UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

☒ **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: 001-40655

ICOSAVAX, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**82-3640549**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1930 Boren Avenue, Suite 1000 Seattle, Washington	**98101**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (206) 737-0085

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	ICVX	Nasdaq Global Select Market

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 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. ☑

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 the voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price of the shares of common stock on the Nasdaq Stock Market on June 30, 2022, was approximately $184 million.

As of March 21, 2023, the registrant had 41,395,981 shares of common stock ($0.0001 par value) outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain sections of the registrant's definitive proxy statement for the 2023 annual meeting of stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form 10-K are incorporated by reference into Part III of this Form 10-K.

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PART I

Forward-Looking Statements and Market Data

This annual report on Form 10-K (Annual Report) contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations and financial position, business strategy, research and development plans, the potential of our technology, the anticipated timing, costs, design, conduct and results of our ongoing and planned preclinical studies and clinical trials for our vaccine candidates, the timing and likelihood of regulatory filings and approvals for our vaccine candidates, our ability to commercialize our vaccine candidates, if approved, the pricing and reimbursement of our vaccine candidates, if approved, the potential to develop future vaccine candidates, the potential benefits of strategic collaborations and our intent to enter into any strategic arrangements, the timing and likelihood of success, plans and objectives of management for future operations, and future results of anticipated product development efforts, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions. The forward-looking statements in this Annual Report are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report and are subject to a number of risks, uncertainties and assumptions, including those described in Part II, Item 1A, “Risk Factors” of this Annual Report. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

We use our trademarks in this annual report as well as trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this Annual Report appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these trademarks and tradenames.

This Annual Report also contains industry, market and competitive position data from our own internal estimates and research, as well as from independent market research, industry and general publications and surveys, governmental agencies and publicly available information. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires. In addition, while we believe the industry, market and competitive position data included in this report is reliable and based on reasonable assumptions, such data involve risks and uncertainties and are subject to change based on various factors, including those discussed in the section titled “Risk Factors.” These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

Item 1. Business

Overview

We are a biopharmaceutical company leveraging our innovative virus-like particle (VLP) platform technology to develop vaccines against infectious diseases, with an initial focus on life-threatening respiratory diseases. Our VLP platform technology is designed to enable multivalent, particle-based display of complex viral antigens, which we believe will induce broad, robust, and durable protection against the specific viruses targeted. Our pipeline includes vaccine candidates targeting some of the most prevalent viral causes of pneumonia. We are developing these candidates for older adults, a patient population with high unmet need. Our lead vaccine candidate IVX-A12 is a bivalent candidate, or a mixture of two different VLP candidates. IVX-A12 combines IVX-121, a vaccine candidate designed to target respiratory syncytial virus (RSV), and IVX-241, a vaccine candidate designed to target human metapneumovirus (hMPV). There are currently no vaccines approved that target both RSV and hMPV, which are two common causes of pneumonia in older adults. In September 2021, we began the clinical development of IVX-A12 by conducting a Phase 1/1b clinical trial of IVX-121 targeting RSV, and we reported positive interim topline and six-month durability data with respect to IVX-121 in June 2022 and December 2022, respectively. As planned, we then transitioned development to our IVX-A12 bivalent RSV/hMPV candidate. In October 2022, we received allowance for our investigational new drug application (IND) from the U.S. Food and Drug Administration (FDA) and initiated a Phase 1 clinical trial of IVX-A12, with topline interim data expected in the second quarter of 2023. In February 2023, we announced that the FDA granted IVX-A12 fast track designation for the prevention of disease caused by RSV and hMPV in older adults aged 60 or older.

We are developing additional vaccine candidates as part of our strategy to develop combination VLP vaccines targeting the viral causes of pneumonia in older adults, including influenza and SARS-CoV-2. In the future we may also develop candidates in other areas of unmet need where VLP vaccines have the potential to offer differentiated benefits.

Our Strategy

Our goal is to utilize our VLP platform technology to develop vaccines against infectious diseases with an initial focus on life-threatening respiratory diseases and a vision of creating pan-respiratory vaccines for older adults. Key elements of our strategy include:

- **Advancing our combination RSV-hMPV VLP vaccine candidate, IVX-A12, through clinical development and regulatory approval for the prevention of respiratory disease including pneumonia in older adults.** Following positive interim topline and six-month durability data for IVX-121 in RSV, we initiated a Phase 1 trial for IVX-A12. We expect topline interim data for this trial in the second quarter of 2023 and, assuming positive results, plan to thereafter initiate a Phase 2 trial of IVX-A12. While monovalent RSV vaccines may soon be approved by the FDA, there is no approved vaccine for hMPV, and we believe that our bivalent RSV- and hMPV-targeted VLP vaccine is differentiated by targeting two leading causes of pneumonia in one vaccine, as well as other potential benefits.

- **Leveraging our VLP platform technology to pursue additional vaccine candidates and combinations in indications with high unmet need.** We believe our VLP vaccine technology has broad potential applicability beyond RSV and hMPV, including in influenza and SARS-CoV-2, and we have programs in both of these indications. We plan to evaluate the development of VLP candidates for other indications with high unmet need and where VLP vaccines have the potential to offer differentiated benefits. We also plan to continue to evaluate the potential of our VLP platform technology in combination vaccines in support of our vision to ultimately create pan-respiratory vaccines.

- **Building manufacturing scale-up capability early in the development process.** For all our vaccine candidates, we plan to identify and contract with large-scale commercial contract development and manufacturing organizations early in the development process. Our strategy is to initiate scale-up of manufacturing process development activities immediately following commencement of clinical trials to enable incorporation of manufacturing process changes early in development. We believe that this will lower manufacturing risk for our programs as well as accelerate our timelines to regulatory approval.

- **Further optimizing our VLP platform technology and enhancing our antigen design capability.** We intend to invest in process enhancements that we believe could enable more rapid development of future vaccine candidates. As part of this plan, we intend to evaluate alternative manufacturing processes that we

believe could reduce time from candidate selection to availability of clinical trial material and enable us to rapidly respond to annual strain changes as needed in our influenza program. We have also added a research team deploying cutting edge antigen design and VLP scaffold design in the development of our pipeline programs.

- **Maximizing the value of our vaccine candidates through selective partnerships.** As we continue to build and advance our vaccine candidate pipeline, we may explore on a candidate-by-candidate or regional-basis partnerships or strategic collaborations to accelerate development or commercialization with third parties who have complementary capabilities that allow us to enhance the value of our pipeline.

Our VLP Technology

Our technology platform is based on the VLP approach to vaccine development, which we believe has been validated through the regulatory approvals and commercial success of third-party, naturally occurring VLP vaccines and has several benefits. These naturally occurring VLPs have shown the ability to induce high and sustained levels (titers) of neutralizing antibodies (nAbs) in both older and younger adults, which have generally been associated with protective immunity. In addition, we believe VLPs can be used in combination vaccines as VLPs enable multivalent display of antigens in a manner that closely resembles viruses but contain no genetic material. However, VLPs engineered to display complex viral antigens have in general been difficult to develop or successfully manufacture at scale, limiting the pathogens that can be addressed by this approach.

Our vaccine technology was licensed from the Institute for Protein Design at the University of Washington (UW) and is designed to enable the application of VLP-based vaccines against a broader array of pathogens than has been possible with naturally occurring VLPs and to overcome the manufacturing challenges experienced with these VLPs as well as some additional VLP technologies. Our licensed VLP technology utilizes a computationally designed protein structure that self-assembles without interfering with the structure of the displayed antigens. The individual protein components are expressed and purified using traditional recombinant protein techniques, which we believe will allow us to manufacture our VLP vaccine candidates efficiently at scale.

Vaccines are designed to prevent disease by providing a safe exposure to key components of pathogens capable of inducing protective immunity. Infants and young children have typically not been exposed to many pathogens and have limited immunity following the disappearance of maternal antibodies. As infants grow into adults the immune system becomes stronger and more capable of fighting off several pathogens that cause disease, owing to both vaccines and natural exposure to infections as children. However, as adults age, their immune system becomes weaker and less capable of mounting an effective immune response. This phenomenon is called immunosenescence, and it leaves older adults more susceptible to disease than younger adults. Recently, several vaccines have been approved or recommended specifically for use in older adults and we believe that novel approaches to vaccine development will continue to drive the market for prevention of disease in this population.

Our initial focus is on the development of vaccines to prevent respiratory disease including pneumonia caused by viral pathogens in older adults. We believe there is a need for effective vaccines to combat infections in older adults, who are generally less able to mount an immune response against pathogens compared to other age groups due to immunosenescence. Immunosenescence causes older adults to be more susceptible to severe symptoms and death from

infections and results in a weaker response to vaccination with conventional vaccines. For many infectious diseases, including RSV, hMPV, influenza and SARS-CoV-2, there is a strong correlation between nAb levels and increased protection against disease. For this reason, vaccines able to induce the highest and most durable nAb titers will likely be the most protective against infection, particularly in older adults. We believe that VLP vaccines may be effective in generating the high and durable nAb responses needed. In addition, we believe our platform has the potential to address the global need for thermostable, low-cost, and readily manufacturable vaccines.

Benefit of Combination Vaccines

We plan to utilize our innovative VLP platform technology to develop and deliver combination vaccine products, initially targeting respiratory pathogens in older adults. Combination vaccines have had commercial success in both pediatric and young adult populations with significant patient access and market penetration. This is because combination vaccines can be developed to protect against diverse pathogens or multiple strains or variants of the same pathogen with a single product while having the potential to reduce the number of injections and simplifying the immunization schedule.

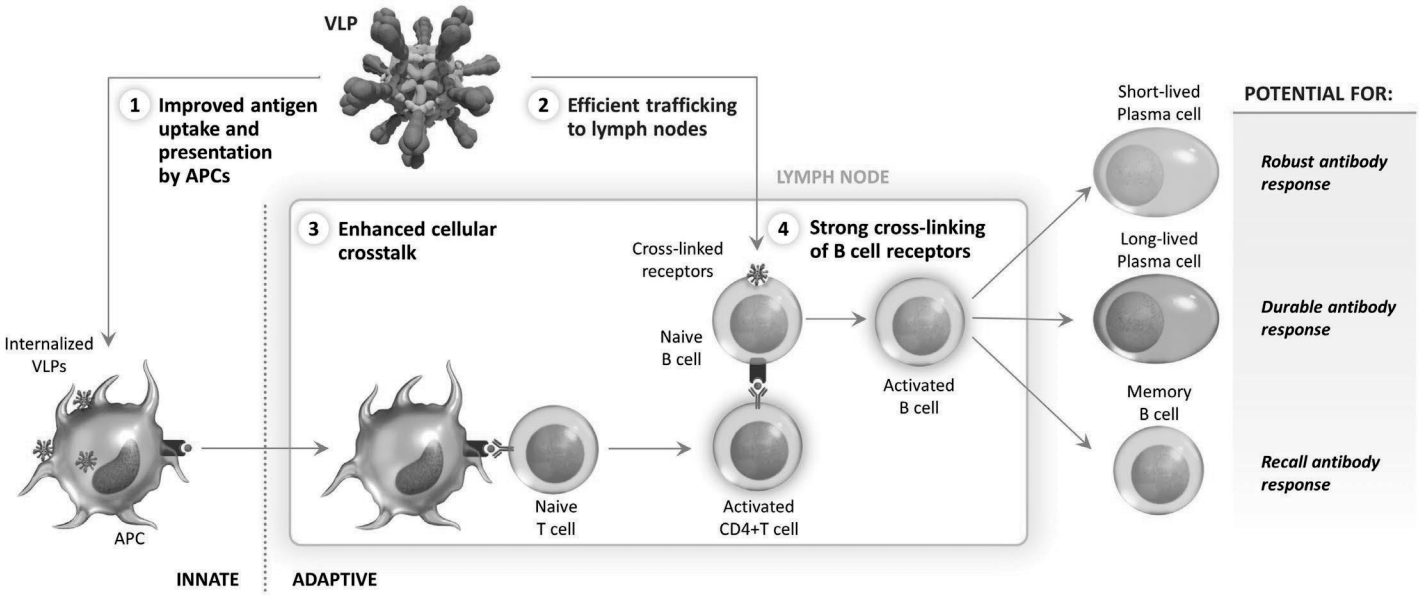
We predict that as more vaccines targeting the older adult community are developed, combination vaccines will become the preferred approach for older adults, similar to what has occurred with pediatric and young adult vaccines. We believe an early focus on combination vaccine candidates against respiratory viruses in older adults will give us a competitive advantage over monovalent vaccine candidates in development, and our ultimate vision is to develop pan-respiratory vaccines.

Potential Benefits of VLP Vaccines

There are a number of highly effective VLP vaccines on the market (e.g., for HPV and HBV) and vaccines in development (e.g., for norovirus) that are based on naturally occurring VLPs. In these instances, the vaccines contain proteins from the target pathogen that naturally self-assemble into VLPs and are capable of inducing a protective immune response. Data from third-party and our preclinical studies and clinical trials suggest that VLPs are capable of inducing a robust and durable immune response that in some cases was superior to soluble protein antigens alone.

The robust response to VLPs is believed to be due to their interaction with several aspects of both the innate and adaptive arms of the immune system, which are responsible for driving immediate and lasting immune responses. The innate immune system involves a diverse set of cells, including dendritic cells, mast cells, eosinophils, basophils, neutrophils and macrophages, all of which generate a rapid response to pathogens or other foreign bodies. The adaptive immune system is a second line of defense that is specific to a pathogen or antigen and is triggered when antigen presenting cells (APCs) from the innate immune system activate and recruit cells from the adaptive immune system. The adaptive immune system is composed of T cells and B cells which can form immunologic memory and therefore be activated upon reintroduction of the initial antigen or pathogen.

As illustrated in the figure below, VLPs are believed to induce robust immune responses through (1) improved uptake and presentation of VLP-based antigens by APCs that “instruct” T cells on pathogenic threats, (2) efficient trafficking of VLPs to the lymph nodes, a critical site for adaptive immune responses, (3) enhanced cellular crosstalk between APCs, T cells and B cells and (4) the potential of multivalent, VLP-based antigens to effectively cross-link and stimulate antigen receptors on B cells, which mature into short-lived plasma cells, long-lived plasma cells and memory B cells following exposure to antigens. Compared to soluble antigens, the observed strength of B cell receptor cross-linking by multivalent, VLP-based vaccines are believed to increase the induction of long-lived plasma cells, which provide a durable antibody response. As an example, marketed HPV vaccines have demonstrated high levels of immunogenicity and efficacy for 9-10 years following vaccination while 80% people vaccinated with the hepatitis B virus (HBV) VLP vaccine showed protective titers at least 10 years after their primary immunization.



We believe there are several other potential advantages to VLP-based vaccines. VLPs are non-replicating and non-infectious, which we believe has the potential to make them safer to use in all populations. In addition, since they do not replicate, VLPs have the potential to stimulate immune responses even in the presence of pre-existing immunity (through either previous infection or vaccination), which has limited the utility of some viral vector-based vaccine platforms. VLPs have also been observed to induce robust nAb levels in older adults, despite immunosenescence. VLPs have also been effective in the development of combination vaccines. For example, the Gardasil and Cervarix vaccines for use against HPV, among others, incorporate combinations of VLPs targeting different viral strains. For Gardasil, the initial formulation contained four VLPs, and serotype coverage was expanded through the inclusion of five additional HPV type VLPs in a second-generation product, showing the feasibility of expanding VLP formulations. Gardasil/Gardasil-9 generated $6.9 billion in 2022 worldwide sales. In addition, the Takeda/HilleVax norovirus VLP candidate, a combination of two VLPs targeting different norovirus genotypes, has successfully completed Phase 2 clinical trials. Evaluation of nAb titers induced by this vaccine candidate showed no difference between the response seen in adults aged 22-48 and adults aged 60 and over. In 2022, we announced positive Phase 1b clinical data with respect to our IVX-121 VLP vaccine candidate, as described above and below, that indicated that IVX-121 was generally well-tolerated and generated a robust nAb response in both young and older adults that was sustained for at least 6 months after administration.

