Notes, the "Reorganization Convertible Notes") for $2.0 million in aggregate proceeds, received in three tranches. The 2018 Related Notes bore simple interest at an annual rate of 5% and contain a number of provisions addressing events of default and prepayment. In accordance with the Contribution and Exchange Agreement, on March 2, 2021, the 2018 Related Notes were converted into Series A preferred stock.

During the year ended December 31, 2021, the Company recognized interest expense of less than $0.1 million on the 2018 Related Notes.

2019 Executive Note

In November 2019, the Company borrowed $0.1 million from its Chief Executive Officer (the "2019 Executive Note"). No formal loan agreement was executed. However, the Company has elected to accrue interest at an annual rate of 5%, consistent with the terms and conditions of the Convertible Notes and 2018 Related Notes, which was the closest benchmark the Company could evaluate. The 2019 Executive Note was repaid in August 2021.

The activity of the 2018 Related Notes and 2019 Executive Note is as follows (in thousands):

	2018 Related Notes and 2019 Executive Note		
	Related Party Principal	Accrued Interest	Balance
December 31, 2020	$ 2,100	$ 194	$ 2,294
Accrued interest	—	19	19
Repayment	(100)	—	(100)
Interest paid	—	(8)	(8)
Conversion	(2,000)	(205)	(2,205)
December 31, 2021	$ —	$ —	$ —

Note Payable—Airplane

In connection with the acquisition of an airplane, the Company entered into a note payable agreement (the "2025 Note") in June 2020 for $11.5 million, with an annual interest rate of 3.4% and a maturity date of June 9, 2025. Principal and interest payments are payable monthly in the amount of $0.07 million with a final payment of $9.4 million at maturity. The 2025 Note is guaranteed by the co-founders of the Company. In addition, the Company incurred debt issuance costs of $0.3 million, which are being amortized over the term of the loan. There are no financial covenants associated with the 2025 Note.

The carrying value of the 2025 Note is as follows (in thousands):

	December 31,	
	2022	2021
Principal	$ 10,455	$ 10,883
Unamortized debt issuance cost	(131)	(184)
Carrying amount	10,324	10,699
Less: current portion	(391)	(376)
Note payable, net of current portion and debt issuance cost	$ 9,933	$ 10,323

As of December 31, 2022, the remaining principal payments for the 2025 Note, are as follows (in thousands):

	Amount
2023	$ 444
2024	458
2025	9,553
	$ 10,455

Interest expense associated with the 2025 Note was $0.4 million and $0.4 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, accrued interest of less than $0.1 million was included in accrued expenses and other liabilities in the accompanying consolidated balance sheets.

Note Payable—Paycheck Protection Program

The Company applied for and received a loan, which is in the form of a note dated May 5, 2020, from HSBC Bank USA, National Association ("HSBC") in the aggregate amount of approximately $0.3 million (the "PPP Loan"), pursuant to the Paycheck Protection Program ("PPP"). The PPP, established as part of the Coronavirus Aid, Relief and Economic Security Act ("CARES Act"), provides for loans to qualifying businesses for amounts up to 2.5 times of the average monthly payroll expenses of the qualifying business. As of December 31, 2021, there were no events of default under the PPP Loan.

The Company paid off the PPP Loan in full, including all accrued but unpaid interest to the repayment date, in August 2021.

Promissory Note with Related Party

In October 2022, the Company entered into a related party unsecured promissory note (the "2022 Promissory Note") with UBI for $4.2 million. The 2022 Promissory Note accrues interest at 7.0% per annum and is due October 1, 2026. The 2022 Promissory Note was issued to satisfy accounts payable to UBI totaling $4.2 million. As of December 31, 2022 the outstanding principal under the 2022 Promissory Note was $4.2 million. During the year ended December 31, 2022 the Company incurred less than $0.1 million in interest expense and no interest was paid related to the Promissory Note.

The carrying value of the 2022 Promissory Note is as follows (in thousands):

	December 31,
	2022
Principal	$ 4,225
Less: current portion	(1,113)
Note payable, net of current portion	$ 3,112

As of December 31, 2022, the remaining principal payments for the 2022 Promissory Note, are as follows (in thousands):

	Amount
2023	$ 1,113
2024	1,029
2025	1,103
2026	980
	$ 4,225

11. Convertible Preferred Stock

In connection with the Reorganization, each UNS convertible preferred share was exchanged for 0.2191 shares of Vaxxinity preferred stock and each share of COVAXX convertible preferred stock was exchanged for 3.4233 shares of Vaxxinity preferred stock. During the first and second quarters of 2021, the Company raised gross proceeds of $122.8 million in connection with its Series B preferred stock financing. The Company issued a total of 15,365,574 shares at a price of $8.00 per share. All shares of the Company's Series B preferred stock converted into shares of the Company's Class A common stock concurrently with the closing of the initial public offering.

As of December 31, 2022 and 2021, Vaxxinity's Amended and Restated Certificate of Incorporation authorized 50,000,000 shares of preferred stock with a par value of $0.0001 per share. There were no shares of preferred stock outstanding as of December 31, 2022 and 2021.

The table below details the Company's Class A common stock which was issued upon conversion of Series A and Series B preferred stock concurrently with the closing of the IPO in November 2021. The common stock issued upon conversion reflects the application of the stock split described in Note 1.

As of December 31, 2021	Issuance Dates	Shares Issued and Outstanding Prior to IPO	Class A Common Stock Issued Upon IPO Conversion
Series A preferred stock	March 2021	62,223,095	39,989,083
Series B preferred stock	March 2021	5,441,863	3,497,338
Series B preferred stock	June 2021	9,923,711	6,377,699
		77,588,669	49,864,120

12. Simple Agreement for Future Equity—SAFE

During the years ended December 31, 2021 and 2020, the Company executed SAFE arrangements. The SAFEs were not mandatorily redeemable, nor did they require the Company to repurchase a fixed number of shares. The Company determined that the SAFEs contained a liquidity event provision that embodied an obligation indexed to the fair value of the Company's equity shares and could require the Company to settle the SAFE obligation by transferring assets or cash. For this reason, the Company recorded the SAFEs as a liability under ASC 480 and re-measured the fair value at the end of each reporting period, with changes in fair value reported in earnings.

In March 2020, the Company issued a SAFE ("SAFE 1") for $0.4 million, which converted into 463,162 shares of Series Seed-2 convertible preferred stock at $0.7773 per share in April 2020. In June, July, and August 2020, the Company issued a series of SAFEs ("SAFE 2") for $14.7 million, which converted into 6,307,690 shares of Series A-2 convertible preferred stock ("Series A-2 preferred") at $2.3241 per share in August 2020.

The Company determined the fair value of the SAFE 2 investment on the date of conversion and recognized the difference between the fair value on the date of conversion and the initial fair value of SAFE 2 investment in the consolidated statements of operations.

In December 2020, the Company issued a series of SAFEs (collectively, "SAFE 3") for $24.3 million. In January 2021, the Company issued additional SAFEs for $2.9 million which had the same terms as SAFE 3. Key provisions of SAFE 3 are as follows:

Equity Financing—Upon initial closing of a qualified financing of at least $50.0 million, SAFE 3 will automatically convert into the greater of (1) the number of shares of SAFE 3 preferred stock equal to the purchase amount divided by the SAFE 3 price, defined as the price per share equal to the post-money valuation divided by all shares outstanding, all convertible securities, all issued, outstanding and promised options, and the unissued option pool, or (2) the number of shares of SAFE 3 preferred stock equal to the purchase amount

divided by the discount price, defined as the price per share of the standard preferred stock sold in a qualified financing multiplied by eighty percent (80%).

Liquidity Event—If there is a liquidity event, as defined, before the termination of SAFE 3, SAFE 3 will automatically be entitled to receive a portion of proceeds, subject to the liquidation priority set forth in the agreement, due and payable immediately prior to, or concurrent with, the consummation of such liquidity event, equal to the greater of (i) the purchase amount or (ii) the amount payable on the number of shares of common stock equal to the purchase amount divided by the liquidity price, as outlined in the agreements.

Dissolution Event—If there is a dissolution event, as described in the agreements, before the termination of SAFE 3, the investor will automatically be entitled, subject to the liquidation priority set forth in the agreement, to receive a portion of proceeds equal to the purchase amount, due and payable to the investor immediately prior to the consummation of the dissolution event.

Termination—SAFE 3 will automatically terminate immediately following the earliest to occur of: (i) the issuance of capital stock to the investor pursuant to the automatic conversion provisions of SAFE 3 or (ii) the payment, or setting aside for payment, of amounts due the investor. In connection with the Contribution and Exchange Agreement, the holders of SAFEs agreed to convert such SAFEs into shares of Series A-3 preferred stock of COVAXX, which shares were then exchanged for shares of Vaxxinity's preferred stock.

The SAFEs were converted into shares of the Company's Series A preferred stock pursuant to the Contribution and Exchange Agreement. Prior to the Reorganization, all the holders of outstanding COVAXX SAFEs agreed to convert such SAFEs into shares of Series A-3 preferred stock of COVAXX, which shares were then exchanged for shares of the Company's Series A preferred stock, which were converted into Series A Common Stock in connection with the Company's IPO.

13. Common Stock

As explained in Note 1, in accordance with the Contribution and Exchange Agreement, on March 2, 2021, all outstanding shares of common stock of UNS and COVAXX were contributed to Vaxxinity and exchanged for an aggregate of 60,360,523 shares of Vaxxinity's Class A common stock and 10,999,149 shares of Vaxxinity's Class B common stock. Each UNS share of common stock was exchanged for 0.2191 shares of Vaxxinity common stock and each share of COVAXX common stock was exchanged for 3.4233 shares of Vaxxinity common stock.

In June 2021, the Company converted 2,874,983 shares of Class A common stock held by the Company's Chief Executive Officer and Executive Chairman on a one-to-one basis for shares of Class B common stock.

Vaxxinity's Amended and Restated Certificate of Incorporation dated November 15, 2021 authorized 1,100,000,000 shares of common stock with a par value of $0.0001 per share, of which 1,000,000,000 shares have been designated as Class A common stock and 100,000,000 shares have been designated as Class B common stock.

Holders of Class A common stock and Class B common stock have identical rights, except with respect to voting and conversion. Except as otherwise expressly provided in Vaxxinity's Amended and Restated Certificate of Incorporation or Bylaws, or required by applicable law, holders of Class A common stock will be entitled to one vote per share on all matters submitted to a vote of stockholders and holders of our Class B common stock will be entitled to ten votes per share on all matters submitted to a vote of stockholders.

Holders of Class A common stock and Class B common stock vote together as a single class on all matters submitted to a vote of stockholders, except (i) amendments to Vaxxinity's Amended and Restated Certificate of Incorporation to increase or decrease the par value of a class of capital stock, in which case the applicable class would be required to vote separately to approve the proposed amendment and (ii) amendments to Vaxxinity's Amended and Restated Certificate of Incorporation that alter or change the powers, preferences or special rights of a class of capital stock in a manner that affects its holders adversely, in which case the applicable class would be required to vote separately to approve the proposed amendment.

Holders of common stock are entitled to receive, ratably, dividends as may be declared by Vaxxinity's board of directors out of funds legally available therefor if the board of directors, in its discretion, determines to issue dividends.

The voting, dividend, and liquidation rights of the holders of common stock are subject to and qualified by the rights, powers, and preferences of the holders of Vaxxinity's preferred stock.

The Company has reserved shares of common stock for issuance for the following purposes:

	December 31,	
	2022	2021
Options and RSU issued and outstanding	20,716,760	21,387,909
Options available for future grants	6,064,003	7,209,538
Warrants issued and outstanding	1,928,020	1,928,020
	28,708,783	30,525,467

14. Equity Incentive Plan

Stock Options

In March 2021, the Company replaced the 2017 and 2020 Stock Option and Grant Plans with the 2021 Stock Option and Grant Plan (the "Existing 2021 Plan"), which provided for the Company to grant qualified incentive options, nonqualified options, restricted stock awards, unrestricted stock awards, and restricted stock units to employees and non-employees to purchase the Company's Class A common stock. The Existing 2021 Plan authorized the issuance of up to 21,593,830 shares of Class A common stock pursuant to awards.

In August 2021, the Company canceled existing options to purchase, in aggregate, 6,362,455 shares of Class A common stock in exchange for an equal number of options to purchase shares of Class B common stock. The Company accounted for this exchange as a stock option modification.

In November 2021, the Company replaced the Existing 2021 Plan with the 2021 Omnibus Incentive Compensation Plan (the "New 2021 Plan"), which provides for the Company to grant nonqualified stock options, incentive (qualified) stock options, stock appreciation rights, restricted share awards, restricted stock units, performance awards, cash incentive awards and other equity-based awards (including fully vested shares). The New 2021 Plan replaced the Existing 2021 Plan and no further grants will be made under the Existing 2021 Plan. The following is a summary of certain terms and conditions of the New 2021 Plan.

At its inception in November 2021, the maximum number of shares of common stock that could be issued under the New 2021 Plan was 8,700,000 shares of Class A equity. This number increases automatically on January 1 of each year, commencing January 1, 2023, by the number of shares equal to the lesser of (i) 4% of the outstanding shares of the Company's common stock on the immediately preceding December 31, (ii) the number of shares determined by the Compensation Committee, if any such determination is made, and (iii) the number of shares underlying any awards granted during the preceding calendar year, net of the shares underlying awards canceled or forfeited under the New 2021 Plan. On January 1, 2023, in accordance with the automatic "evergreen" provision of the New 2021 Plan, the maximum number of shares that can be issued under the plan was increased to 11,886,306.