Limitations of Earlier VLP Technologies

The major drawback of naturally occurring VLPs is that they often cannot be easily engineered to display complex antigen targets or manufactured at commercially relevant scale. Since very few pathogens have protective antigens that naturally form VLPs, where the manufactured proteins naturally fold into the shape of a multimeric particle, this limits the specific pathogens that can be targeted with this approach. Several developers have and are currently utilizing various other approaches to develop and manufacture VLP-based vaccines. One approach is to use proteins from viruses that naturally form VLPs (e.g., tobacco mosaic virus and HBV) as scaffolds for protective antigens that fail to form VLPs on their own. There are also naturally occurring proteins that self-assemble into particles (e.g., bacterial protein ferritin or lumazine synthase) that can be used as scaffolds for presenting heterologous antigens. The main limitation of the natural scaffold-based approaches is that the structure is fixed resulting in limitations on the size and nature of the antigens that can be incorporated into these particles, as well as the valency and geometry of the antigens presented. Another approach is to use an enveloped VLP that buds from the host cell and contains cellular lipids that make up the lipoprotein envelope. Although this allows for incorporation of complex heterologous antigens, enveloped VLPs can be challenging to purify, with concerns about viral contamination as well as host-cell proteins being carried through to the enveloped VLP, particularly when mammalian expression systems are used. In addition, enveloped VLPs have historically had poor yields, scalability, and stability challenges.

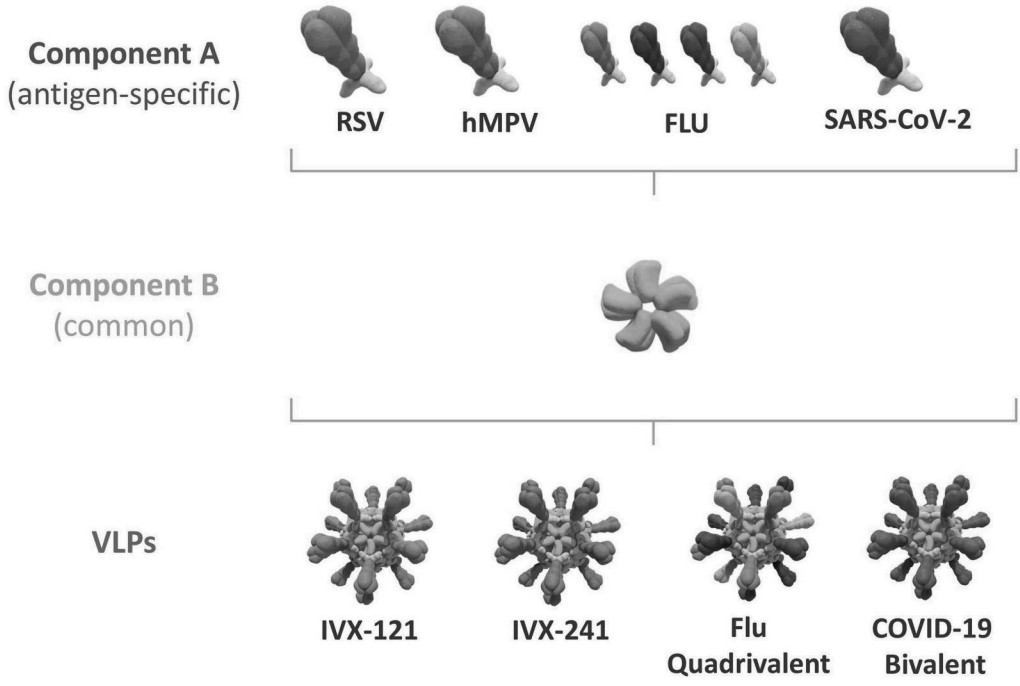
Our Solution—Computationally Designed VLP Technology

We believe that our computationally designed VLP platform technology, licensed from UW, retains the benefits of the naturally occurring VLPs while potentially overcoming the constraints and limitations seen in some other VLP

technologies to date. Our platform is based on technology developed by scientists at UW, who pioneered a computationally designed VLP system with potential to address a wide range of vaccine targets.

Our licensed VLP technology includes VLPs formed from one and two protein components that are separately produced using traditional recombinant protein manufacturing techniques. With respect to our two component VLP technology, the antigen-bearing Component A consists of a trimeric protein that is genetically fused to the target protein of interest and is produced in eukaryotic or prokaryotic cells. The trimeric Component A assembly domain is derived from a thermophilic bacterium and has shown stability at above 70 degrees Celsius, which we believe has the potential to confer stability to the assembled VLP. The second protein, Component B, is a pentameric protein that is produced by bacterial fermentation and assembles cooperatively with Component A to form the two component VLP.

We are focusing our current development efforts on a single two component VLP scaffold, which allows for the same Component B to be shared across multiple vaccine candidates featuring different antigens presented on Component A, as illustrated in the graphic below.



Component A and Component B are expressed and purified separately prior to assembly. Upon mixture, the two protein components self-assemble into an icosahedral VLP displaying multiple copies of a trimeric or monomeric antigen, such as the 20 copies of the trimeric RSV or hMPV antigens in IVX-121 or IVX-241, respectively. VLPs may also be assembled using multiple Component As incorporating the same antigen, or by mixing Component As incorporating more than one antigen as shown with the mosaic influenza particle in the graphic above.

Using our VLP platform technology we engineer vaccine candidates comprised of self-assembling proteins that are designed to have the following potential benefits:

- **Robust, durable, and broad immune responses.** The icosahedral symmetry of our VLPs mimics viral geometry and is designed to allow for increased antigen density. In addition, we believe our VLPs are within the optimal size range (20-100 nm) that enables efficient trafficking to the lymph nodes as seen with natural VLPs. Both increased antigen density and lymph node trafficking are known to trigger robust B cell immune responses. We believe that preclinical data and initial clinical data support the potential of our platform to generate VLPs that provide one or more of the following benefits: high nAb levels, durable immunogenicity, cross-protection against related viral strains, and a favorable tolerability profile.

- **Potential to display complex heterologous antigens.** Our approach allows for the multivalent display of complex antigens that would not normally form into VLPs.

- **Highly scalable manufacturing and ease of purification.** Our technology facilitates the use of standard, scalable recombinant protein production methods for vaccine manufacturing and purification with well-established cell line and fermentation technologies.

- **Increased antigen stability.** Our VLPs are designed to confer increased stability to our vaccine candidates, which we believe will allow for improved storage and distribution.

Vaccine Market Overview

The 2021 global vaccine market was estimated to be over $140 billion, including an estimated $100 billion for COVID-19, $8 billion for influenza, and $7 billion for pneumococcal. Although sales for COVID-19 vaccines are projected to decline over time, sales for other vaccines are expected to increase. Influenza and pneumococcal vaccines are each projected to reach $13 billion by 2030. Recombinant, conjugate and subunit vaccines, which include VLP-based vaccines, make up over 50% of the non-COVID vaccine market.

Respiratory disease, including pneumonia, was the leading cause of death and hospitalization from infections and the fourth highest cause of death globally prior to the COVID-19 pandemic. Older adults are particularly susceptible to respiratory pathogens and it is estimated that prior to COVID-19, lower respiratory infection (LRI) caused over one million deaths globally in people over the age of 70 every year. The world adult population over the age of 60 is expected to double by 2050, so prevention of respiratory disease in older adults is a growing commercial opportunity. Many of the viral causes of pneumonia have no approved vaccines, limited treatment options, and result in high morbidity and mortality in the older adult population.

Our Programs

Our initial focus is on developing vaccine candidates for viral causes of pneumonia in older adults. The following chart summarizes our current programs.

VLP technology underlying all candidates is licensed from UW.

* We do not plan to pursue the IVX-121 RSV monovalent candidate as a standalone candidate for RSV in older adults and are transitioning development to the IVX-A12 bivalent RSV/hMPV candidate following Phase 1.

† FDA Fast Track Designation

‡ We have worldwide nonexclusive rights with the exception of South Korea (which is not included in the licensed territory), which will convert to exclusive rights in North America and Europe (including Switzerland and United Kingdom) starting in 2025, with non-exclusivity maintained elsewhere.

Our current development efforts are focused on addressing the unmet need for safe and effective vaccines against leading causes of LRIs, including pneumonia, in older adults. Prior to the COVID-19 pandemic, LRIs were the fourth leading cause of death worldwide, with morbidity and mortality increasing with age and pre-existing conditions. LRIs caused by pathogens other than SARS-CoV-2 typically lead to over one million deaths worldwide per year in people over

70 years of age and pneumonia is the most common LRI. Many of the viruses found to be associated with pneumonia and LRIs have no approved vaccines as of March 2023, including RSV and hMPV. While two RSV vaccines are likely to be approved by the FDA in 2023, there is no approved vaccine that targets hMPV or the combination of hMPV and RSV. Other viruses associated with pneumonia, such as influenza, have marketed vaccines but efficacy is often low and variable from year to year.

We have developed each of our vaccine candidates using a robust selection process to identify what we believe is the best antigen. Our selection process includes screening for expression, protein conformation, stability, VLP assembly competence, and evaluation of immunogenicity in multiple animal models, including those that have been previously infected with the pathogen (i.e., primed) when relevant. We in-license antigens where we believe that others' discoveries may be optimally suited for our technology. We also develop our own antigens in-house.

IVX-A12 (RSV-hMPV vaccine candidate), a bivalent combination of IVX-121 (RSV vaccine candidate) and IVX-241 (hMPV vaccine candidate)

IVX-A12 is a bivalent combination of IVX-121, which is designed to target RSV, and IVX-241, which is designed to target hMPV. Both IVX-121 and IVX-241 have been designed to display prefusion stabilized F antigens of RSV and hMPV, respectively. The F (fusion) proteins of these viruses are critical for viral entry. F proteins are also one of the main targets for nAbs and are a focus of most vaccine efforts for respiratory viruses such as RSV and hMPV.

Although we believe the F protein of RSV was validated as a target in 1998 through Synagis, a monoclonal antibody used to protect high-risk infants from infection, it was only more recently that F antigen-based vaccines began to show proof of concept in clinical development. The conceptual breakthrough came in 2013 with the resolution of the crystal structure of the prefusion F antigen, its form before viral entry into a cell, and the recognition that there is a significant change and loss of critical protective epitopes in the molecule's postfusion F form, its form following viral entry. The subsequent design of stabilized RSV F prefusion antigens reinvigorated the field, leading to substantially improved immune responses and protection. More recently, GlaxoSmithKline, Pfizer and Moderna reported positive Phase 3 efficacy studies of their RSV vaccines incorporating stabilized RSV F prefusion antigens. Preclinical work suggests a similar structural transition occurs to the hMPV F antigen following viral entry, and that the hMPV prefusion F antigen provides superior protection to the hMPV F postfusion antigen.

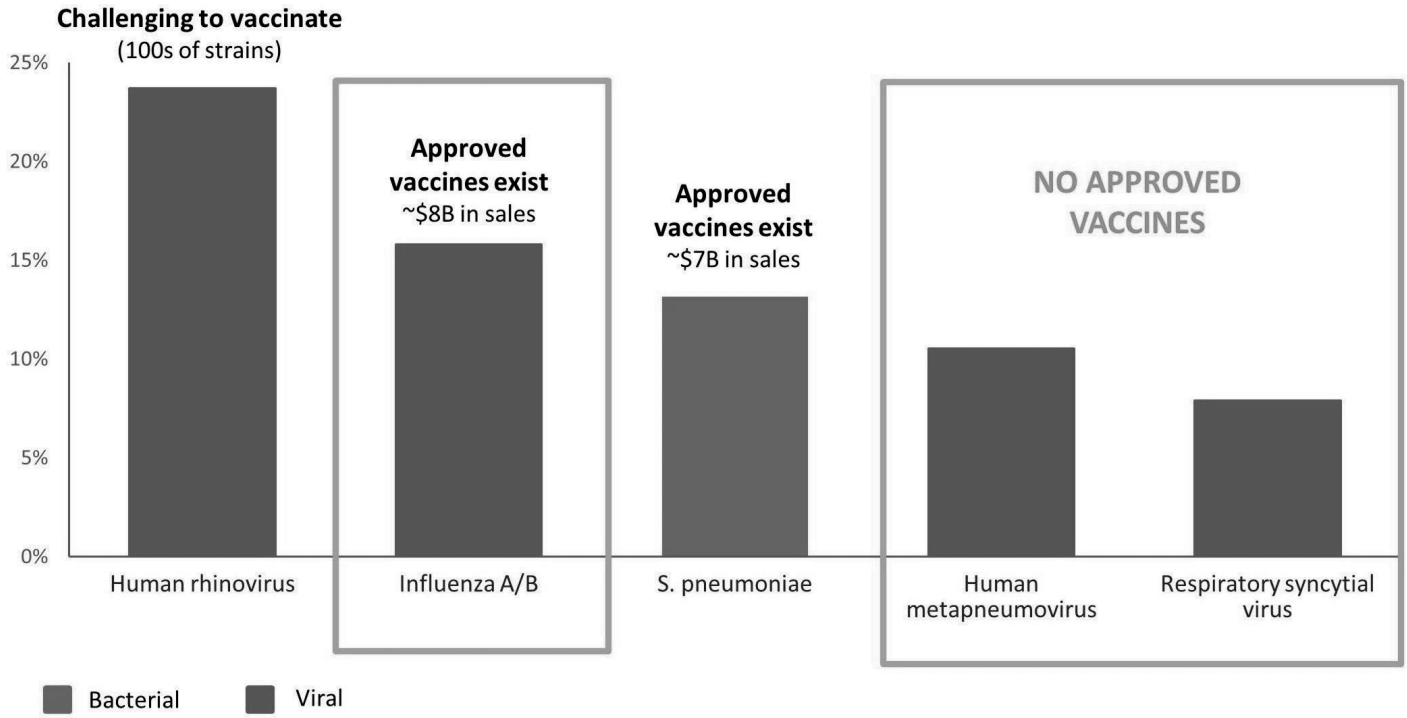
We have licensed a prefusion stabilized form of the RSV F antigen, DS-Cav1, from the National Institute of Health (NIH) that has been demonstrated in clinical trials conducted by the NIH to be a robust immunogen. An initial clinical trial with DS-Cav1 showed an induction of nAb titers much higher than had previously been seen with other postfusion vaccine approaches to RSV. We have incorporated DS-Cav1 into our VLP candidate IVX-121. Preclinical data with hMPV antigens provide support for the F antigen as a potential target for protective immunity, and we have incorporated a prefusion F antigen into our VLP candidate IVX-241. The prefusion F antigen in IVX-241 incorporates key mutations that we have licensed from the NIH and the University of Texas at Austin (UT). We assessed different ratios of IVX-121 and IVX-241 in preclinical studies in an effort to identify the ratio least likely to induce immunologic interference between them prior to initiating clinical trials of IVX-A12, and we are currently evaluating ratios of IVX-121 to IVX-241 in our IVX-A12 clinical trial. We believe that multivalent display of these prefusion F antigens on the surface of our VLPs has the potential to induce a robust nAb response capable of conferring protection against infection of both viruses, which we are assessing in clinical trials.

We believe that a bivalent VLP vaccine targeting RSV and hMPV is an optimal approach to prevent these two common causes of pneumonia. We initiated clinical development of IVX-A12 with a clinical trial of IVX-121. We conducted a Phase 1/1b clinical trial to assess the safety and immunogenicity of IVX-121 in adults aged 18-45 and 60-75, and in June 2022, we announced positive topline interim results. These topline interim data showed that IVX-121 induced a robust immune response, consistent across both young and older adult groups, including at the lowest non-adjuvanted dose tested and was generally well-tolerated across all dosage groups. We received allowance to proceed from the FDA under our IND and in October 2022, we announced initiation of a Phase 1 IVX-A12 clinical trial, with topline interim data expected in the second quarter of 2023. In December 2022, we reported positive six-month IVX-121 immunogenicity data, demonstrating a sustained nAb response against RSV, lasting for at least six months after a single administration of IVX-121. We are also conducting a Phase 1b extension study for IVX-121, in which a subset of older adults from the Phase 1b cohort will be followed out to 12 months to assess durability of response, and response to an additional vaccine dose. Twelve-month IVX-121 immunogenicity data is expected for this study in mid-2023. In February 2023, the FDA granted fast track designation to IVX-A12 for the prevention of disease caused by RSV and hMPV in older adults aged 60 or older.