As of December 31, 2022, 6,064,003 shares were available for future grant. Shares issued under the New 2021 Plan that are forfeited, canceled, reacquired by the Company prior to vesting, satisfied without the issuance of stock, withheld to cover the exercise price or tax withholdings, or otherwise terminated, other than by exercise, shall be added back to the shares available for issuance under the New 2021 Plan.

The exercise price for grants made pursuant to the terms of the New 2021 Plan is determined in the applicable grant by the board of directors. Any incentive options granted to persons possessing less than 10% of the total combined voting power of all classes of stock may not have an exercise price of less than 100% of the fair market value of the common stock on the grant date. Any incentive options granted to persons possessing more than 10% of the total combined voting power of all classes of stock may not have an exercise price of less than 110% of the fair market value of the common stock on the grant date.

The option term for incentive awards may not be greater than ten years from the date of the grant. Incentive options granted to persons possessing more than 10% of the total combined voting power of all classes of stock may not have an option term of greater than five years from the date of the grant. The vesting period for equity-based awards is determined at the discretion of the board of directors.

As of December 31, 2022 there were options to purchase 14,054,305 shares of Class A common stock outstanding and options to purchase 6,362,455 shares of Class B common stock outstanding, of which 9,830,751 Class A and 4,968,437 Class B shares, respectively were exercisable.

Stock Option Activity

The following table summarizes stock option activity for the year ended December 31, 2022:

	Number of Stock Options Outstanding	Weighted Price Per Share	Weighted Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2021	21,387,909	$ 5.25	7.4	$ 49,684
Granted	1,387,221	2.96		
Exercised	(1,066,586)	(3.26)		
Forfeited	(1,291,784)	(7.14)		
Balance at December 31, 2022	20,416,760	$ 5.07	6.8	$ 7,166
Options vested and exercisable at December 31, 2022	14,799,188	$ 4.62	6.5	$ 6,923

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the options and the fair value of the common stock for those options that had exercise prices lower than the fair value of the common stock.

The intrinsic value of options exercised during each of the years ended December 31, 2022 and 2021 was $4.5 million and less than $0.1 million, respectively.

The weighted-average grant-date fair value per share of options granted during the years ended December 31, 2022 and 2021 was $2.21 and $4.21, respectively.

The total fair value of options vested during the years ended December 31, 2022 and 2021 was $8.8 million and $24.5 million, respectively.

Valuation of Stock Options Granted that Contain Service Conditions Only

The fair value of each option award granted with service-based vesting is estimated on the date of the grant using the Black-Scholes option valuation model based on the assumptions noted in the table below for those options granted in the years ended December 31, 2022 and 2021:

	December 31,	
	2022	2021
Risk-free interest rate	1.46% - 4.22%	0.59% - 1.35%
Expected term (in years)	5.5 - 6.1	5.0 - 6.3
Expected volatility	90.01% - 97.82%	71.6% - 93.4%
Expected dividend yield	0.00%	0.00%

In August 2021, the Company canceled 378,786 existing Class A common stock options with service-based conditions held by Mei Mei Hu in exchange for an equal number of options to purchase shares of Class B common stock. The Company accounted for this exchange as a stock option modification. There was no incremental stock-based compensation expense as a result of this modification as the fair-value-based measures of the modified award immediately after the modification were less than the fair-value-based measures of the original award immediately before the modification.

Stock Options Granted to Employees that Contain Performance and Market Conditions

Included in the stock options granted during the year ended December 31, 2021 were stock options to purchase 6,799,625 shares of Class A common stock that contain performance- and market-based vesting conditions granted to the Mei Mei Hu, Louis Reese, and Peter Diamandis.

In August 2021, the stock option awards for the Mei Mei Hu and Louis Reese totaling 5,983,670 shares were cancelled in exchange for an equal number of options to purchase shares of Class B common stock. The Company accounted for this exchange as a stock option modification. The fair value of the awards granted to Mei Mei Hu and Louis Reese at the modification date was $23.8 million, valued using the Monte-Carlo simulation model. The assumptions used in the Monte-Carlo simulation model were as follows:

Time to expiration (in years)	4.5
Volatility	75%
Risk-free interest rate	58%
Cost of equity	25%
Fair value of underlying common stock (as of valuation date)	$10.07

The stock option awards for Peter Diamandis totaling 815,955 shares had a grant date fair value of $0.3 million. The assumptions used in the Monte-Carlo simulation model were as follows:

Time to expiration (in years)	1
Volatility	90%
Risk-free interest rate	0.09%
Cost of equity	25%
Fair value of underlying common stock (as of valuation date)	$4.12

The compensation expense for these awards is recognized when the vesting condition is met for the performance-based criteria, and over the derived service period for the market-based criteria.

The condition for the performance-based criteria in the stock options was based on the Company's completion of its IPO, and the condition for the market-based criteria in the stock options was based on the future price of the Company's common stock trading at or above a specified threshold. During the year ended December 31, 2021, stock options for an aggregate of 5,439,700 of the total 6,799,625 shares containing performance- and market-based vesting conditions were vested following the satisfaction of the performance-based condition achieved through the Company’s completion of its IPO. As of December 31, 2022, the market-based vesting conditions had not been achieved.

Restricted Stock

The following table summarizes the Company’s restricted stock activity for the year ended December 31, 2022:

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Unvested at December 31, 2021	—	$ —
Issued	300,000	3.76
Unvested at December 31, 2022	300,000	$ 3.76

The aggregate fair value of restricted stock that vested was less than $0.1 million for the year ended December 31, 2021. No restricted stock vested during the year ended December 31, 2022.

Stock-Based Compensation Expense

The Company recorded stock-based compensation expense in the following expense categories in the accompanying consolidated statements of operations (in thousands):

	Years Ended December 31,	
	2022	2021
Research and development	$ 3,276	$ 1,343
General and administrative	5,438	29,069
Total stock-based compensation expense	$ 8,714	$ 30,412

As of December 31, 2022, total unrecognized compensation cost related to the unvested stock-based awards was $16.2 million, which is expected to be recognized over a weighted average period of 2.7 years.