IVX-A12 Market Opportunity

Marketed vaccines for pneumococcus and influenza, two major causes of pneumonia, had an estimated combined annual 2021 global revenue of $15 billion. RSV and hMPV are also highly prevalent respiratory pathogens that occur seasonally. The largest epidemiological study assessing prevalence of RSV and hMPV that compared with influenza and pneumococcal in adults was the EPIC study published in 2015. Based on this study, the two most common pathogens causing pneumonia in adults after human rhinovirus, influenza pneumococcus and influenza were RSV and hMPV, which were found in 8% and 11%, respectively, of U.S. adults hospitalized for community acquired pneumonia where any pathogen was detected, as shown below.

Top 5 Pathogens Detected in Adults Hospitalized with Community-Acquired Pneumonia (EPIC Study*)



* EPIC study data from supplementary information published in Jain et al., 2017

Pneumococcal and influenza vaccines are important vaccines in the current respiratory vaccine market. Both are recommended for immunization by healthcare policy makers in the United States and other major markets. The global pneumococcal market was estimated to be around $7 billion in 2021, and is projected to grow to around $13 billion in 2030. The global influenza market size is estimated to be around $8 billion in 2021, and is projected to grow to around $13 billion by 2030. Older adults make up a significant proportion of these sales. Uptake of influenza vaccines in U.S. adults over the age of 65 increased from 70% in the 2019-2020 season to 74% in the 2021-2022 season. Pneumococcal vaccine uptake is also estimated to be around 70% in adults over 65 years of age. Pneumovax23, a pneumococcal vaccine with uptake primarily in the older adult population, had 2022 sales of $600 million. We believe that sales of vaccines for older adults will grow substantially in the future, as the world adult population over the age of 60 is expected to double by 2050.

RSV is estimated to cause 177,000 hospitalizations and 14,000 deaths in adults 65 years of age or older annually in the United States alone. Costs per hospitalization for RSV in older adults are estimated to be at least as great as those of influenza due to longer hospital stays and greater pulmonary complications. The U.S. economic burden for RSV-related hospitalizations alone is estimated to be greater than $2.5 billion per year. Rates of hospitalization and severity of disease

for hMPV have been shown to be similar to those seen with RSV and influenza. There are currently no marketed vaccines that target both RSV and hMPV, two common causes of pneumonia.

In addition, recent data show that both morbidity and mortality in U.S. adults hospitalized with viral pneumonia is higher with both RSV (16.1% likelihood of ICU admission and 5.2% likelihood of death) and hMPV (16.5% likelihood of ICU admission and 3.9% likelihood of death) than with influenza (11.5% likelihood of ICU admission and 3.3% likelihood of death). Given these data, a combined RSV-hMPV vaccine could address a substantial unmet medical need.

We have conducted a primary and quantitative research campaign including interviews with 35 U.S. and EU payors and policy makers and a quantitative survey with 140 U.S. vaccinators (physicians and pharmacists). Data from the study suggest that once launched, an effective RSV vaccine targeting the older adult population could be included in policy (e.g., Advisory Committee on Immunization Practices; ACIP) guidelines. This applied to both monovalent (RSV only) and combination vaccines that incorporate an RSV component. These guidelines drive recommendations by the Centers for Disease Control and Prevention (CDC), and equivalent organizations outside the United States, and can lead to inclusion on payor formularies. Inclusion of GlaxoSmithKline and/or Pfizer RSV vaccines into older adult immunization guidelines in the United States could happen as early as 2023 based on the upcoming Prescription Drug User Fee Act dates and scheduled ACIP review for these vaccine candidates. The quantitative survey results suggested that policy recommendations were likely to drive immediate vaccine utilization of an RSV vaccine. Survey results also suggested that vaccinators were likely to have a strong (90%) preference for a combination RSV-hMPV vaccine over an RSV monovalent vaccine, assuming equivalent efficacy against RSV. Overall, we believe that the survey results supported continued development of a bivalent RSV/hMPV vaccine candidate. In February 2023, the FDA granted fast track designation to IVX-A12. Fast Track is a process designed to facilitate the development, and expedite the review of, investigational drugs to treat serious conditions and fulfill an unmet medical need.

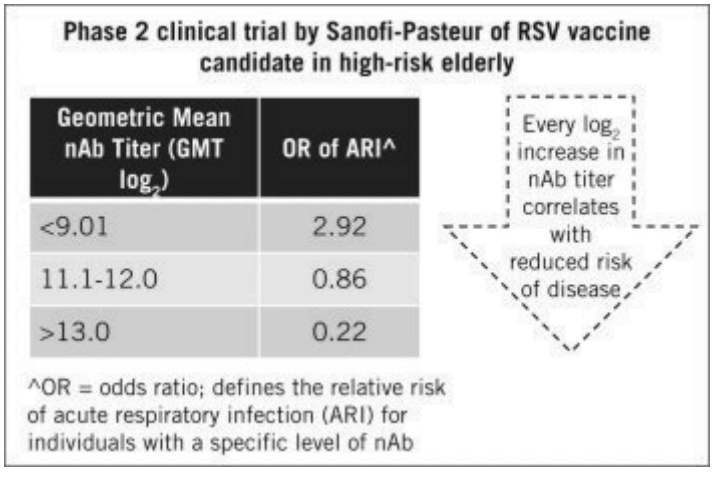
IVX-121—RSV VLP Vaccine Candidate

Overview of RSV

RSV is an RNA virus that replicates in the nose and lungs and is a major viral cause of LRI worldwide. There are two major subtypes of RSV, A and B, which may co-circulate in a single RSV season. Re-infection is common, and all older adults are expected to have been exposed to RSV and have RSV-specific antibodies. The most common symptoms are cough, fatigue, dyspnea, congestion, wheezing, and fever.

High Neutralizing Antibody Titers Correlate with Reduced Risk of Infection and Disease

There is substantial data correlating high nAb titers with protection against RSV. Published preclinical data, natural history studies, human challenge studies, and clinical data all demonstrate reduced risk of infection and disease when higher nAb titers are present. Published natural history studies have demonstrated that once partial protection is achieved, every additional doubling in RSV nAb titer may be associated with an 22-25% decrease in RSV-associated hospitalization. Data from a Phase 2 clinical trial conducted by Sanofi that followed 1,180 subjects aged 65 or older with cardiopulmonary disease over two years at U.S. sites provided additional support that increasing titers correlate with a reduced risk of respiratory illness. As illustrated in the figure below, a doubling of RSV nAb titer was observed to be correlated with a reduced risk of acute respiratory infections (ARIs). Based on these and similar findings, we have designed IVX-121 to increase the magnitude, quality, and durability of the nAb response.



Graph based on data published in Falsey et al., 2008

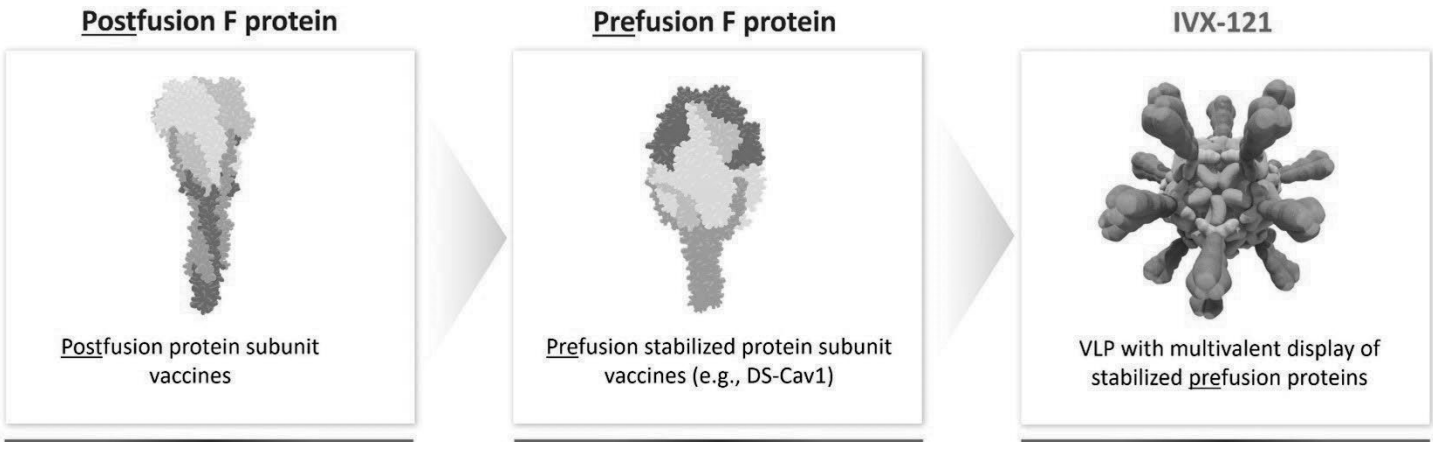
Prefusion RSV-F Protein-Based Vaccines May Generate Higher Neutralizing Antibody Titers than Postfusion Vaccines

RSV contains several glycoproteins that are important for different functions of the virus, including the surface fusion protein F (RSV-F). RSV-F is a highly conserved glycoprotein that contains the majority of the neutralizing epitopes, specific regions of antigens that bind protective antibodies. We believe RSV-F was validated as a target for protection by the reported positive efficacy results from Phase 3 studies of multiple vaccine candidates, including from GlaxoSmithKline and Pfizer, and by the clinical efficacy and approval of Synagis, a monoclonal antibody used to protect against serious lower respiratory tract disease caused by RSV in infants at high risk of RSV disease. RSV-F is critical for fusion of the virus with the host cell membrane and the conformation of RSV-F changes significantly between the prefusion or postfusion state. nAbs that bind to prefusion F can block viral entry into cells, thereby reducing viral replication and the severity of RSV-related disease.

The RSV-F protein naturally shifts to the postfusion state and vaccine developers initially focused on vaccines containing the postfusion conformation. These vaccine candidates induced approximately two- to four-fold increases in nAb titers, which was not a sufficient increase in nAb titers to protect a large enough portion of the trial participants to justify continued development.

Data now show that the majority of the nAbs against RSV-F in human sera are directed against the prefusion conformation, and that prefusion directed antibodies have greater neutralizing activity than antibodies directed against the postfusion protein. Researchers at the NIH developed an antigen called DS-Cav1, a prefusion stabilized form of RSV-F that has elicited high titers of nAbs against RSV in mice and nonhuman primates. The NIH conducted an initial Phase 1 trial of DS-Cav1 that showed the antigen induced high nAb titers in humans, much higher than had been seen with postfusion F antigens tested by other developers, as further described below. Although DS-Cav1 provided proof-of-concept (PoC) for prefusion RSV F antigens, DS-Cav1 is not fully stabilized in the prefusion conformation and converts over time to a postfusion structure, which has limited its commercial viability.

We have in-licensed the prefusion RSV-F antigen DS-Cav1 and related technology from the NIH and have incorporated the DS-Cav1 antigen assessed in the NIH Phase 1 trial onto our VLP scaffold. IVX-121 has been designed to display 20 copies of DS-Cav1 as a novel two-component VLP, as shown on the right of the figure below.



We believe that multivalent, particle-based display of the DS-Cav1 antigen has the potential to improve antigen presentation and B cell receptor cross-linking as has been observed with other VLPs. In addition, we have observed that the fusion of DS-Cav1 to the assembly domain of Component A of the VLP further stabilizes the prefusion structure of RSV-F so that the prefusion conformation is maintained under normal storage conditions.

IVX-121 Prefusion F Protein Stability

In preclinical studies, we have observed that the fusion of DS-Cav1 to Component A further stabilized the prefusion conformation and the resultant assembled VLP was very stable at two to eight degrees Celsius, which is a typical temperature range for vaccine storage. In comparison, long-term storage of DS-Cav1 at four degrees Celsius resulted in a

shift away from the prefusion stabilized structure as measured by reduction of prefusion specific antibody binding, including D25 binding, by 102 days.

IVX-121 Clinical Results

Following preclinical studies, we advanced IVX-121 into the clinic in September 2021, and the results of our Phase 1/1b clinical study are described below.

IVX-241 hMPV VLP Vaccine Candidate

Overview of hMPV

hMPV is an RNA virus that is related to the RSV virus. hMPV was first identified in 2001, though it was likely in circulation for at least 50 years prior to discovery. Infection with hMPV brings a similar symptomatic profile as RSV with the most common symptoms being cough, wheezing, dyspnea, congestion and fatigue. Similar to RSV, there are two genetic lineages of hMPV, hMPV/A and hMPV/B, which show a high degree of sequence homology and co-circulate with varying annual prevalence of each strain. The hMPV virus has several highly conserved viral proteins including a fusion protein (F). Preclinical studies have demonstrated that immunization with the F protein is capable of inducing nAbs and protecting against viral challenge in animal models. Vaccination with an F protein from one lineage has been shown to result in nAb titers capable of protection against both hMPV strains, though titers against the heterologous strain are often lower. Similar to RSV, the F protein of hMPV undergoes a conformational change from the prefusion to the postfusion structure to enable entry into the host cell. Recent data indicate that prefusion stabilization of the F protein results in an improved immunogenicity profile in mice, similar to results previously seen with RSV. Our development is focused on a pre-fusion stabilized hMPV antigen.

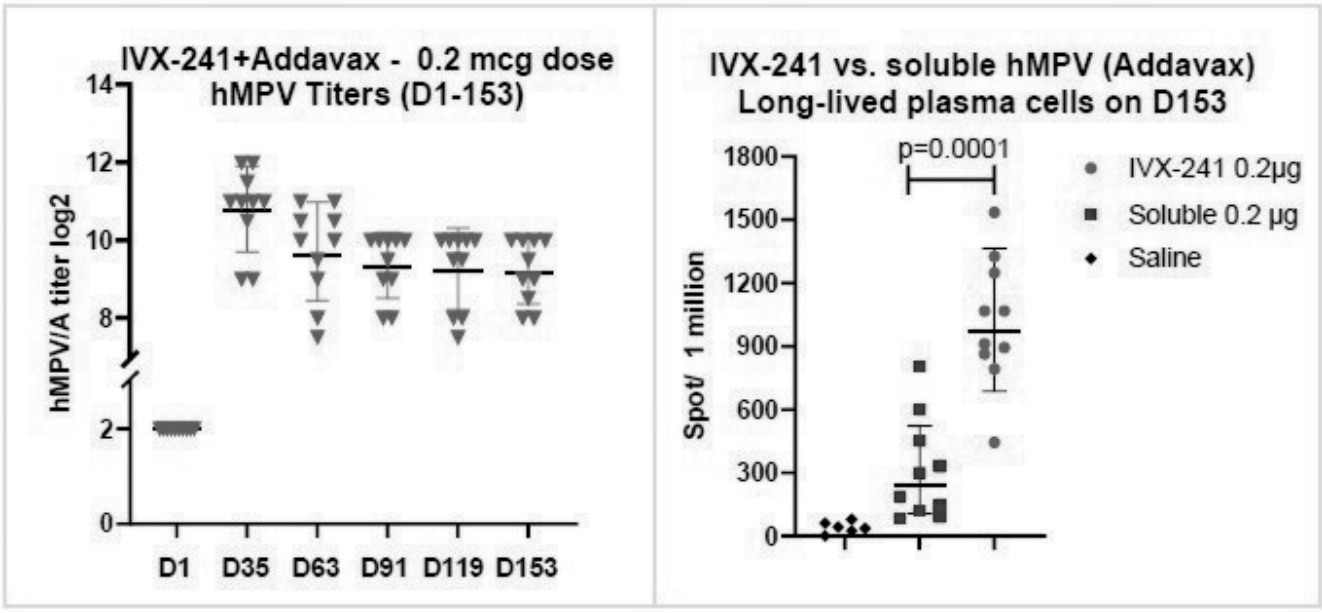
RSV, hMPV, and influenza seasons show high though not complete seasonal overlap, and hMPV is underdiagnosed and often mistaken for RSV or influenza given the similarity in clinical presentation. As diagnostic tools improve, hMPV is being increasingly recognized as a major contributor to ARI and LRI. Similar to RSV, prospective cohorts from third-party clinical trials have shown that higher baseline hMPV nAbs were associated with reduced risk of hMPV symptomatic virus infection, so the goal of vaccination is to increase hMPV nAbs. There are currently no FDA-approved antivirals or vaccines to treat or prevent hMPV.

hMPV Antigen Selection and Immunogenicity Results

Expression of the hMPV F protein has been shown to be challenging and efforts have been made to introduce modifications within the protein to improve expression and stabilize the prefusion structure. We evaluated a number of potential candidate antigens for compatibility with our two-component VLP platform and selected IVX-241. IVX-241 incorporates an F antigen from hMPV/A and was selected based on key criteria, including: high expression, prefusion conformation, monodispersity, VLP stability, and high nAb titers following VLP administration in rodent studies.