15. Income Taxes

The sources of losses from continuing operations, before income taxes, classified between domestic entities and those entities domiciled outside of the U.S., are as follows (in thousands):

	Years Ended December 31,	
Losses before taxes	**2022**	**2021**
Domestic entities	$ (69,943)	$ (128,538)
Entities outside the U.S.	(5,477)	(8,636)
	$ (75,420)	$ (137,174)

Tax Expense (Benefit)

The components of the provision for income taxes are as follows for the years ended December 31, 2022 and 2021 (in thousands):

	Years Ended December 31,	
	2022	**2021**
Current:		
Federal	$ —	$ —
State and local	—	—
Foreign	—	—
Total current tax expense	—	—
Deferred tax (benefit):		
Federal	—	—
State and local	—	—
Foreign	—	—
Total deferred tax (benefit)	—	—
Provision for income taxes	$ —	$ —

Tax Rate Reconciliation

The Company's effective tax rate for the years ended December 31, 2022 and 2021 was 0.00% and 0.00%, respectively.

A reconciliation of the provision for income taxes at the statutory rate to the amount reflected in the consolidated statements of operations is as follows (in thousands):

	Years Ended December 31,	
	2022	**2021**
Income taxes at statutory rate	21.00 %	21.00 %
State income taxes, net of federal benefit	(1.17) %	0.50 %
Stock compensation	(0.68) %	(3.65) %
Foreign rate differential	(0.59) %	(0.74) %
Uncertain tax positions	0.0 %	0.0 %
Other	1.41 %	(1.90) %
Change in valuation allowance	(19.98) %	(15.21) %
Provision for income taxes	0.0 %	0.0 %

Deferred Tax Assets (Liabilities)

The Company computes income taxes using the liability method. This method requires recognition of deferred tax assets and liabilities, measured by enacted rates, attributable to temporary differences between the financial statements and the income tax basis of assets and liabilities. In assessing the realizability of deferred tax assets, the Company considers whether it is more likely than not that certain deferred tax assets will be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income in those specific jurisdictions prior to the dates on which such net operating losses expire. The Company maintained a full valuation allowance against its net deferred tax assets as of December 31, 2022 and 2021 because the Company has determined that it is more likely than not that these assets will not be fully realized based on a current evaluation of expected future taxable income and the Company is in a cumulative loss position. The valuation allowance increased by $15.0 million during the year ended December 31, 2022 and $20.9 million during the year ended December 31, 2021, primarily as a result of net operating losses generated during the periods. The Company reevaluates the positive and negative evidence at each reporting period.

Significant components of the Company's deferred tax assets and liabilities are as follows (in thousands):

	As of December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 39,184	$ 32,405
Stock Compensation	2,090	1,735
Section 174 Costs	7,424	—
Other	559	27
Total deferred tax assets	49,257	34,167
Less: valuation allowance	(49,173)	(34,106)
Net deferred tax assets	$ 84	$ 61
Deferred tax liabilities:		
Depreciation	$ (84)	$ (61)
Net deferred tax liabilities	(84)	(61)
Net deferred income taxes	$ —	$ —

Net Operating Losses

The Company had total net operating loss carryforwards for U.S. federal income tax purposes of $165.1 million, and $134.6 million as of December 31, 2022 and 2021, respectively, that have no expiration date and foreign net operating loss carryforwards of $29.2 million and $24.0 million, respectively, that have no expiration date.

Utilization of the NOL carryforwards and credits may be subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code Sections 382 and 383 (the "Code"), as amended, and similar state provisions. The Company has not completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since the Company's formation due to the complexity and cost associated with such a study, and the fact that there may be additional ownership changes in the future. If the Company experienced an ownership change at any time since its formation, utilization of the NOL or tax credit carryforwards to offset future taxable income and taxes, respectively, would be subject to annual limitation under the Code. The annual limitation may result in the expiration of the NOL and credits before utilization. If impaired, the NOL and credit carryforwards would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance.

On March 27, 2020, the President of the United States signed into law the CARES Act, which, along with earlier issued IRS guidance, contains numerous provisions that may benefit the Company, including the deferral of certain taxes. The CARES Act did not have a material impact on the Company's tax provision for the years ended December 31, 2022 and 2021.

The Consolidated Appropriations Act, 2021, which was enacted on December 27, 2020, has expanded, extended, and clarified selected CARES Act provisions, specifically on Paycheck Protection Program loan and Employee Retention Tax Credit, 100% deductibility of business meals as well as other tax extenders. The Consolidated Appropriations Act did not have a material impact on the Company's tax provision for the year ended December 31, 2022 and 2021.

The Inflation Reduction Act (IRA) was signed into law on August 16, 2022. The IRA introduces a 15% corporate alternative minimum tax (CAMT) for corporations whose average annual adjusted financial statement income (AFSI) for any consecutive three-tax-year

period ending after December 31, 2021 and preceding the tax year exceeds $1.0 billion and a 1% excise tax on stock repurchases made by publicly traded U.S. corporations. Since the Company does not meet the book income threshold to be subject to CAMT, the excise tax is not an ASC 740 tax, they are not expected to have any impact. The other tax law updates are not expected to have any material impact to the Company's consolidated financial statements and related disclosures.

The CHIPS and Science Act was signed into law on August 9, 2022. The Act introduces the advanced manufacturing investment tax credit, a 25% tax credit for investments in semiconductor manufacturing. It also includes incentives for manufacturing semiconductors, as well as specialized tooling equipment required in the semiconductor manufacturing process. The Company is not currently claiming any such tax credits, as such the tax law updates are not expected to have any material impact to the Company's consolidated financial statements and related disclosures.

Enacted in 2017, the Tax Cuts and Jobs Act ("TCJA") included significant changes in tax law including a change to Internal Revenue Code section 174 regarding the deductibility of research and experimentation expenses ("R&E expenses"). The section 174 tax law change had a delayed effective date and became effective for the Company in 2022. New section 174 requires that companies capitalize and amortize R&E expenses performed in the U.S. over five years and further provides for a fifteen-year amortization period for R&E expenses incurred outside the U.S. The Company has factored any impact of section 174 in the Company's consolidated financial statements and related disclosures.

The Company is subject to tax in the United States and many state and local jurisdictions. The Company, with certain exceptions, is subject to income tax examinations by U.S. federal, state and local for tax years 2017 and future periods. The Company is not currently under audit for any US federal or state or foreign income tax audits.

Uncertain Tax Positions

A summary of the Company's unrecognized tax benefits activity and related information is presented as follows (in thousands):

	Years Ended December 31,	
	2022	2021
Uncertain tax position liability at the beginning of the year	$ 652	$ 652
Increases (decreases) related to tax positions taken during current period	—	—
Uncertain tax position liability at the end of the year	$ 652	$ 652

The unrecognized tax benefits for U.S. jurisdiction of $0.7 million, if recognized, would not have an impact on the Company's effective tax rate assuming the Company continues to maintain a full valuation allowance position against its U.S. deferred tax assets. The remaining unrecognized tax benefits of less than $0.1 million, if recognized, will have an impact on the effective tax rate. The Company recognizes accrued interest and penalties related to unrecognized tax benefits in income tax expense. We accrued $0.2 million in interest and penalties related to prior year's tax filings, as of December 31, 2022.