Activity of IVX-241 in BALB/c Mice

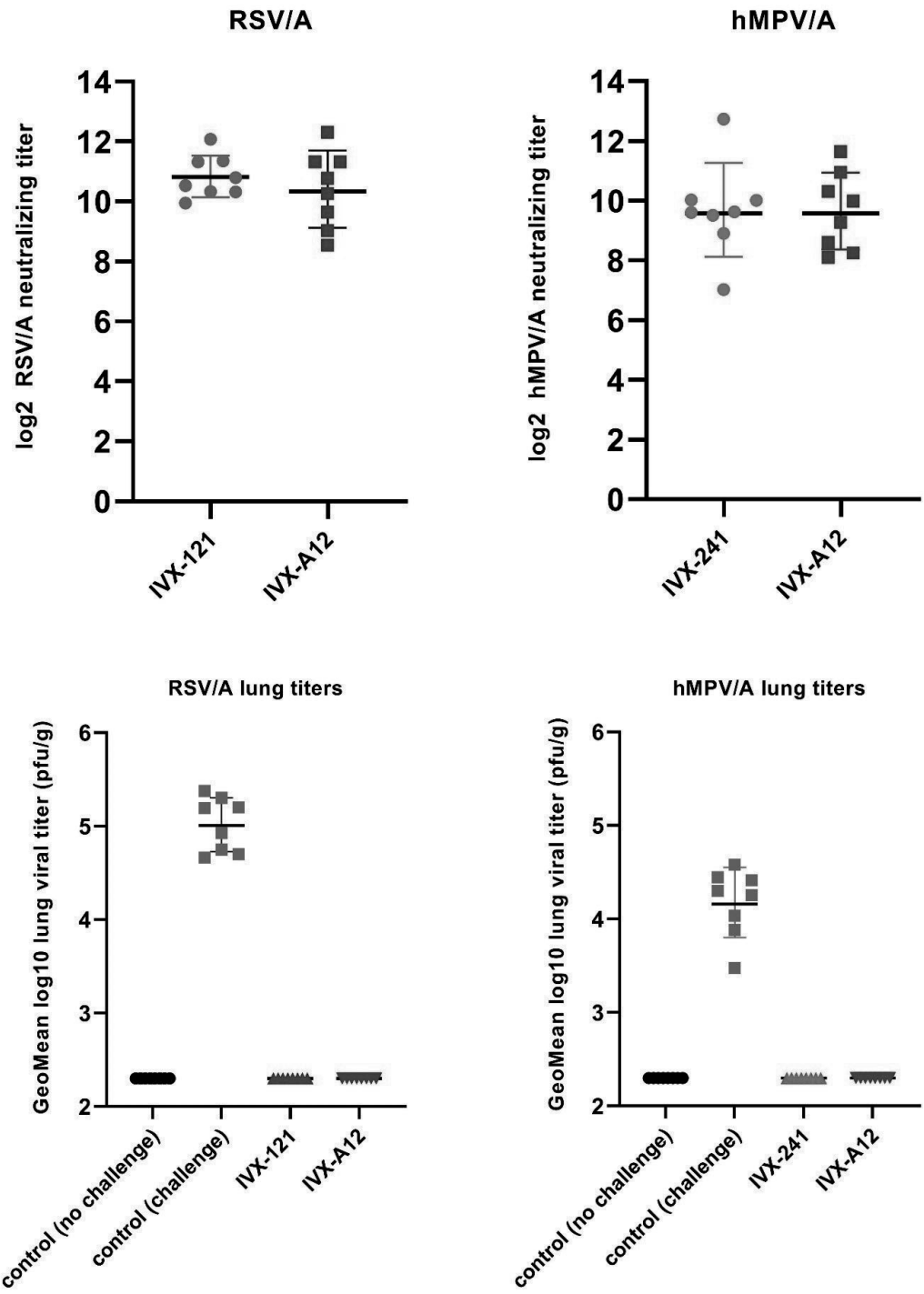
In order to evaluate the longevity of the immune response induced by IVX-241, BALB/c mice were immunized twice at Day 1 and Day 21, and sera was collected over a 153-day period. Titers peaked at Day 35 and then stabilized, with titers of >9 $\log_2$ maintained out through Day 153. To explore the mechanism for the durability of the antibody response we quantified antigen-specific long-lived plasma cells (LLPCs) in animals immunized with either soluble trimeric antigen or IVX-241 by ELISpot. The animals immunized with the multivalent VLP version of the hMPV F prefusion antigen showed significantly higher numbers of antigen-specific LLPCs.



Activity of IVX-A12 via Intramuscular Administration in Cotton Rat Model

To evaluate the potential of IVX-121, IVX-241 or IVX-A12 formulated with Addavax (oil-in-water adjuvant) to protect in a live virus (RSV/A and hMPV/A) challenge model, cotton rats were administered two doses of IVX-121, IVX-241 or IVX-A12 (1 ug of each VLP) on day 0 and day 21 and subsequently challenged with RSV/A or hMPV/A two weeks post the second administration.

Strong nAb titers against RSV and hMPV were observed in the animals two weeks post the second VLP administration and prior to challenge. Titers in monovalent and bivalent formulations were equivalent. The animals were challenged intranasally with 10^5 plaque forming units (PFU) of either RSV/A2 or hMPV/A and lung tissue samples tested 5 days post challenge for viral replication. Cotton rats that were not vaccinated but challenged with RSV or hMPV resulted in substantial viral titers in the lung. Monovalent or bivalent formulations blocked viral replication of each of RSV and hMPV to below the lower limit of quantitation.



We have advanced IVX-A12 into the clinic and we describe our clinical development plan below.

IVX-A12 RSV-hMPV Combination Vaccine Candidate Clinical Development Plan

We intend to pursue regulatory approval of our RSV/hMPV combination VLP candidate IVX-A12 in the older adult population. As is standard for vaccine development where correlates of protection have not been identified, we are first evaluating the safety and immunogenicity of our vaccine candidate in a Phase 1 first-in-human (FIH) trial in healthy older

adults including measuring the change in RSV and hMPV nAb levels compared to baseline antibody levels. We are also assessing different combinations of RSV and hMPV for potential immune interference caused by the addition of hMPV VLPs to the RSV VLP vaccine candidate and to inform the ratio of each VLP in the combination vaccine candidate. Contingent upon favorable safety results, demonstration of immunogenicity and determination of our RSV-hMPV dose combination based on Phase 1 and Phase 2 studies, we plan to assess the efficacy of our RSV-hMPV combination vaccine candidate. For example, the efficacy may be assessed by measuring incidence of LRI caused by either RSV or hMPV in patients receiving IVX-A12 compared to those receiving placebo, or a similar, alternative proof of concept for efficacy.

Based on the clinical and preclinical data for IVX-121, preclinical data for IVX-241, and different formulations of IVX-A12, we also plan to assess whether to advance an adjuvanted or non-adjuvanted formulation of IVX-A12 to later stages of development. Specifically, in our current Phase 1 trial of IVX-A12 we are evaluating varying doses of IVX-A12 with and without CSL Seqirus' proprietary MF59® adjuvant.

IVX-121 Phase 1/1b and IVX-121 Phase 1b Extension Trial

Our plan for the clinical development of IVX-A12 has been to first assess safety and immunogenicity of the RSV monovalent VLP candidate IVX-121 in an initial Phase 1/1b trial in Belgium, for which we reported positive topline interim and six-month durability data in June 2022 and December 2022, respectively.

This FIH trial with IVX-121 was a randomized, observer-blind, placebo-controlled multi-center Phase 1/1b trial designed to evaluate the safety and immunogenicity of three dose levels of non-adjuvanted and Alhydrogel-adjuvanted IVX-121 in two adult cohorts: 18-45 years of age (Phase 1, n = 90) and 60-75 years of age (Phase 1b, n = 130). All subjects in the trial were evaluated for safety and persistence of antibody response for six months following a single intramuscular administration of either IVX-121 or placebo.

In June 2022, we announced positive topline interim results from the Phase 1/1b trial. These topline interim data showed that IVX-121 was generally well-tolerated across all dosage groups and induced a robust immune response, consistent across both young and older adult groups, and including at the lowest non-adjuvanted dose tested. In December 2022, we reported positive six-month immunogenicity data, demonstrating a sustained nAb response against RSV in young and older adults, lasting for at least six months after a single administration of IVX-121. In these data, IVX-121 showed geometric mean titers (GMT) against RSV-A through day 180 persisting at 64-98% of the GMTs at day 28 in older adults. GMTs against RSV-B showed greater variability but were maintained above baseline through day 180.

We are also conducting a Phase 1b extension study for IVX-121 in Belgium, in which a subset of older adults from the Phase 1b cohort will be followed out to 12 months to assess durability of response. We expect twelve-month immunogenicity data in mid-2023.

IVX-A12 Phase 1 Trial

Following a pre-IND interaction with the FDA for the IVX-A12 combination bivalent RSV-hMPV VLP vaccine candidate in the fourth quarter of 2021, and IND allowance by the FDA, we announced the initiation of our Phase 1 trial for IVX-A12 in October 2022. We are evaluating the combination candidate IVX-A12 in this trial, with no evaluation of IVX-241 as a monovalent vaccine candidate.

The goal of the Phase 1 trial of IVX-A12 is to assess safety and immunogenicity of varying doses of IVX-A12, with and without CSL Seqirus' proprietary MF59® adjuvant, in older adults 60-75 years of age (n = approximately 120). Dosing of subjects is now complete. In this Phase 1 trial, subjects were administered a single shot of IVX-A12 at one of three combination dosage levels, or placebo. We expect this design will enable evaluation of the immune responses to both individual components of IVX-A12 and whether the combination of VLPs increases the reactogenicity or leads to immune interference (i.e., imbalanced immune responses to component VLPs). Subjects in the Phase 1 trial are being evaluated for safety and antibody response for twelve months following administration of IVX-A12 or placebo. We expect initial interim immunogenicity data from this trial in the second quarter of 2023.

IVX-A12 Phase 2 Dose-Confirmation Trial

Following and subject to positive topline interim data from the IVX-A12 Phase 1 clinical trial, we plan to initiate a Phase 2 dose-confirmation clinical trial in older adults over the age of 60. We plan to select the formulations and dose regimen for evaluation in the Phase 2 clinical trial based on data from the IVX-A12 Phase 1 trial. Our planned Phase 2 clinical trial is intended to guide final dose selection for a subsequent PoC efficacy trial.

IVX-A12 PoC Trial

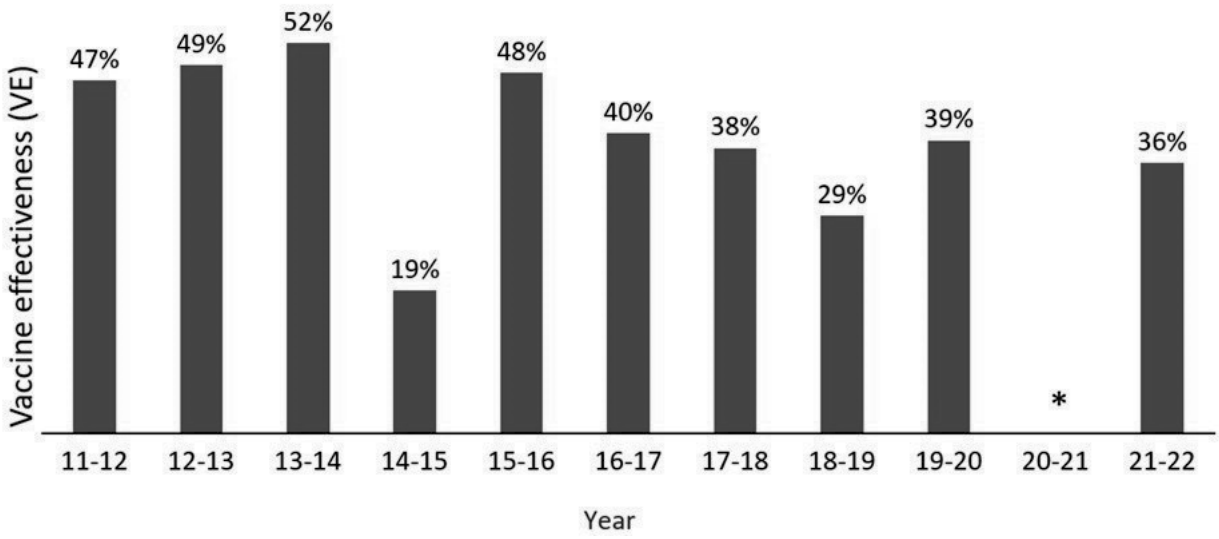
Following the Phase 2 dose-confirmation trial, we subsequently plan to conduct a PoC efficacy trial of IVX-A12. Anticipated PoC objectives include assessment of safety, immunogenicity, and efficacy against illness caused by either RSV or hMPV. Given recent data from Phase 3 trials of vaccines incorporating prefusion RSV antigens and our corporate strategy, we are continuing to evaluate and working to optimize our clinical development plans for IVX-A12.

Influenza Program

Overview of Influenza

Influenza is caused by a respiratory viral pathogen that infects the nose, throat, and lungs. There are two main types of influenza viruses: types A and B. Viral nomenclature is based on two genes in the virus, hemagglutinin (HA) and neuraminidase (NA), that are critical for viral entry and release from cells, as well as species specificity. There are multiple distinct versions of both HA and NA that are numbered to describe related sequences and result in the name of specific viruses. The influenza A and B viruses that routinely spread in people are responsible for seasonal influenza epidemics each year. Existing vaccines have sub-par efficacy (ranging from approximately 20% to 50% year to year) and need to be updated seasonally due to changes in the genetic sequences of the dominant viral variants that circulate in response to human immune pressure.

The reduced efficacy of seasonal influenza vaccines is due in part to the fact that current vaccines are designed to target a narrow subset of predicted strains, and mispredictions about the dominant circulating strain are common as manufacturing must proceed based on data from the previous seasonal epidemic. Another cause of reduced efficacy is that influenza vaccines are often manufactured in chicken eggs, and egg-adapted mutations in protective antigens (i.e., HA) can occur during the manufacturing process that reduce the potency of those vaccines for the viruses that are circulating in humans. The low efficacy of current influenza vaccines leaves an unmet need for an influenza vaccine with improved efficacy. This is particularly needed in the older adult population, who are less likely than other age groups to respond to conventional vaccines. In seasonal influenza, vaccines have historically been up to approximately two times less effective in adults 65 and older compared to other adult age groups.



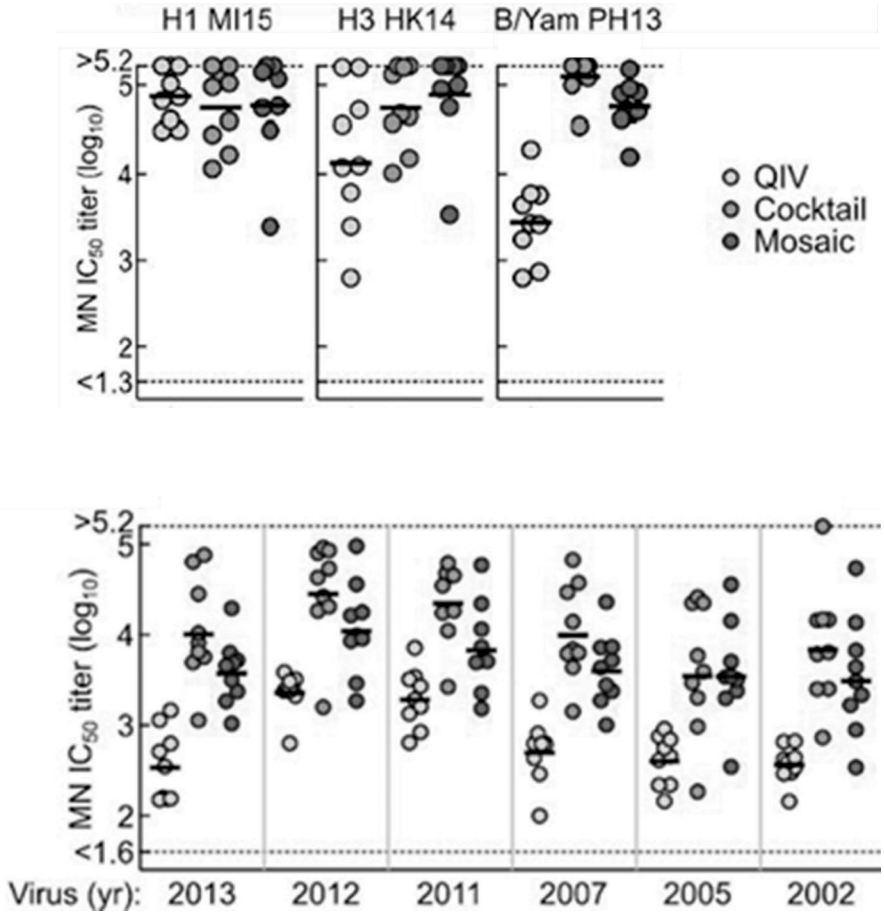
Source: CDC influenza seasonal burden and seasonal influenza vaccine effectiveness studies
* 2020-2021 influenza vaccine effectiveness was not estimated due to low influenza virus circulation during the 2020-2021 influenza season

Influenza results in an estimated 500,000 hospitalizations and 35,000 deaths per year in the United States despite numerous marketed vaccines. Many of these hospitalizations and deaths are in people over the age of 65. In the 2019-2020 influenza season, for example, 45% of the hospitalizations and 59% of the deaths were in people over the age of 65.

In addition to the recurring burden of disease of seasonal influenza, there are concerns about the potential for influenza pandemics, which occur when novel animal viruses jump the species barrier to humans as has occurred with SARS2. In 1917, the H1N1 pandemic is estimated to have killed between 50-100 million individuals. Improved vaccine

technologies that can rapidly scale vaccine production and provide robust protection against future pandemics are also needed.

Data from a collaboration between the UW and National Institutes of Health provided initial PoC for improved responses to influenza vaccines based on the two-component VLP vaccine technology when compared to commercial quadrivalent influenza vaccines (QIV). In preclinical studies in mice, ferrets and NHPs HA proteins from 4 influenza strains (either as a mixture of 4 different VLPs, called a cocktail, or on a single VLP presenting all 4 HA proteins, called a mosaic) generated equal or superior neutralizing responses to the homologous influenza virus as commercial QIV. Importantly, antibodies induced by the VLPs were better able to neutralize viruses that were mismatched to the vaccine strain than QIV. This included strains of avian influenza such as H5N1 that were absent from the vaccine, the mechanism of which was thought to be in part based on the induction of "universal" antibodies (i.e., anti-HA stalk, the portion of HA that is directly responsible for membrane fusion and viral entry into the cell) that are not readily induced by QIV.



Source: Boyoglu-Barnum et al. 2021

The ability to neutralize "drifted" strains is potentially indicative of a broader immune response that could provide superior protection in years when the selection of antigens for influenza vaccines is imperfectly matched to the dominant circulating strains. In addition, the ability to generate neutralizing antibodies against H5N1 with seasonal HA antigens suggests VLP-based vaccines could potentially contribute to protection against influenza pandemics. The NIH is currently running a Phase 1 trial with mosaic VLPs based on the two-component VLP platform, with initial results expected in 2023.

Influenza Candidate Development

Icosavax is developing a recombinant influenza vaccine candidate based on the two-component VLP platform. We licensed the rights to develop and commercialize an influenza VLP vaccine from UW based on technology developed by UW and NIH, and in December 2022, we also entered into a patent license agreement with UW for use of modified neuraminidase antigens developed by UW and the NIH in the influenza field. We have initiated preclinical development on influenza HA and NA antigens with the goal to select a candidate in 2023. We see our emerging influenza program as part of our strategy to develop combination or pan-respiratory VLP vaccines targeting the viral causes of pneumonia in older adults.

SARS-CoV-2 Program

We are developing a preclinical bi-valent VLP vaccine candidate displaying computationally engineered RBD antigens for SARS-CoV-2, with the goal to select a candidate in 2023. Specifically, given the evolving pandemic, we are seeking to design antigen prototypes that would improve the stability of the RBD subdomain from the SARS2 S protein and allow for the successful presentation of any variant of interest, including omicron and subsequent derivatives. We are conducting this preclinical development work for optionality to include a SARS-CoV-2 candidate as a potential component of a future pan-respiratory combination vaccine candidate.

For our SARS-CoV-2 vaccine candidate, we have a license from the UW that is nonexclusive worldwide, with the exception of South Korea (which is not included in the licensed territory). This license will become exclusive in the United States, Canada, Mexico and Europe (including Switzerland and the United Kingdom) starting in 2025 with non-exclusivity maintained elsewhere. SK Biosciences (SK) has also licensed the technology for use in COVID-19 vaccines. SK has completed a Phase 3 clinical trial and obtained marketing approval in South Korea for a COVID-19 vaccine based on this technology.

Our Early-Stage Programs

We are exploring several other viral and bacterial pathogens to potentially incorporate into VLP vaccine candidates that may be added to our pipeline in vaccine areas where a VLP approach can lead to a differentiated product profile. We review technical feasibility, demonstrated market need and potential and clinical program design and timelines with our outside scientific and commercial advisors and board of directors before selecting new vaccine programs for development.

Competition

Overview

Our industry is highly competitive and subject to rapid and significant regulatory and technological change. The current vaccine market is concentrated among a few key global biopharmaceutical companies including GlaxoSmithKline, Merck, Sanofi, Pfizer, Moderna, and CSL Bering, which together account for the majority of vaccine sales globally. Other pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions are also active in the vaccine market given the continuing global need for both existing and new vaccines. The large markets for respiratory virus vaccines make them attractive targets for new vaccines and we face competition from numerous vaccine developers. While we believe that our technology, strategy, and our employee and consultant knowledge and experience can provide us with competitive advantages, many of our competitors have significantly greater financial, technical, clinical development, manufacturing, marketing, sales and supply resources or experience than we do.

The key competitive factors affecting the success of all of our vaccine candidates, if approved, are likely to be their efficacy, reactogenicity, safety, breadth, durability, convenience, and price, the number of other vaccines on the market in the specific target indications, the recommendation of vaccines by policy makers, the inclusion of vaccines on the national immunization schedules, and the availability of reimbursement from government and other third-party payors.

VLP-Based Vaccines

A number of pharmaceutical and biotechnology companies are developing VLP or protein-based nanoparticle vaccine candidates. Some of these candidates are enveloped vaccines that require budding from the host cell membrane which can result in inclusion of host cell protein components leading to manufacturing complexities, such as additional purification needs. This includes, but is not limited to, VBI Vaccines. Other technologies incorporate the antigen to naturally occurring viral VLP scaffolds which may be less flexible and suitable for presentation of complex antigens; this includes, but is not limited to, SpyBiotech. We are aware of other vaccine companies developing protein-based nanoparticle vaccines, such as ModeX, or those developing VLP technology that is closely related to ours, including UVax Bio. In addition, the field of VLP vaccines is increasingly competitive and we expect competition to intensify.

RSV and hMPV Vaccines for Older Adults

As of March 2023, there is no vaccine approved for prevention of disease due to RSV infections or for prevention of disease due to hMPV infections in any population, including older adults. We are aware of companies currently developing vaccines against RSV for use in older adults, including GlaxoSmithKline, Pfizer, Bavarian Nordic, Janssen, Moderna, with vaccines developed by Pfizer and GlaxoSmithKline expected to receive FDA marketing approval in 2023.

As far as we are aware, no company other than us has a VLP-based RSV vaccine in clinical trials. In addition, as far as we are aware, there are no companies with a vaccine in clinical development against hMPV for use in older adults, nor are there any companies with a vaccine in clinical development against the combination of RSV and hMPV for use in older adults; however, Moderna has an RSV and hMPV combination vaccine in preclinical development for pediatric use, and Sanofi has announced that it is exploring RSV monovalent and RSV and hMPV combination vaccines for older adults preclinically. We believe the induction of nAbs is key for both RSV and hMPV vaccine efficacy in older adults and that multivalent VLP display of the prefusion RSV and hMPV antigens on our VLP candidates has the potential to induce a stronger or more durable nAb response than other vaccine technologies.

Influenza Vaccines

We expect that, if approved, any influenza VLP candidate we develop will compete with currently approved vaccines against influenza. There are several vaccines approved for influenza, most of which are egg-based, including Fluzone, Fluad, and Fluarix manufactured by Sanofi, Seqirus, and GSK, respectively. There is one subunit protein-based vaccine marketed in the United States, Flublok, manufactured by Sanofi, and one mammalian cell-based vaccine marketed in the United States, Flucelvax, manufactured by Seqirus. Novavax also has an adjuvanted protein-based vaccine that has completed clinical studies as a monovalent and is in Phase 2 studies as a combination with Novavax's COVID-19 vaccine. There are currently no marketed VLP-based influenza vaccines. Three of the marketed influenza vaccines in the United States were recently recommended for older adult immunization by the ACIP: Fluzone High-Dose, Fluad, and Flublok. We anticipate that these vaccines will be our main competitors in the older adult market.

COVID-19 Vaccines

Moderna, Pfizer/BioNTech, AstraZeneca, Janssen, and Novavax, along with many other companies, are currently marketing COVID-19 vaccines. We are also aware of numerous COVID-19 vaccines in clinical development, including VLP approaches being developed by Bavarian Nordic, SpyBiotech and VBI Vaccines. As mentioned above, we see our SARS-CoV-2 candidate as providing optionality for inclusion in a pan-respiratory candidate.

Combination Vaccines

We expect increasing numbers of combination and pan-respiratory vaccine candidates. For example, Moderna is developing a COVID-19/influenza/RSV combination vaccine in Phase 1 and an RSV/hMPV combination vaccine preclinically, and Sanofi has a RSV/hMPV combination vaccine in preclinical development. We are unaware of any protein-based RSV/hMPV combination vaccines currently in clinical development in older adults other than IVX-A12.

Manufacturing

We do not own or operate, and currently have no plans to establish, any large-scale or current cGMP manufacturing facilities. To date, we have successfully worked in conjunction with our third-party manufacturers to complete development and cGMP manufacturing campaigns for key components, VLP drug substance, and formulated drug product for all of our vaccine candidates. We are working with our existing manufacturers to scale up our manufacturing capabilities to support our clinical plans.

To date, we do not own or manufacture adjuvants and for vaccine candidates that we move forward as adjuvanted vaccines, we must rely on non-proprietary commercially available adjuvants or access to proprietary adjuvants through license or supply agreements with adjuvant manufacturers.

We believe our outsourced manufacturing strategy allows us to maintain a more efficient infrastructure by eliminating the need to for us to invest in our own manufacturing facilities, equipment, or personnel. This enables us to focus our time, expertise, and resources on the development of our vaccine candidates.

Commercialization Plan

Our current development plans focus on development and regulatory submissions in the United States and Europe. We currently have no sales, marketing, or commercial product distribution capabilities and have no experience as a company commercializing products. We intend to build the necessary infrastructure and capabilities over time for the United States and Europe, and potentially other regions, following further advancement of our vaccine candidates. We may work in partnership with one or more pharmaceutical partners for certain vaccine candidates, for certain target populations, or for certain geographies where we believe that others' capabilities and resources may be ideally suited for development, commercialization, or distribution of our vaccine candidates.

Intellectual Property

We strive to protect the proprietary technology that we believe is important to our business, including seeking and maintaining rights in patents intended to cover our current and future vaccine candidates and compositions, their methods of use and processes for their manufacture and any other inventions that are commercially important to the development of our business. We seek to protect our proprietary position by, among other methods, filing or in-licensing U.S. and foreign patents and patent applications related to technology, inventions and improvements that are important to the development and implementation of our business. We also rely on our agreements with UW, NIH and UT for intellectual property rights that are important or necessary for the development of our vaccine candidates. We also rely, in some circumstances, on trade secrets and know-how to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

For each vaccine candidate we develop and plan to commercialize, as a normal course of business, we intend to pursue composition and preventative use patents. We also seek patent protection with respect to novel methods of manufacture, formulations, or antigen combinations. We have sought and plan to continue to seek patent protection, either alone or jointly with our collaborators.

Regardless of the coverage we seek in our patent applications, there is always a risk that an alteration to the product or process may allow a competitor to avoid infringement claims. In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued and courts can reinterpret patent scope after issuance. Moreover, many jurisdictions, including the United States, permit third parties to challenge issued patents in administrative proceedings, which may result in further narrowing or even cancellation of patent claims. Moreover, we cannot provide any assurance that any patents will be issued from our pending or any future applications or that any current or future issued patents will adequately protect our intellectual property.

In summary, as of February 15, 2023, our patent estate of company-owned and licensed rights included eight issued U.S. patents, 14 pending U.S. patent applications, five pending international (PCT) patent applications, as well as counterpart foreign patent applications. These include both claims directed to our VLP platform and our vaccine candidates. On a worldwide basis, our patent estate for our VLP platforms includes three U.S. patents, with pending continuation applications; more than 15 patents and patent applications jointly covering our RSV and hMPV products specifically; more than 10 patent applications covering other infectious disease targets; a non-exclusive license from UW to a Patent Cooperation Treaty (PCT) application covering coronavirus, that will become exclusive in the United States, Canada, Mexico and Europe (including Switzerland and United Kingdom) starting in 2025; a non-exclusive license from UW to patent applications directed to nanoparticle-based influenza vaccines; and an exclusive license, with the exception of nucleic acid-based vaccines for which the license is non-exclusive, from UW to a patent application directed to engineered influenza neuraminidase antigens.

More specifically, we have exclusively licensed our main VLP icosahedral platform (as well as several alternative platforms) from UW. Three issued U.S. patents that will expire in 2035 and 2036, absent any patent term adjustment or extension that may potentially be available, and one pending U.S. patent application include composition of matter claims directed to such platforms.

We also have a license from UW to a pending U.S. patent with an expected expiry of 2034 with claims directed to the computational methods used to develop these and other two-component, symmetrical nanoparticles / VLPs. A parent application has already issued as a U.S. patent with an adjusted expiration date in 2036; it claims several tetrahedral nanoparticle / VLP platforms as compositions of matter. These blocking patent rights are joined by an issued U.S. patent and its continuation application, and by two issued U.S. patents and their continuation application, having actual or expected expirations in 2038 and 2036, respectively, that cover various alternative icosahedral nanoparticles.

For our RSV product, composition-of-matter and method-of-use patent rights are provided by a patent family being prosecuted in the United States and Europe, as well as in Australia, Brazil, Canada, China, Hong Kong, Indonesia, Israel, India, Japan, South Korea, Mexico, Malaysia, Philippines, Russia, Singapore, Thailand, Vietnam and South Africa. The U.S. and Australia patents that have issued, and any further patents that issue from this patent family, are expected to expire in 2038, absent any patent term adjustment or extension that may potentially be available. UW's inter-institutional agreements (IIA) with the Institute for Research in Biomedicine in Bellinzona, Switzerland conferred to UW the right to license this patent family to us.

We have licensed certain patent rights from NIH directed to the antigenic portion of our RSV product for stabilization of the antigen in a prefusion conformation. These patent rights are assigned to the U.S. Department of Health and Human Services (HHS), based on inventions made at the Vaccine Research Center of the National Institute for Allergy and

Infectious Diseases (NIAID). Specifically, we have non-exclusively licensed three issued U.S. patents directed to the compositions of matter, which will expire in 2034, absent any patent term adjustment or extension that may potentially be available.

HHS and the Institute for Research in Biomedicine in Bellinzona, Switzerland jointly own two U.S. patents directed to conformationally stabilized hMPV antigens, which we have non-exclusively licensed, subject to an inter-institutional agreement between HHS and the Institute for Research in Biomedicine. These two licensed patents are expected to expire in 2035. A continuation application and corresponding European patent application are currently pending in this patent family. The same non-exclusive license further includes an international patent application from HHS, also directed to conformationally stabilized hMPV antigens. Any patents that issue from this patent family are expected to expire in 2041, absent any patent term adjustment or extension that may potentially be available.