The Company is subject to U.S. federal income tax as well as income tax of various foreign jurisdictions. Generally, the statute of limitations for examination of the Company's U.S. federal and foreign income tax filings are open for the years ending December 31, 2017 and future periods.

16. Net Loss Per Share

The Company's unvested restricted common shares have been excluded from the computation of basic net loss per share.

The Company's potentially dilutive securities, which include options, unvested restricted stock, convertible notes payable and convertible preferred stock, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share for the years ended December 31, 2022 and 2021 because including them would have had an anti-dilutive effect:

	December 31,	
	2022	2021
Unvested restricted stock	300,000	-
Options issued and outstanding	20,416,760	21,387,909
Warrants issued and outstanding	1,928,020	1,928,020
	22,644,780	23,315,929

17. Commitments and Contingencies

Contractual Obligations

The Company enters into agreements with contract research organizations ("CROs") to conduct clinical trials and preclinical studies and contract manufacturing organizations ("CMOs") to produce vaccines and other potential product candidates. Contracts with CROs and CMOs are generally cancellable, with notice, at the Company's option.

As of December 31, 2022, the Company had remaining prepayments to CROs of $2.9 million and remaining prepayments to CMOs of less than $0.1 million for activities associated with the conduct of its clinical trials and for the production of the Company's product candidates.

Michael J. Fox Foundation Grant

On November 3, 2021, the Company was awarded a grant from the Michael J. Fox Foundation for Parkinson's Research ("MJFF") in the amount of $0.8 million to be used in a project for the exploration of markers for target engagement in individuals immunized with UB-312, an active **a**-Synuclein immunotherapy. The Company will oversee sample management, sample preparation (IgG fractions) and distribution, as well as characterize the binding properties of the antibodies against pathological forms of aSyn. As funding is expected to be utilized over a two-year period, as cash is received, the amount expected to the utilized within twelve months is recognized to short-term restricted cash/deposits, with a corresponding short-term accrued liability, which is released as the related expenses are offset. The Company recognizes payments from MJFF as a reduction of research and development expenses, in the same period as the expenses that the grant is intended to reimburse are incurred. The remaining balance of cash received is recognized to long-term restricted cash/deposits, with a corresponding long-term accrued liability. As of December 31, 2022, there was no balance remaining in the accrued liability related to this grant. For the years ended December 31, 2022 and 2021, the Company recognized $0.1 million and less than $0.1 million, respectively, as a reduction of research and development expenses for amounts reimbursed through the grant.

Coalition for Epidemic Preparedness Innovations ("CEPI") Grant

In April 2022, the Company entered into an agreement with the Coalition for Epidemic Preparedness Innovations ("CEPI") whereby CEPI has agreed to provide funding of up to $9.3 million to co-fund a Phase 3 clinical trial of Vaxxinity's next generation UB-612 COVID-19 vaccine candidate as a heterologous – or 'mix-and-match' – booster dose. The Phase 3 trial, which began in 2022, is evaluating the ability of UB-612 to boost COVID-19 immunity against the original strain and multiple variants of concern including Omicron - in people aged 16 years or older, who have been previously immunized with an authorized COVID-19 vaccine.

The Company will also be performing further manufacturing scale-up work to enable readiness for potential commercialization. Under the terms of the agreement with CEPI, if successful, a portion of the released doses of the commercial product will be delivered to the COVID-19 Vaccines Global Access ("COVAX") consortium for distribution to developing countries at low cost.

Cash payments received in advance under the CEPI Funding Agreement are restricted as to their use until expenditures contemplated in the funding agreement are incurred. As funding is expected to be received in tranches over an eighteen month period, and the amounts received in each tranche are expected to the utilized within twelve months, the funds received are reflected within restricted cash with a corresponding short-term accrued liability. The Company recognizes payments from CEPI as a reduction of research and development expenses, in the same period as the expenses that the grant is intended to reimburse are incurred. As of December 31, 2022, the balance of the restricted cash and short-term accrued liability was $1.0 million. For the year ended December 31, 2022, the Company recognized a reduction of $7.5 million of research and development expenses.

Lease Agreements

The Company has two operating lease agreements for office and laboratory space. The Company is also required to pay certain operating costs under its leases.

In August 2022, the Company entered into a lease for 9,839 square feet of lab and office space with Space Florida in Exploration Park, Florida commencing August 12, 2022. The lease has an initial one-year term with an annual lease obligation of $0.5 million, after Lessee credits. Additionally, the lease requires the Company to provide a security deposit in the amount of less than $0.1 million.

In April 2022, the Company entered into a facility lease agreement for 4,419 square feet of office space in New York, New York. The lease commenced in April 2022 and will expire March 2029 with no option to renew. This lease and its terms were reviewed using the guidance found in ASC 842. Since the lease has a non-cancellable period of one year, and after the first year both the Company and the landlord have the option to early terminate the lease for any or no reason, the Company has elected to apply the short-term expedient, which does not subject the New York lease to capitalization.

Rent expense for each of the years ended December 31, 2022 and 2021 amounted to $0.5 million and less than $0.1 million, respectively.

License Agreements

In October 2014, the Company entered into a contribution agreement with UBI, whereby UBI contributed and assigned to the Company assets and granted a non-exclusive license to certain technologies deemed necessary or reasonably useful in the utilization of the licensed intellectual property. In consideration, the Company issued 32,505,306 shares of common stock to UBI. The agreement allowed for exploitation of all diagnostic, prophylactic, and therapeutic uses and indications in humans in the field of neurology. The agreement was amended in August 2019 to provide the Company with exclusivity (except as to UBI) in the field of neurology and the flexibility to pursue indications outside the initial field limitations.

In connection with the amendment, the Company agreed to execute an exclusive, worldwide license agreement for any product that is developed by the Company outside the original field. The terms and conditions are to be negotiated in good faith and mutually agreed upon. The Company anticipates that if it is required to enter into an exclusive license agreement, it will be able to negotiate financial terms for the license at prevailing market rates within the pharmaceutical industry. Accordingly, the Company may be required to pay UBI upfront fees, revenue royalties, development milestones, commercial milestones, sublicense fees, and other related fees.

Vaxxinity's COVAXX subsidiary was formed in March 2020 through a transfer of technology from UBI, UBI IP Holdings, and UBI US Holdings, LLC, all related parties of the Company, whereby the Company, pursuant to an April 2020 license agreement, obtained exclusive rights to intellectual property and technology related to the discovery of vaccines, diagnostic assays, and antigens for use against all coronaviruses including, without limitation, SARS, MERS, and COVID-19 in all strains in humans. The license is worldwide, perpetual, exclusive and fully paid-up. There are no future royalty or milestone payment obligations associated with the agreement. The Company has the right to grant sublicenses.

The Company considered ASC 805, "Business Combinations" and ASC 730, "Research and Development" in determining how to account for the issuance of common stock. The license agreement is considered to be a common control transfer; however, the related party did not have any basis in the assets licensed, so there was no accounting impact for the Company.

In August 2021, Vaxxinity entered into a license agreement (the "Platform License Agreement") with UBI and certain of its affiliates that expanded intellectual property rights previously licensed under previously issued license agreements with UBI. As part of the agreement, Vaxxinity obtained a worldwide, sublicensable (subject to certain conditions), perpetual, fully paid-up, royalty-free license to research, develop, make, have made, utilize, import, export, market, distribute, offer for sale, sell, have sold, commercialize or otherwise exploit peptide-based vaccines in the field of all human prophylactic and therapeutic uses, except for such vaccines related to human immunodeficiency virus (HIV), herpes simplex virus (HSE) and Immunoglobulin E (IgE). The patents and patent applications licensed under the Platform License Agreement include claims directed to a CpG delivery system, artificial T helper cell epitopes and certain designer peptides and proteins utilized in UB-612. As described above, in consideration for the Platform License Agreement, the Company issued to UBI a warrant to purchase Class A common stock (the "UBI Warrant").

The Company considered ASC 805, "Business Combinations" ("ASC 805") and ASC 730, "Research and Development" ("ASC 730") in determining how to account for the issuance of the Class A common stock warrants. The Class A common stock warrants were issued to a related party in exchange for a license agreement. The majority of the voting interests in the related party and that of the Company were held by a group of immediate family members, at the time of the transaction, and as such the transaction constitutes a common control transaction, which requires the license to be accounted for at the carrying value in the books of the transferor. As the related party did not have any basis in the assets licensed, there was no accounting impact for the Company.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to employees, consultants, vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered

into indemnification agreements with members of its board of directors and executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnification obligations. The Company is not aware of any indemnification arrangements that could have a material effect on its financial position, results of operations, or cash flows, and it has not accrued any liabilities related to such obligations as of December 31, 2022 or 2021.

Legal Proceedings

From time to time, the Company may become involved in legal proceedings arising in the ordinary course of business. As of December 31, 2022 and 2021, the Company was not a party to any material legal matters or claims.

In December 2022, the Board became aware of pending litigation filed by the Company's CEO against a significant stockholder, Ask America, LLC ("Ask America"). The CEO filed the lawsuit in Texas in May 2022 regarding an alleged private agreement between the CEO, the Company's Chairman, and Ask America, relating to the potential purchase of stock by Ask America in the Company's November 2021 initial public offering, on behalf of a former director. Ask America asserts that the CEO and Chairman guaranteed a loan by Ask America to fund the former director's contemplated purchase. The lawsuit seeks a declaration that no enforceable transaction was ever completed or consummated. Although the Company is not a party to the litigation, the Board formed a special committee, comprised of independent directors who are being advised by independent legal counsel, to conduct an investigation into the circumstances of the litigation and the purported transaction. The investigation concluded in the first quarter of 2023, and the company is evaluating certain additional control measures, including (i) additional training for executives and directors on securities regulations, (ii) additional internal reporting requirements regarding transactions between Company insiders, stockholders, or other related parties, and (iii) retention of a consultant or other advisor with public company and capital markets experience to assist management in connection with capital markets strategy and activity.

Loss Contingency

In April 2021, the Company engaged United Biopharma, Inc. (UBP) to begin acquiring raw materials for use in the production of GMP grade recombinant protein for UB-612, our Covid vaccine candidate. It was anticipated that $7.2 million in raw materials would be needed to produce the initial 30kg of protein. An Authorization to Proceed (ATP) agreement authorized UBP to acquire the first $3 million of materials using an advance payment from Vaxxinity, pending execution of a final supply agreement between the parties.

Through August 2021, $7.2 million of materials were ordered, $3 million of materials were received by UBP and paid for with the advance payment, and the Company expensed $1.2 million as these raw materials were used to produce proteins. During 2022, Vaxxinity recognized an additional $1.8 million in expense related to the materials UBP had taken possession of but had not yet used in production.

When Vaxxinity asked to pause further manufacture of protein upon rejection of the EUA by Taiwan in August 2021, UBP requested that its suppliers cancel the remaining $4.2 million in orders where it had not taken possession of the materials. In the fourth quarter of 2022, the Company learned that most of the suppliers refused to cancel the orders, although some agreed to seek other buyers for the materials. For these orders, management has not yet concluded that a loss for Vaxxinity for this entire amount is probable, since they were not originally authorized by the ATP, and UBP's suppliers may be able to dispose of some amount to other buyers. Hence, an expense has not been recognized for them.

18. Benefit Plans

In March 2018, the Company established a defined contribution savings plan under Section 401(k) of the Code. This plan covers substantially all U.S. employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. The Company does not make matching contributions to the Plan.

The Company offers its Ireland-based employees a Personal Retirement Savings Account ("PRSA") that allows participants to defer a portion of their annual compensation. The Company provides contributions equal to 5% of each participant's annual salary. During the years ended December 31, 2022 and 2021, the Company contributed less than $0.1 million per year to the PRSA accounts.

19. Related Party Transactions

The Company has a Related Party policy which defines related parties, and assigns oversight responsibility for related party transactions to the Company's Audit Committee. The Committee reviews in advance related party transactions, and considers multiple factors, including the proposed aggregate value of the transaction, or, in the case of indebtedness, the amount of principal that would be involved, the benefits to the Company of the proposed transaction, the availability of other sources of comparable products or services, and an

assessment of whether the proposed transaction is on terms that are comparable to the terms available to or from, as the case may be, unrelated third parties. Under the policy, related party transactions are approved only if the Audit Committee determines in good faith that the transaction is not inconsistent with the interests of the Company and its shareholders.

The Company has related party arrangements with UBI and a number of its affiliated companies listed namely, United Biomedical, Inc., Asia ("UBI-Asia"), UBI Pharma, Inc. ("UBI-P"), United BioPharma, Inc ("UBP") and UBI IP Holding ("UBI-IP").

As of December 31, 2022 UBI and its affiliated companies owned 44% of the Company's stock. The majority of the voting interests in both UBI and the Company were held by a group of immediate family members, and as such the entities are under common control.

These related parties are governed by various Master Services Agreements ("MSA") detailed below.

UBI MSA - UBI provides research, development and clinical functions to the Company. There is also a purchase arrangement with UBI for the production and shipment of the Company's diagnostic test kits.

UBIA MSA - UBI-Asia for manufacturing, quality control, testing, validation, and supply services.

UBP MSA - United BioPharma, Inc provide the Company with manufacturing, testing and validation.