The specific mutations found in our hMPV product are also protected by patent rights based on inventions made at the University of Texas. We have exclusively (for all vaccine fields other than mRNA) licensed one pending PCT patent application directed to composition of matter, national stage entries of which, if issued, will expire in 2041, absent any patent term adjustment or extension that may potentially be available.

We also have a non-exclusive license from UW to a patent family with claims directed to our coronavirus vaccine candidate, which includes a pending PCT application. This non-exclusive license that will become exclusive in the United States, Canada, Mexico and Europe (including Switzerland and United Kingdom) starting in 2025. We have also filed a company-owned PCT application with pharmaceutical composition and method of treatment claims related to a COVID-19 vaccine candidate. Any patents that issue from this PCT application are expected to expire in 2042, absent any patent term adjustment or extension that may potentially be available.

We have a non-exclusive license from UW and HHS to patents directed to nanoparticle-based influenza virus vaccines. Specifically, we have non-exclusively licensed a patent family being prosecuted in the United States and Europe, as well as in Australia, China, Hong Kong, and South Korea, which is directed to the compositions of matter and methods of use, and which will expire in 2040, absent any patent term adjustment or extension that may potentially be available.

We have an exclusive license from UW and HHS under certain patent applications directed to engineered influenza neuraminidase (NA) antigens for the prophylactic and/or therapeutic treatment of influenza that includes a neuraminidase antigen, except that such license is non-exclusive with respect to nucleic acid based delivery mechanisms for delivery of neuraminidase antigens. Specifically, we have exclusively licensed a patent family being prosecuted in the United States and Europe, as well as Australia, Canada, China, Japan, Singapore and South Korea, which is directed to the compositions of matter and methods of use. Any patents that issue in this patent family are expected to expire in 2041, absent any patent term adjustment or extension that may potentially be available.

Further patent protected related to other indications is provided by a family of more than 10 patent applications filed in the United States and foreign jurisdictions, which is also exclusively licensed in relevant fields from UW. Any patents that ultimately issue from this patent family are expected to expire in 2039, absent any patent term adjustment or extension that may potentially be available. Foreign jurisdictions where patent applications are pending include Australia, Canada, China, Colombia, Europe including the United Kingdom, Indonesia, India, South Korea, Russia, Vietnam and South Africa.

We continue to prepare and file provisional patent applications directed to vaccine composition improvements, manufacturing methods, and formulations, as appropriate.

For more information regarding our license agreements with UW, UT, and the U.S. Department of Health and Human Services, please see “—Material Agreements.”

Generally, we submit patent applications directly with the USPTO as provisional patent applications. Provisional applications for patents were designed to provide a lower-cost first patent filing in the United States. Corresponding non-provisional patent applications must be filed not later than twelve months after the provisional application filing date. The corresponding non-provisional application benefits in that the priority date(s) of the patent application is/are the earlier provisional application filing date(s), and the patent term of the finally issued patent is calculated from the later non-provisional application filing date. This system allows us to obtain an early priority date, add material to the patent application(s) during the priority year, obtain a later start to the patent term and to delay prosecution costs, which may be useful in the event that we decide not to pursue examination in an application. While we intend to timely file non-

provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage.

We file U.S. non-provisional applications and PCT applications that claim the benefit of the priority date of earlier filed provisional applications, when applicable. The PCT system allows a single application to be filed within 12 months of the original priority date of the patent application and to designate all of the 153 PCT member states in which national patent applications can later be pursued based on the international patent application filed under the PCT. The PCT searching authority performs a patentability search and issues a non-binding patentability opinion which can be used to evaluate the chances of success for the national applications in foreign countries prior to having to incur the filing fees. Although a PCT application does not issue as a patent, it allows the applicant to seek protection in any of the member states through national-phase applications.

At the end of the period of two and a half years from the first priority date of the patent application, separate patent applications can be pursued in any of the PCT member states either by direct national filing or, in some cases by filing through a regional patent organization, such as the European Patent Organization. The PCT system delays expenses, allows a limited evaluation of the chances of success for national/regional patent applications and enables substantial savings where applications are abandoned within the first two and a half years of filing.

For all patent applications, we determine claiming strategy on a case-by-case basis. Advice of counsel and our business model and needs are always considered. We file patents containing claims for protection of all useful applications of our proprietary technologies and any products, as well as all new applications and/or uses we discover for existing technologies and products, assuming these are strategically valuable. We continuously reassess the number and type of patent applications, as well as the pending patent claims to ensure that maximum coverage and value are obtained for our processes and compositions, given existing patent office rules and regulations. Further, claims may be modified during patent prosecution to meet our intellectual property and business needs.

We recognize that the ability to obtain patent protection and the degree of such protection depends on a number of factors, including the extent of the prior art, the novelty and non-obviousness of the invention and the ability to satisfy the enablement requirement of the patent laws. The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted or further altered even after patent issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our future vaccine candidates or for our platform technology. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

In addition to patents, we have trademark registrations in the U.S., European Union and United Kingdom for ICOSAVAX and our company logo. We also have pending trademark applications for ICOSAVAX and our company logo in the U.S. Furthermore, we rely upon trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our commercial partners, collaborators, employees and consultants and invention assignment agreements with our employees. We also have confidentiality agreements or invention assignment agreements with our commercial partners and selected consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Our commercial success will also depend in part on not infringing the proprietary rights of third parties. In addition, we have licensed, or expect to be able to license on commercially reasonable terms, rights under proprietary technologies of third parties to develop, manufacture and commercialize specific aspects of our future products and services. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, alter our processes, obtain licenses or cease certain activities. The expiration of patents or patent applications licensed from third parties or our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our future technology may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the USPTO to determine priority of invention.

For a more comprehensive discussion of the risks related to our intellectual property, please see “Risk Factors—Risks Related to Our Intellectual Property".

Material Agreements

Agreements with University of Washington

License Agreement with respect to RSV and Other Pathogens

In June 2018, we entered into a license agreement with UW as amended in July 2019, November 2020, and June 2022 (UW License Agreement). Pursuant to the UW License Agreement, UW granted to us an exclusive, worldwide, royalty-bearing, sublicensable license under certain UW patents to make, use, sell, offer to sell, import, and otherwise exploit any product covered by the licensed patents, or licensed products, for the prophylactic and/or therapeutic treatment of RSV infection and eight other infectious diseases. UW also granted us a non-exclusive license to use certain know-how related to the licensed patents. The licensed patents and know-how generally relate to computationally designed nanoparticles and vaccines based upon such designs, and relate to our proprietary two-component virus-like-particle technology as well as certain one-component virus-like-particle technology. As of March 2023, the UW License Agreement is applicable to our IVX-121, IVX-241, and IVX-A12 programs.

The rights granted to us by UW are subject to certain rights of UW, the United States federal government, and the Howard Hughes Medical Institute (HHMI). UW retained rights under the licensed patents for research and educational purposes and for UW to comply with its obligations under applicable laws for federally funded inventions. The federal government has (i) a worldwide, nonexclusive, nontransferable, irrevocable, paid-up license to the licensed patents, (ii) march-in rights exercisable if public health crises so demand, and (iii) to the extent required by Title 35, Section 204 of the United States Code, a requirement that for any products licensed for use in the United States, that these products be substantially manufactured in the United States, because the inventions covered by the licensed patents arose in whole or in part from federal funding. HHMI has a paid-up, non-exclusive, sublicensable, irrevocable license for research use owing to the involvement of HHMI employees in developing the inventions of the licensed patents. HHMI’s right to sublicense is limited to non-profit and governmental entities.

Owing to grant funding provided to UW by BMGF in connection with the licensed patents and know-how, UW granted a humanitarian license and made certain global access commitments with respect to the funded developments for six of the nine pathogens (excluding RSV and two others) for humanitarian purposes if UW has utilized grant funding to support its efforts with regards to any of these six pathogens. UW may require us to grant sublicenses to third parties to make such licensed developments available at an affordable price in developing countries, or if we do not offer such sublicenses on reasonable terms, UW may grant such licenses directly to third parties to enable affordable access in developing countries. Currently, our hMPV vaccine program is the only active program subject to this UW humanitarian license to BMGF.

We are obligated to use commercially reasonable efforts to diligently develop, manufacture, and commercialize vaccines incorporating the licensed products, and to achieve specified development and regulatory milestone events, including, with respect to IVX-121, initiating clinical trials of specified phases by certain dates between 2022 and 2026 and making first commercial sale by a specified date thereafter, and with respect to IVX-241 and IVX-A12, conducting activities necessary to enable clinical trials and initiating clinical trials of specified phases, in each case, by certain specified dates between 2022 and 2028, and making first commercial sale by a specified date thereafter. If we are unable to meet our diligence obligations and cannot agree with UW to modify such obligations or do not cure by meeting such obligations, then UW may terminate the UW License Agreement in whole, or in part, on a pathogen-by-pathogen basis.

In connection with the execution of the UW License Agreement, we issued 192,276 shares of our common stock to UW in August 2018. We are required to pay an annual license maintenance fee in the mid four figures. We are required to pay UW development and regulatory milestone payments up to an aggregate amount of three hundred and fifty thousand dollars for each of the nine licensed vaccine candidates. We are also required to pay UW commercial milestone payments of one million dollars for each of the nine licensed vaccine candidates upon reaching a certain net sales threshold. We are also required to pay UW a fixed low single digit percentage royalty on net sales of licensed products, subject to certain reductions if we are required to pay for third-party intellectual property rights in order to commercialize the licensed products, and we are not required to pay duplicate royalties for combination products incorporating technology covered by multiple UW license agreements. After first commercial sale of a licensed product, we must meet a certain minimum royalty requirement in the low to mid five figures range on an annual basis. If we sublicense our rights under the UW License Agreement, we are obligated to pay UW a mid-single digit to mid-double digit percentage of all sublicensing revenue received, depending on when we grant such sublicenses in relation to the development stage of the most

advanced licensed product, and adjusted for any development expenses and development or regulatory milestone payments already made.

The UW License Agreement will remain in effect until all licensed patent rights have terminated and all obligations due to UW have been fulfilled. The last-to-expire licensed patents, if issued, is expected to expire in 2041, subject to any adjustment or extension of patent term that may be available. UW can terminate the UW License Agreement if we breach or fail to perform one of our material duties under the UW License Agreement and our unable to remedy the default within an agreed upon time period that can be extended by UW. We can terminate the UW License Agreement at will with prior written notice to UW. We can also terminate certain of our licensed rights through an amendment to the UW License Agreement.

Option and License Agreement with Respect to COVID-19

In July 2020, we entered into an option and license agreement with UW, as amended in August 2020, May 2021, and July 2022 (UW Option and License Agreement). Pursuant to the UW Option and License Agreement, UW granted to us a non-exclusive, worldwide (excluding South Korea), sublicensable license under certain UW patents to make, use, sell, offer to sell, import, or otherwise exploit any product covered under the licensed patents for the prophylactic and/or therapeutic treatments of SARS-CoV-2 infection. UW also granted us a non-exclusive, worldwide license to use certain know-how related to the licensed patents. The licensed patents and know-how generally relate to computationally designed nanoparticles and vaccines based upon such designs, and used in our proprietary two-component virus-like-particle technology. As of March 2023, the UW Option and License Agreement is applicable to our SARS-CoV-2 program.

The license included, and we have since exercised, an option to obtain an exclusive license under the UW Option and License Agreement for the United States, Canada, Mexico, and the countries of the European Patent Organization (including Switzerland and the United Kingdom) starting in 2025. There was no option exercise fee. However, the option right is subject to certain rights of the United States federal government, UW, BMGF, and HHMI, as described above in connection with the UW License Agreement.

We are required to pay UW a low single digit percentage royalty on net sales of licensed products, subject to certain reductions if we are required to pay for third party intellectual property rights in order to commercialize the licensed products. However, we are not required to pay duplicate royalties on net sales of any licensed products under the UW Option and License Agreement if we are already required to pay royalties on such net sales under the UW License Agreement.

Our diligence obligations under the UW Option and License Agreement and the parties' rights to terminate the UW Option and License Agreement are substantially the same as the analogous obligations and rights under the UW License Agreement. We incorporate the descriptions above regarding termination rights by reference. The last-to-expire relevant patents under the UW Option and License Agreement, if issued, are expected to expire in 2041, subject to any adjustment or extension of patent term that may be available.

License Agreement with Respect to Influenza

In September 2021, we entered into a license agreement with UW (UW Flu License Agreement). Pursuant to the UW Flu License Agreement, UW granted us a non-exclusive, worldwide, royalty-bearing, sublicensable (subject to certain restrictions) license under certain UW patents to make, use, sell, offer to sell, import, and otherwise exploit any product covered by the licensed patents (Licensed Flu Products), for the prophylactic and/or therapeutic treatment of influenza. UW also granted us a non-exclusive, worldwide license to use certain know-how related to the licensed patents. The licensed patents and know-how generally relate to computationally designed nanoparticles and vaccines based upon such designs, and relate to our proprietary two-component virus-like-particle technology and nanoparticle-based influenza virus vaccines. As of March 2023, the UW Flu License Agreement is applicable to our preclinical influenza program.

The United States federal government and HHMI have similar rights under the UW Flu License Agreement and the UW License Agreement described above in "License Agreement with respect to RSV and Other Pathogens".

We are obligated to use commercially reasonable efforts to commercialize Licensed Flu Products, and to initiate a clinical trial with respect to such Licensed Flu Products by a specified date in 2025. If we are unable to initiate a clinical trial by the specified date and cannot agree with UW to modify such obligation or do not cure by meeting such obligation, then UW may terminate the UW Flu License Agreement.

Under the UW Flu License Agreement, we paid UW a one-time upfront license fee, and after September 2023 and for the remainder of the term of the UW Flu License Agreement, we are required to pay tiered minimum annual fees ranging from the mid four figures to the mid five figures, with such fees creditable against royalty payments. We are required to pay UW up to an aggregate of $350 thousand for payments related to development milestones and up to an aggregate of $6 million for payments related to commercial milestones based upon reaching certain cumulative net sales thresholds for all Licensed Flu Products. We are also required to pay UW a fixed low single digit percentage royalty on net sales of Licensed Flu Products by us and our sublicensees, subject to certain reductions if we are required to pay for third-party intellectual property rights in order to commercialize the Licensed Flu Products. We are not obligated to pay duplicate royalties on net sales of any Licensed Flu Products if we are already required to pay a royalty on such net sales under the UW License Agreement or the UW Option and License Agreement.

The UW Flu License Agreement will remain in effect until all licensed patent rights have terminated and all obligations due to UW have been fulfilled. The last-to-expire licensed patent, if issued, is expected to expire in 2041, subject to any adjustment or extension of patent term that may be available. UW can terminate the UW Flu License Agreement if we breach or fail to perform one of our material duties under the UW Flu License Agreement and are unable to remedy the default within an agreed upon time period that can be extended by UW. We can terminate the UW Flu License Agreement at will with prior written notice to UW. We can also terminate certain of our licensed rights through an amendment to the UW Flu License Agreement.

NIH Patent License Agreement

On June 28, 2018, we and the NIAID of the NIH entered into a non-exclusive license agreement for certain intellectual property rights and biological materials, as amended on September 10, 2018 and September 9, 2020 (NIH Agreement). Pursuant to the NIH Agreement, NIAID granted us a worldwide, nonexclusive, sublicensable license to certain patent rights, data, information, and materials directed to immunogens and antibodies and components and processes thereof relating to RSV and hMPV to allow us to make, use, sell, offer to sell, and import adjuvanted or non-adjuvanted vaccines that combine technology covered by the licensed patent rights with our proprietary protein-based nanoparticle technology, for the prevention, cure, amelioration or treatment of RSV and hMPV infections in humans, for administration alone or in combination with one or more other vaccines, and specifically excluding nucleic acid-based vaccines. NIAID also transferred to us certain biological materials relating to the foregoing for our development purposes. As of March 2023, the NIH Agreement is applicable to our IVX-121, IVX-241, and IVX-A12 programs.