COVID MSA ("COVID MSA") - COVID MSA provides that UBI acts as COVAXX's agent with respect to matters relating the Company's COVID-19 program and provides research, development, manufacturing and back office administrative services to the Company.

COVID-19 Relief MSA - A four-company MSA with UBI, UBI-Asia and UBP. The Company is an exclusive licensee of technologies related to diagnostics, vaccines, and therapies for COVID-19. The MSA established the terms under which UBI-Asia provides research, development, testing and manufacturing services to the Company and UBP provides contract development and manufacturing services to the Company.

Total amounts due to related parties were $12.8 million and $19.4 million as of December 31, 2022 and 2021, respectively. Total amounts due from related parties were $0.4 million and $0.4 million as of December 31, 2022 and 2021, respectively. Total service fees incurred were $4.2 million and $35.4 million for the years ended December 31, 2022 and 2021, respectively.

Taiwan Centers for Disease Control Grant ("Taiwan CDC")

UBI-Asia, which is responsible for applying for and managing grants on our behalf under the COVID-19 program, was awarded a grant by the Taiwan CDC for COVID-19 vaccine development. The Company contracted with UBI-Asia to conduct a two-phase clinical trial of a COVID-19 vaccine candidate in Taiwan, which was completed in 2021. Costs that were incurred to complete the two phases of the clinical trial were reimbursed based on the achievement of certain milestones as provided in the agreement.

Total related party operating activity, including the activity described above is as follows (in thousands):

	December 31,	
	2022	2021
Consolidated balance sheet		
Assets		
Prepaid expenses and other current assets	$ 237	$ 3,517
Property and equipment, net	—	337
Amounts due from related parties	414	393
Liabilities		
Accrued expenses	—	—
Amounts due to related parties	12,772	19,407
Current portion of note payable	1,113	—
Note payable	3,112	—
Accrued interest payable	$ 73	$ —

	Years Ended December 31,	
	2022	2021
Consolidated statements of operations		
Revenue	$ —	$ —
Cost of revenue	—	—
Operating expenses		
Research and development		
Services provided by related parties	4,172	41,430
Taiwan CDC grant reimbursement from related party	—	(7,199)
General and administrative		
Services provided by related parties	—	1,173
Other (income) expense		
Related party interest expense	$ 73	$ —

20. Subsequent Events

On March 9, 2023, the Company completed its rolling submission of a conditional authorization application to the UK MHRA for UB-612 based on the Phase 3 study results.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated, as of and for the year ended of the period covered by this Annual Report on Form 10-K, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs. Based on management's evaluation our principal executive officer and principal financial officer concluded that, as of December 31, 2022, our disclosure controls and procedures were effective at the reasonable assurance level.

Report on Internal Control Over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting. The internal control process has been designed under management's supervision to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the Company's consolidated financial statements for external reporting purposes in accordance with U.S. GAAP.

Management conducted an assessment of the effectiveness of the Company's internal control over financial reporting as of December 31, 2022 utilizing the framework established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this assessment, management has determined that the Company's internal control over financial reporting as of December 31, 2022 is effective.

The Company's internal control over financial reporting includes policies and procedures that pertain to the maintenance of records that accurately and fairly reflect, in reasonable detail, transactions and dispositions of assets; and provide reasonable assurances that: (1) transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP; (2) receipts and expenditures are being made only in accordance with authorizations of management and the directors of the Company; and (3) unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the Company's consolidated financial statements are prevented or timely detected.

All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm due to an exemption established by the JOBS Act for "emerging growth companies."

Changes in Internal Control Over Financial Reporting

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual and interim consolidated financial statements will not be detected or prevented on a timely basis.

During 2022, we invested resources to remediate the material weaknesses identified in the preparation of our audited consolidated financial statements for the year ended December 31, 2021 and in the preparation of our unaudited consolidated financial statements for the quarter ended March 31, 2022. These remediation activities involved the following:

- hiring additional accounting personnel with the appropriate level of skill and experience for public company financial reporting;
- designing and implementing a formal financial close process that includes multiple levels of reviews of accounting entries; and
- supplementing our resources for evaluating and accounting for complex transactions and stock options through the use of third-party advisors.

Other than the measures described in "Remediation Measures" above, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

The disclosure required by this item is not applicable.

PART III

Items 10, 11, 12, 13 and 14.

Our independent registered public accounting firm is Armanino LLP, San Ramon, California, Auditor Firm ID: 32.

The information required by these items is incorporated by reference to our definitive proxy statement relating to our 2023 Annual Meeting of Shareholders. We currently anticipate that our definitive proxy statement will be filed with the SEC not later than 120 days after December 31, 2022, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) Documents filed as part of this Report:

(1) Financial Statements. The following consolidated financial statements and the notes thereto, and the Reports of Independent Registered Public Accounting Firm are incorporated by reference as provided in Item 8 and Item 9A of this Report:

Audited Consolidated Financial Statements as of and for the years ended December 31, 2022 and 2021

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(2) Financial Statement Schedules.

(b) Exhibits:

The following exhibits required by Item 601 of Regulation S-K are filed herewith or have been filed previously with the SEC as indicated below:

Exhibit No.	Index to Exhibits
3.1	Amended and Restated Certificate of Incorporation of Vaxxinity, Inc. (incorporated by reference to Exhibit 3.1 of our Current Report on Form 8-K (File No. 001-41058) filed on November 17, 2021).
3.2	Amended and Restated Bylaws of Vaxxinity, Inc. (incorporated by reference to Exhibit 3.2 of our Current Report on Form 8-K (File No. 001-41058) filed on November 17, 2021).
4.1	Warrant to Purchase Shares of Class A Common Stock of Vaxxinity, Inc. (incorporated by reference to Exhibit 4.1 of our Registration Statement on Form S-1/A (File No. 333-260163) filed on November 5, 2021).
4.2	Description of Registered Securities*