Pursuant to the NIH agreement, we are required to use commercially reasonable efforts to develop the licensed products using the licensed processes to make the licensed products available to the United States public on reasonable terms, including by adhering to a commercial development plan and meeting specified benchmarks with regards to specified deadlines for regulatory filings, initiation of clinical trials, and gaining regulatory approval for the licensed products, in each case by certain specified dates between 2022 and 2032. To the extent required by Title 35, Section 204 of the United States Code, we agreed to manufacture substantially in the United States all licensed products that are to be used or sold in the United States, to make reasonable quantities of the licensed product, if commercialized, available to patient assistance programs in the United States, to develop educational materials relating to the licensed product, and to supply reasonable quantities of the licensed products made by the licensed processes to NIAID for research, education and display purposes.

In consideration of the rights granted under the NIH Agreement, we paid NIAID a one-time upfront payment in the low six figures and amendment issue fees in the high five figures. We are required to make tiered, low single-digit percentage royalty payments on specified portions of annual net sales of licensed products outside of least developed countries, subject to certain specified reductions if we are required to pay royalties to third parties in order to commercialize the license products. We are required to make aggregate development and regulatory milestone payments of up to $1.15 million for the approval of the first indication for a licensed product, up to $650,000 for the approval of the second indication for a licensed product, up to $375,000 for the approval of the third indication for a licensed product, and $50,000 for each subsequent indication. We are further required to make sales milestone payments upon achieving certain aggregate net sales thresholds for all licensed products of up to $6.5 million in aggregate. We are also required to pay NIAID a mid-single to low double-digit percentage of any sublicensing revenue we receive, depending on when we grant such sublicense in relation to the development stage of the licensed product and the number of indications that we sublicense. Additionally, our payment obligations to NIAID are subject to annual minimums ranging from low-mid five figures to low six figures depending on the year and commercialization stage.

The NIH Agreement will expire upon the expiration of the last-to-expire licensed patent. NIAID may terminate the agreement for our uncured material breach, our insolvency or bankruptcy. Further, NIAID has the right to terminate or modify the NIH Agreement if (i) we do not execute the commercial development plan, (ii) we do not take effective steps to

develop the licensed products to make them available for the public on reasonable terms, (iii) we do not achieve specified benchmarks, (iv) we do not keep at least one licensed product or process available to the public after commercial use commences, (v) to the extent required to do so under Title 35, Section 204 of the United States Code, (vi) we do not receive a U.S. manufacturing waiver from NIAID, NIH and do not justify a failure to manufacture the licensed products substantially in the United States, if intending to use in the United States (vii) we do not reasonably satisfy the public use requirements specified under federal regulations, or (viii) we willfully make a false statement to or omit a material fact from NIAID in connection with the license application and progress reports. We have the unilateral right to terminate the NIH Agreement in its entirety or in any country with prior written notice to NIAID.

Patent License Agreement with the University of Texas at Austin

In June 2021, we entered into a patent license agreement (the UT License Agreement) with UT. Pursuant to the UT License Agreement, we received an exclusive, worldwide, sublicensable license, under certain UT patent rights and know-how relating to human metapneumovirus (hMPV) antigen to manufacture, develop, use, sell, import, and otherwise exploit all vaccines covered by such patents or incorporating such know-how, except for mRNA-based vaccines. Our rights and obligations under the UT License Agreement, are subject to certain U.S. government rights and UT's retained rights under the licensed patent rights for academic or non-commercial publication, manufacture, and use, including sublicensable rights to academic and non-profit institutions. As of March 2023, the UT License Agreement is applicable to our IVX-241 and IVX-A12 programs.

Under the UT License Agreement, we are required to use commercially reasonable efforts to meet certain specified development, sales and regulatory milestones related to the licensed products, including maintaining a reasonably funded active research, development, manufacturing, regulatory, marketing or sales program, as applicable and necessary to commercialize the licensed products, and in each case by certain specified dates between 2021 and 2030. In consideration for the rights granted to us under the UT License Agreement, we are required to pay UT an annual license fee, escalating from low to mid five figures dollars, until the first sale of a licensed product. There are milestone payments due upon the completion of certain development, regulatory, and commercial milestones for a licensed product in the future, with potential payments for such future development, regulatory, and sales-based milestones in the aggregate in the mid-single figure million dollars. Additionally, we have agreed to pay UT low single-digit percentage royalties on net sales of all licensed products, with a reduced royalty rate if the licensed product expresses more than one unique antigen or if we are required to pay royalties to a third party for rights to such third party's intellectual property in order to commercialize the licensed product. Our royalty payment obligations are subject to specified minimums in the mid-five to low-six figure dollars that are creditable to royalties owed. If we sublicense our rights under the UT License Agreement, we are obligated to pay UT a mid-single digit to low-mid-double digit percentage of all non-royalty sublicensing revenue received, depending on when we grant such sublicenses in relation to the development stage of the licensed product. We are also required to pay UT low six figure dollars if we assign the UT License Agreement to a third party.

The UT License Agreement will continue until the expiration of the last-to-expire licensed patent. We have the right to terminate the UT License Agreement by providing UT with prior written notice. UT may terminate the UT License Agreement in its entirety, or partially terminate the licensed patent rights, narrow the vaccine field, reduce the territory, or convert the license from exclusive to non-exclusive if we: (i) fail to meet our payment obligations, (ii) commit an uncured breach, (iii) commit three or more cured breaches within a specified time period, (iv) challenge the validity, enforceability, or scope of the licensed patent rights, or (v) undergo certain insolvency-related events.

Government Regulation and Product Approval

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our vaccine candidates. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Biologics Regulation

In the United States, biological products, or biologics, such as vaccines are subject to regulation under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and other federal, state, local and foreign statutes and

regulations. The process required by the FDA before biologics may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's GLPs and other applicable regulations;
- submission to the FDA of an IND, which must become effective before clinical trials may begin;
- approval by an institutional review board (IRB) or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic vaccine candidate for its intended use;
- preparation of and submission to the FDA of a biologics license application (BLA), after completion of all pivotal clinical trials and other necessary studies;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP, and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with Good Clinical Practices (GCPs); and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

Prior to beginning the first clinical trial with a product candidate in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical trials. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the protocol for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical trials and clinical study results to public registries, including clinicaltrials.gov.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

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

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may also be made a condition to approval of the BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must 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 product. 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.

BLA Submission and Review by the FDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by independent investigators. The submission of a BLA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the FDA accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. Once a BLA has been accepted for filing, the FDA's goal is to review standard applications within ten months after the filing date, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process may also be extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may also convene an advisory committee to provide clinical insight on application review questions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

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

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter (CRL). An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable

regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy (REMS) to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy implemented to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. For example, the fast track program is intended to expedite or facilitate the process for reviewing product candidates that are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a fast track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the application may be eligible for priority review. A BLA for a fast track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Any marketing application for a drug or biologic submitted to the FDA for approval, including a product candidate with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A BLA is eligible for priority review if the product candidate is designed to treat a serious or life-threatening disease or condition, and if approved, would provide a significant improvement in safety or effectiveness compared to available alternatives for such disease or condition. For original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to ten months under standard review).

Additionally, product candidates studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product candidate has 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, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled confirmatory clinical trials to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required confirmatory studies in a timely manner or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

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

U.S. Post-Approval Requirements

Biologics are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products. 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 up. 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. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

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

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- 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.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Biosimilars and Reference Product Exclusivity

The Affordable Care Act, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act (BPCIA) which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a

clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the licensure of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Other U.S. Regulatory Requirements

In addition to FDA regulation of pharmaceutical products, pharmaceutical companies are also subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business and may constrain the financial arrangements and relationships through which we research, as well as sell, market and distribute any products for which we obtain marketing authorization. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, data privacy and security, and transparency laws and regulations related to drug pricing and payments and other transfers of value made to physicians and other healthcare providers. If their operations are found to be in violation of any of such laws or any other governmental regulations that apply, they may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, integrity oversight and reporting obligations, exclusion from participation in federal and state healthcare programs and imprisonment.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any vaccine candidate for which we may seek regulatory approval. Sales in the United States will depend, in part, on the availability of sufficient coverage and adequate reimbursement from third-party payors, which include government health programs such as Medicare, Medicaid, TRICARE and the Veterans Administration, as well as managed care organizations and private health insurers. Prices at which we or our customers seek reimbursement for our vaccine candidates can be subject to challenge, reduction or denial by third-party payors.

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

The process for determining whether a third-party payor will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payor will pay for the product. In the United States, there is no uniform policy among payors for coverage or reimbursement. Decisions regarding whether to cover any of a product, the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that can require manufacturers to provide scientific and clinical support for the use of a product to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. Third-party payors may not consider our vaccine candidates to be medically necessary or cost-effective compared to other available therapies. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product that receives approval.

In some foreign countries, the proposed pricing for a vaccine candidate must be approved before it may be lawfully marketed. The requirements governing product pricing vary widely from country to country. For example, in the European Union (EU) pricing and reimbursement of pharmaceutical products are regulated at a national level under the individual EU member states' social security systems. Some foreign countries provide options to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and can control the prices and reimbursement levels of medicinal products for human use. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available vaccines. A country may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for products will allow favorable reimbursement and pricing arrangements for any of our vaccine candidates. Even if approved for reimbursement, historically, vaccine candidates launched in some foreign countries, such as some countries in the EU, do not follow price structures of the United States and prices generally tend to be significantly lower.

Healthcare Reform

In the United States, there have been, and continue to be, legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the profitable sale of product candidates, and similar healthcare laws and regulations exist in the EU and other jurisdictions. Among policy makers and payors in the United States, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

By way of example, in March 2010, the Patient Protection and Affordable Care Act (the ACA) was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical industry. The ACA, among other things, increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1% of the average manufacturer price; required collection of rebates for drugs paid by Medicaid managed care organizations; required manufacturers to participate in a coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs; implemented a new methodology by which the average manufacturer price under the Medicaid Drug Rebate Program is calculated for drugs that are inhaled, infused, instilled, implanted, or injected; expanded eligibility criteria for Medicaid programs; creates a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare and Medicaid Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, executive and political challenges to certain aspects of the ACA, and on June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden had issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, with the exception of a temporary

suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, beginning January 1, 2024.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. On August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023), and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated.

Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure and other transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs and suppliers will be included in their healthcare programs Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare product candidates and services, which could result in reduced demand for our product candidates once approved or additional pricing pressures.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our vaccine candidates. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

Whether or not we obtain FDA approval for a vaccine candidate, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the vaccine candidates in those countries. The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Failure to comply with applicable foreign regulatory requirements, may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Preclinical Studies and Clinical Trials

Similar to the United States, the various phases of preclinical and clinical research in the EU are subject to significant regulatory controls.

Preclinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Preclinical studies must be conducted in compliance with the principles of good laboratory practice (GLP) as set forth in EU Directive 2004/10/EC. In particular, preclinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for preclinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Conference on Harmonization (ICH), guidelines on good clinical practices (GCP) as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative.

The sponsor must take out a clinical trial insurance policy, and in most EU countries, the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

Certain countries and jurisdictions outside of the United States, including the EU, have a similar process that requires the submission of a clinical study application much like the IND prior to the commencement of human clinical trials. A CTA must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and the IRB, respectively. Once the CTA is approved by the national health authority and the ethics committee has granted a positive opinion in relation to the conduct of the trial in the relevant member state(s), in accordance with a country's requirements, clinical study development may proceed.

The CTA must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. Currently, CTAs must be submitted to the competent authority in each EU member state in which the trial will be conducted. Under the new Regulation on Clinical Trials, which became applicable in January 2022, there is a centralized application procedure where one national authority takes the lead in reviewing the application and the other national authorities have only limited involvement. Any substantial changes to the trial protocol or other information submitted with the CTA must be notified to or approved by the relevant competent authorities and ethics committees. Medicines used in clinical trials must be manufactured in accordance with good manufacturing practice (GMP). Other national and EU-wide regulatory requirements may also apply.

Marketing Authorizations

In the EU, medicinal products can only be placed on the market after obtaining a marketing authorization (MA). To obtain regulatory approval of an investigational biological product under EU regulatory systems, we must submit a marketing authorization application (MAA). The application used to file the BLA in the United States is similar to that required in the EU, with the exception of, among other things, country specific document requirements. The process for doing this depends, among other things, on the nature of the medicinal product.

The centralized procedure results in a single MA, issued by the European Commission, based on the opinion of the European Medicines Agency's (EMA) Committee for Human Medicinal Products (CHMP) which is valid across the entire territory of the EU. The centralized procedure is compulsory for human medicines that are: (i) derived from biotechnology processes, such as genetic engineering, (ii) contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases, autoimmune and other immune dysfunctions and viral diseases, (iii) designated orphan medicines and (iv) ATMPs, such as gene therapy, somatic cell therapy or tissue-engineered medicines. The centralized procedure may at the request of the applicant also be used in certain other cases.

National MAs, which are issued by the competent authorities of the EU member states and only cover their respective territory, are available for products not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in an EU member state, this national MA can be recognized in another member state through the mutual recognition procedure. If the product has not received a national MA in any member state at the time of application, it can be approved simultaneously in various member states through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the national competent authority of each of the member states in which the MA is sought, one of which is selected by the applicant as the Reference member state.

Under the centralized procedure, the maximum timeframe for the evaluation of a MAA by the EMA is 210 days. In exceptional cases, the CHMP might perform an accelerated review of a MAA in no more than 150 days (not including clock stops). Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the PRIME scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. Product developers that benefit from PRIME designation can expect to be eligible for accelerated assessment but this is not guaranteed. The benefits of a PRIME designation include the appointment of a CHMP rapporteur before submission of a MAA, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review earlier in the application process. Innovative medicines fulfilling a medical need may also benefit from different types of fast track approvals, such as a conditional MA or a MA under exceptional circumstances granted on the basis of less

comprehensive clinical data than normally required (respectively in the likelihood that the sponsor will provide such data within an agreed timeframe or when comprehensive data cannot be obtained even after authorization).

Classical MAs have an initial duration of five years. After these five years, the authorization may be renewed for an unlimited period on the basis of a reevaluation of the risk-benefit balance.

Data and Marketing Exclusivity

The EU also provides opportunities for market exclusivity. For example, in the EU, upon receiving MA, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic or biosimilar application. During the additional two year period of market exclusivity, a generic/biosimilar MA can be submitted, and the innovator's data may be referenced, but no generic/biosimilar product can be marketed until the expiration of the market exclusivity. The overall ten-year market exclusivity period may be extended to a maximum of eleven years if, during the first eight years a new therapeutic indication with significant clinical benefit over existing therapies is approved. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity.

There is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product, for example, because of differences in raw materials or manufacturing processes. For such products, the results of appropriate preclinical or clinical trials must be provided, and guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product. There are no such guidelines for complex biological products, such as gene or cell therapy medicinal products, and so it is unlikely that biosimilars of those products will currently be approved in the EU. However, guidance from the EMA states that they will be considered in the future in light of the scientific knowledge and regulatory experience gained at the time.

Foreign Post-Approval Requirements

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the member states. The holder of a MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports (PSURs).

All new MAA must include a risk management plan (RMP) describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

The advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another.

The aforementioned EU rules are generally applicable in the European Economic Area (EEA) which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

Failure to comply with EU and member state laws that apply to the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of the MA, manufacturing of pharmaceutical products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

Privacy and Data Protection Laws

Numerous state, federal and foreign laws, regulations and standards govern the collection, use, transfer, processing, access to, confidentiality and security of health-related and other personal information, and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other or other regulatory requirements complicating compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Human Capital

As of December 31, 2022, we had 60 full-time employees and no part-time employees. Of these employees, 15 hold Ph.D. or M.D. degrees and 44 are engaged in research and development. Forty of our employees are located in Seattle, Washington and the remainder are located in the United States and work remotely. Our employees are not represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, and incentivizing our management team and our clinical, scientific and other employees and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and motivate personnel through the granting of stock-based and cash-based compensation awards, in order to align our interests and the interests of our stockholders with those of our employees and consultants.

Corporate Information

We were originally founded as a Delaware corporation on November 1, 2017. Our corporate headquarters are located at 1930 Boren Ave, Suite 1000, Seattle, Washington 98101, and our telephone number is (206) 737-0085.

Available Information

Our internet address is www.icosavax.com. Our investor relations website is https://investors.icosavax.com/. We make available free of charge on our investor relations website under “SEC Filings” our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, our directors’ and officers’ Section 16 reports and any amendments to those reports as soon as reasonably practicable after filing or furnishing such materials to the U.S. Securities and Exchange Commission (SEC). They are also available for free on the SEC’s website at www.sec.gov.