10.1	Form of Indemnification Agreement between Vaxxinity, Inc. and each of its directors and executive officers (incorporated by reference to Exhibit 10.1 of our Registration Statement on Form S-1 (File No. 333-260163) filed on October 8, 2021).
10.2	Registration Rights Agreement (incorporated by reference to Exhibit 10.2 of our Current Report on Form 8-K (File No. 001-41058) filed on November 17, 2021).
10.3	Voting Agreement, dated as of October 1, 2021, among Mei Mei Hu, Louis Reese, Blackfoot Healthcare Ventures LLC and United Biomedical, Inc. (incorporated by reference to Exhibit 10.3 of our Registration Statement on Form S-1 (File No. 333-260163) filed on October 8, 2021).§
10.4	Platform License Agreement, dated as of August 5, 2021, among Vaxxinity, Inc., United Biomedical, Inc., UBI IP Holdings and UBI US Holdings, LLC (incorporated by reference to Exhibit 10.4 of our Registration Statement on Form S-1 (File No. 333-260163) filed on October 8, 2021).§
10.5	United Neuroscience 2017 Share Option and Grant Plan (incorporated by reference to Exhibit 10.5 of our Registration Statement on Form S-1 (File No. 333-260163) filed on October 8, 2021).+
10.6	C19 Corp. 2020 Stock Option and Grant Plan (incorporated by reference to Exhibit 10.6 of our Registration Statement on Form S-1 (File No. 333-260163) filed on October 8, 2021).+
10.7	Vaxxinity, Inc. 2021 Stock Option and Grant Plan (incorporated by reference to Exhibit 10.7 of our Registration Statement on Form S-1 (File No. 333-260163) filed on October 8, 2021).+
10.8	Letter agreement by and between United Neuroscience, LLC and Dr. Farshad Guirakhoo, dated May 4, 2020 (incorporated by reference to Exhibit 10.8 of our Registration Statement on Form S-1 (File No. 333-260163) filed on October 8, 2021).+
10.9	Vaxxinity, Inc. 2021 Omnibus Incentive Compensation Plan (incorporated by reference to Exhibit 10.9 of our Registration Statement on Form S-1/A (File No. 333-260163) filed on November 5, 2021).+
10.10	Vaxxinity, Inc. 2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.10 of our Registration Statement on Form S-1/A (File No. 333-260163) filed on November 5, 2021).+
10.11	Form of Incentive Stock Option Grant Notice under the 2021 Stock Option and Grant Plan (incorporated by reference to Exhibit 10.11 of our Registration Statement on Form S-1/A (File No. 333-260163) filed on November 5, 2021).+
10.12	Form of Non-Qualified Stock Option Grant Notice under the 2021 Stock Option and Grant Plan (incorporated by reference to Exhibit 10.12 of our Registration Statement on Form S-1/A (File No. 333-260163) filed on November 5, 2021).+
10.13	Form of Restricted Stock Award Notice under the 2021 Stock Option and Grant Plan (incorporated by reference to Exhibit 10.13 of our Registration Statement on Form S-1/A (File No. 333-260163) filed on November 5, 2021).+
10.14	Form of Notice of Stock Option Award 2021 Omnibus Incentive Compensation Plan (incorporated by reference to Exhibit 10.14 of our Registration Statement on Form S-1/A (File No. 333-260163) filed on November 5, 2021).+
10.15	Form of Notice of Restricted Stock Unit Award 2021 Omnibus Incentive Compensation Plan (incorporated by reference to Exhibit 10.15 of our Registration Statement on Form S-1/A (File No. 333-260163) filed on November 5, 2021).+
21.1	Subsidiaries of Vaxxinity, Inc.*
24.1	Power of attorney (included on signature page)

31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*
32.1	Certifications of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*‡+
101.INS	Inline XBRL Instance Document*
101.SCH	Inline XBRL Taxonomy Extension Schema Document*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document*
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL document).*

_____

* Filed herewith.

\+ Indicates management contract or compensatory plan, contract or arrangement.

§ Portions of the exhibit, marked by brackets, have been omitted because the omitted information (i) is not material and (ii) is the type of information that the Company treats as private or confidential.

‡ The certifications attached as Exhibits 32.1 that accompany this Form 10-K are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Vaxxinity, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-K, irrespective of any general incorporation language contained in such filing.

(c) Schedules:

None

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized on March 27, 2023.

VAXXINITY, INC.

By: /s/ Mei Mei Hu
Mei Mei Hu, President and
Chief Executive Officer

ADDITIONAL SIGNATURES AND POWERS OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Mei Mei Hu and René Paula, jointly and severally, her or his attorney-in-fact, with the power of substitution, for her or him in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or her or his substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K has been signed below by the following persons and in the capacities indicated on March 27, 2023.

Signature	Capacity in Which Signed
/s/: Mei Mei Hu Mei Mei Hu	President, Chief Executive Officer and Director (Principal executive officer)
/s/: Jason Pesile Jason Pesile	Senior Vice President, Finance & Accounting (Principal financial officer and principal accounting officer)
/s/: Louis Reese Louis Reese	Executive Chairman
/s/: George Hornig George Hornig	Director
/s/: Landon Ogilvie Landon Ogilvie	Director
/s/: Gaby Toledano Gaby Toledano	Director
/s/: Peter Diamandis Peter Diamandis	Director
/s/: Katherine Eade Katherine Eade	Director
/s/: Peter Powchik Peter Powchik	Director
/s/: James Smith James Smith	Director

Board of Directors

Louis Reese
Executive Chairman, Vaxxinity, Inc.

Mei Mei Hu
President and Chief Executive Officer,
Vaxxinity, Inc.

Peter H. Diamandis, M.D.
Chief Executive Officer,
PHD Ventures, Inc.

Katherine Eade
Interim General Counsel,
Standard Biotools Inc.

George Hornig
Chairman of the Board,
Xometry, Inc.

Landon Ogilvie
Chief Executive Officer,
Co-West Inc.

Peter Powchik
Former Executive Vice President,
Research and Development,
Vaxxinity, Inc.

James Smith
Chief Executive Officer,
InvitedHome Inc.

Gabrielle Toledano
Chief Operating Officer,
Keystone Strategy, LLC

Executive Officers

Mei Mei Hu
President and Chief Executive Officer

Louis Reese
Executive Chairman

Ulo Palm, M.D., Ph.D.
Chief Medical Officer

René Paula Molina
Senior Vice President, Legal & Business Affairs,
General Counsel and Secretary

Jason Pesile
Senior Vice President, Finance and Accounting

Stockholders and Stock Listing

Our Class A common stock is traded on the Nasdaq Global Market under the symbol VAXX. On March 15, 2023, the closing price of our Class A common stock was $1.94 per share and our Class A common stock was held by approximately 81 holders of record and our Class B common stock was held by approximately 4 holders of record.

Investor Information

You may obtain a copy of any of the exhibits to our Annual Report on Form 10-K free of charge. These documents are available on our website at https://ir.vaxxinity.com/financials/sec-filings or by contacting Investor Relations at (254) 244-5739.

Requests for information about Vaxxinity, Inc. should be directed to our Investor Relations department.

Annual Meeting

Our 2023 Annual Meeting of Stockholders will be held on Tuesday, June 20, 2023, at 10:00 a.m. ET, via live webcast on the Internet at the following URL: https://web.lumiagm.com/284047551 (password: vaxxinity2023)

Internet Website

www.vaxxinity.com

Legal Counsel

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
Boston, Massachusetts

Independent Registered Public Accounting Firm

Armanino LLP
San Ramon, California

Transfer Agent and Registrar

American Stock Transfer & Trust Company, LLC
6201 15th Avenue
Brooklyn, NY 11219