We use our investor relations website as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD. Investors should monitor such website, in addition to following our press releases, SEC filings and public conference calls and webcasts. Information relating to our corporate governance is also included on our investor relations website The information in or accessible through the SEC and our website are not incorporated into, and are not considered part of, this filing.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information included in this Annual Report, including our financial statements and related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before making an investment decision to purchase or sell shares of our common stock. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that event, the trading price of our common stock could decline, and you could lose part or all of your investment. The risks described below are not the only ones that we may face, and additional risks or uncertainties not known to us or that we currently deem immaterial may also impair our business and future prospects.

Summary of Risks Related to Our Business

The principal risks and uncertainties affecting our business include the following:

- We have a limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.
- We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our development programs, commercialization efforts or other operations.
- We are early in our development efforts. Two of our vaccine candidates are in the clinical stage and the rest are in the preclinical stage. If we are unable to successfully develop, obtain regulatory approval or ultimately commercialize vaccine candidates, or experience significant delays in doing so, our business will be materially harmed.
- Our approach to the discovery and development of vaccine candidates is unproven, including our plan to pursue combination vaccine candidates using our VLP technology, and we do not know whether we will be able to develop any products of commercial value, or if competing approaches will limit the commercial value of our vaccine candidates.
- Our business is highly dependent on the success of IVX-A12, which is in the early stages of development. If we are unable to obtain approval for IVX-A12 or effectively commercialize IVX-A12, our business would be significantly harmed.
- Preclinical and clinical development involves a lengthy and expensive process with an uncertain outcome, and the results of preclinical studies and early clinical trials are not necessarily predictive of future results. We may not have favorable results in preclinical studies or clinical trials, or receive regulatory approval on a timely basis, if at all.
- Any difficulties or delays in the commencement or completion, or the termination or suspension, of our planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue or adversely affect our commercial prospects.
- We rely on third parties to conduct many of our preclinical studies and all of our clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, our development programs and our ability to seek or obtain regulatory approval for or commercialize our vaccine candidates may be delayed.
- We rely on third parties for the manufacture of our vaccine candidates for preclinical and clinical development and expect to continue to do so for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of our vaccine candidates or products or such quantities at an acceptable cost, or on acceptable timing, which could delay, prevent or impair our development or commercialization efforts.
- We face significant competition, and if our competitors develop technologies or vaccine candidates more rapidly than we do or their technologies are more effective, our business and our ability to develop and successfully commercialize products may be adversely affected.
- Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.
- If we are unable to obtain and maintain patent protection for our vaccine candidates and our VLP platform, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our vaccine candidates may be adversely affected.
- We rely heavily on certain license agreements with the UW and also depend on intellectual property licensed from other third parties, and these licensors may not always act in our best interest. If we fail to

comply with our obligations under our intellectual property licenses, if the licenses are terminated, or if disputes regarding these licenses arise, we could lose significant rights that are important to our business.

Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

We have a limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We commenced operations in 2017, and, to date, we have focused primarily on organizing and staffing our company, business planning, raising capital, in-licensing intellectual property rights, developing our VLP platform technology, identifying vaccine candidates, establishing our intellectual property portfolio, developing our manufacturing process, manufacturing our vaccine candidates to support preclinical studies and clinical trials, and preparing for and conducting our preclinical studies and clinical trials. Our approach to the discovery and development of vaccine candidates based on our VLP platform technology is unproven, and we do not know if any of our vaccine candidates will succeed in clinical development or become products of commercial value.

Two of our vaccine candidates are in the clinical stage and the rest are in the preclinical stage. We have not yet completed any late stage clinical trials, obtained regulatory approvals, manufactured a commercial-scale product or arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they would be if we had a history of successfully developing and commercializing vaccines.

We have incurred significant operating losses since our inception. We do not have any products approved for sale and have not generated any revenue since our inception. If our vaccine candidates are not successfully developed and approved, we may never generate any significant revenue. Our net losses were $91.8 million for the year ended December 31, 2022 and $67.0 million for the year ended December 31, 2021. As of December 31, 2022, we had an accumulated deficit of $185.8 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. All of our vaccine candidates will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as we continue our development of, seek regulatory approval for and potentially commercialize any of our vaccine candidates and seek to identify, assess, acquire, in-license or develop additional vaccine candidates.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our vaccine candidates, obtaining regulatory approval for these vaccine candidates, and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. In addition, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry. 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. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable may have an adverse effect on the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our vaccine candidates or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our development programs, commercialization efforts or other operations.

The development of vaccine candidates is capital-intensive. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our ongoing and planned preclinical studies and clinical trials for our

vaccine candidates and seek regulatory approval for our current vaccine candidates and any future vaccine candidates we may develop. In addition, if we are able to progress our vaccine candidates through development and commercialization, we will need to make milestone payments to the licensors and other third parties from whom we have in-licensed or acquired our VLP platform technology or other technologies necessary for our vaccine candidates. If we obtain regulatory approval for any of our vaccine candidates, we also expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Because the outcome of any preclinical study or clinical trial is highly uncertain, we cannot reliably estimate the actual amounts necessary to successfully complete the development and commercialization of our vaccine candidates.

Based on our current operating plan, we believe our existing cash and restricted cash will enable us to fund our operations through at least 2024. We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our existing cash, cash equivalents, restricted cash, and short-term investments will not be sufficient to complete development of our current vaccine candidates, or any future vaccine candidates, and we will require substantial capital in order to advance our current and future vaccine candidates through clinical trials, regulatory approval and commercialization. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other capital sources, including potential collaborations, licenses, non-dilutive sources of financing, such as grants, and other similar arrangements. In addition, we may seek additional capital due to favorable market conditions or liquidity or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. For example, in August 2022, we entered into an Equity Distribution Agreement with Oppenheimer & Co. Inc. (the Agent), under which we may, from time to time, sell shares of common stock having an aggregate offering price of up to $150 million in “at the market” offerings through the Agent. However, there can be no assurance that the Agent will be successful in consummating future sales based on prevailing market conditions or in the quantities or at the prices that we deem appropriate. In addition, the Equity Distribution Agreement may be terminated by us or the Agent at any time upon specified notice to the other party. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our vaccine candidates.

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

- the initiation, type, number, scope, results, costs and timing of, our ongoing and planned clinical trials of our vaccine candidates or other potential vaccine candidates we may choose to pursue in the future, including any modifications to our clinical development plans based on feedback that we may receive from regulatory authorities;
- the costs and timing of manufacturing for current or future vaccine candidates, including commercial scale manufacturing, if any vaccine candidate is approved, including as a result of inflation or supply chain issues;
- the costs, timing and outcome of regulatory reviews of current or future vaccine candidates;
- any delays and cost increases that may result from the COVID-19 pandemic or epidemic diseases, including any associated supply chain disruption and staffing shortages;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our business grows, including additional research, clinical development and manufacturing personnel;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements;
- the timing and amount of the milestone or other payments we must make to current and future licensors;
- the costs and timing of establishing or securing sales and marketing capabilities if any current or future vaccine candidates are approved;
- our ability to achieve sufficient market acceptance, coverage and favorable recommendation from vaccine policy and reimbursement bodies and adequate market share and revenue for any approved products;
- vaccine recipients’ willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors; and

- costs associated with any products or technologies that we may in-license or acquire.

Further, identifying potential vaccine candidates and conducting preclinical studies and clinical trials is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and commercialize our vaccine candidates. If approved, our vaccine candidates may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all, including as a result of financial and credit market deterioration or instability, market-wide liquidity shortages, geopolitical events or otherwise.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or vaccine candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. In addition, although we may seek non-dilutive funding or collaborations to fund the continued development, preclinical studies and clinical trials of our vaccine candidates, we may not be successful in securing such funding in a sufficient amount, if at all. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan.

If we raise additional funds through future collaborations, licenses and other similar arrangements, we may be required to relinquish valuable rights to our future revenue streams, research programs, vaccine candidates or proprietary technology, or grant licenses on terms that may not be favorable to us and/or that may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed or on terms acceptable to us, we would be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market vaccine candidates that we might otherwise prefer to develop and market ourselves.

Risks Related to the Discovery, Development and Regulatory Approval of Our Vaccine Candidates

We are early in our development efforts, with two of our vaccine candidates in the clinical stage. If we are unable to successfully develop, obtain regulatory approval or ultimately commercialize vaccine candidates, or experience significant delays in doing so, our business will be materially harmed.

We are early in our development efforts and have two vaccine candidates in clinical development. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our vaccine candidates. The success of our vaccine candidates will depend on several factors, including the following:

- successful completion of additional preclinical studies with favorable results, including toxicology and other studies designed to be compliant with good laboratory practices (GLP) and dose finding studies in animals;
- acceptance of INDs by the FDA, or of similar regulatory filings by comparable foreign regulatory authorities for the conduct of clinical trials of our vaccine candidates and our proposed design of future clinical trials;
- successful initiation and enrollment of clinical trials and completion of clinical trials with favorable results;
- demonstrating the safety, purity, immunogenicity and efficacy of our vaccine candidates to the satisfaction of applicable regulatory authorities;
- receipt of marketing approvals from applicable regulatory authorities, including approvals of biologics license applications (BLAs) from the FDA, and maintaining such approvals;
- making arrangements with our third-party manufacturers for, or establishing, commercial manufacturing capabilities, successfully managing the increased complexity of manufacturing to support a broadening pipeline, and successfully manufacturing sufficient materials on the required timelines to meet clinical and commercial supply needs;

- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- establishing and maintaining patent and trade secret protection or regulatory exclusivity for our vaccine candidates;
- maintaining an acceptable safety profile of our products following approval; and
- maintaining and growing an organization of people who can develop and commercialize our products and technology.

In addition, our development plan for our IVX-A12 program targets the population of adults greater than 60 years of age. Our interactions and feedback from regulatory agencies could limit our target population to a subset of this population such as a more narrow age range or individuals with certain underlying health conditions common within this age range. These restrictions could negatively impact our ability to complete clinical trials along our planned timeline and could limit our commercial potential.

If we are unable to develop, obtain regulatory approval for, or, if approved, successfully commercialize our vaccine candidates, we may not be able to generate sufficient revenue to continue our business.

Our approach to the discovery and development of vaccine candidates is unproven, including our plan to pursue combination vaccine candidates using our VLP technology, and we do not know whether we will be able to develop any products of commercial value, or if competing approaches will limit the commercial value of our vaccine candidates.

The success of our business depends primarily upon our ability to identify, develop and commercialize our vaccine candidates based on our VLP platform technology. While there are a number of approved vaccines based on VLPs, we have not yet succeeded and may not succeed in demonstrating safety, purity, immunogenicity, and/or efficacy for any vaccine candidates based on our VLP platform technology in clinical trials or in obtaining marketing approval thereafter. In addition, while we believe our pipeline has the potential to yield multiple additional INDs for our development programs in the future, we may not be successful in our discovery efforts, and even if successful, we may not be able to submit, or be allowed to conduct clinical trials under, INDs on the timelines we expect, if at all. Our research methodology and VLP technology may be unsuccessful in identifying additional vaccine candidates, and any vaccine candidates may be shown to have harmful side effects or may have other characteristics that may necessitate additional clinical testing or make the vaccine candidates unmarketable or unlikely to receive marketing approval. If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations. Further, because all of our vaccine candidates and development programs are based on our VLP platform, adverse developments with respect to one of our programs may have a significant adverse impact on the actual or perceived likelihood of success and value of our other programs.

In addition, we are in the process of developing combination candidates using our VLP technology, such as IVX-A12, and our business strategy includes the potential development of pan-respiratory vaccines. Combining multiple vaccine candidates may result in immunologic interference between vaccine candidates or cause other challenges, which may reduce the immunogenicity of either or both of the combined vaccine candidates or otherwise harm the viability of the combination vaccine. We will not be able to ascertain the degree of immunologic interference, if any, between any vaccine candidates within any of our combined vaccine candidates in humans until evaluated in clinical trials. In addition to limiting the prospects of our combined vaccine candidates, immunological interference in VLP combination candidates or other challenges in combining vaccine candidates would reduce our ability to partner with other vaccine companies to develop combination vaccines.

We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process based on our VLP platform technology or transferring that process to third-party manufacturers, and our third-party manufacturers may be delayed in sourcing necessary raw materials and manufacturing according to our timelines, which may prevent us from completing our clinical trials or commercializing our vaccine candidates on a timely or profitable basis, if at all. In addition, since we are early in our clinical development efforts, we do not know the specific doses that may be effective in clinical trials or, if approved, commercially. Any delays in finding a suitable dose may delay our anticipated clinical development timelines.

In addition, the biotechnology and biopharmaceutical industries are characterized by rapidly advancing and often competing technologies. While we believe that clinical data has shown that VLPs may perform more effectively than soluble proteins, to our knowledge there are no published clinical trials conducting a head-to-head comparison. Further, some preclinical studies have suggested that soluble proteins may perform with similar efficacy to VLPs. Our future success will depend in part on our ability to maintain a competitive position with our VLP platform technology. If we fail to

develop VLP technology superior to soluble proteins, or if we otherwise fail to stay at the forefront of technological change in utilizing our VLP platform to create and develop vaccine candidates, we may be unable to compete effectively. Our competitors may render our VLP platform technology obsolete, or limit the commercial value of our vaccine candidates, through advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages that we believe we derive from our scientific approach and technologies. In addition, any adverse safety events associated with our VLP vaccine candidates or technology may negatively impact the actual or perceived value of our VLP platform technology and potential of our vaccine candidates. If any of these events occur, we may be forced to abandon our development efforts for our vaccine candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations.

Our business is highly dependent on the success of IVX-A12, which is in the early stages of development. If we are unable to obtain approval for IVX-A12 or effectively commercialize IVX-A12, our business would be significantly harmed.

We have invested a significant portion of our efforts and financial resources in developing our lead candidate, IVX-A12, a bivalent combination of our vaccine candidates IVX-121 and IVX-241. We only recently commenced clinical testing of IVX-A12 and IVX-121 and, to date, we have only evaluated IVX-241 in preclinical studies. Although IVX-121, IVX-241 and the combination candidate IVX-A12 have produced successful results in animal studies, and although we announced positive interim results from our Phase 1/1b clinical trial of IVX-121 in young and older adults in June 2022, and positive six-month immunogenicity data from this trial in December 2022, IVX-A12 may not demonstrate the same properties in humans and may interact with human biological systems in unforeseen, ineffective or harmful ways. Our business prospects are highly dependent on our ability to develop, obtain marketing approval for and successfully commercialize IVX-A12, which will require us to succeed in a range of challenging activities that are subject to numerous risks and uncertainties, including those described in this “Risk Factors” section. Many of these risks and uncertainties are beyond our control, including the clinical development and regulatory approval process; potential threats to our intellectual property rights; and the manufacturing, marketing and sales efforts of any current or future third-party contractors. Furthermore, given the early stage of development of IVX-A12, it will be years before we are potentially able to demonstrate the safety, purity and potency, and efficacy of IVX-A12 sufficient to warrant marketing approval, and we may never be able to do so. If we are unable to develop, receive marketing approval for and successfully commercialize IVX-A12, or if we experience delays as a result of any of these factors or otherwise, our business would be significantly harmed.

Preclinical and clinical development involves a lengthy and expensive process with an uncertain outcome, and the results of preclinical studies and early clinical trials are not necessarily predictive of our future results. We may not have favorable results in preclinical studies or clinical trials, or receive regulatory approval on a timely basis, if at all.

Preclinical and clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that any preclinical studies or clinical trials will be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the preclinical study or clinical trial process. Despite promising preclinical or clinical results, any vaccine candidate can unexpectedly fail at any stage of preclinical or clinical development. The historical failure rate for vaccine candidates in our industry is high, particularly in the early stages of development.

The results from preclinical studies or clinical trials of a vaccine candidate or a competitor’s vaccine candidate in the same class may not predict the results of later clinical trials of a vaccine candidate, and interim, topline, or preliminary results of a clinical trial are not necessarily indicative of final results. Vaccine candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. While we have conducted preclinical studies of certain of our vaccine candidates and reported positive interim data from our Phase 1/1b clinical trial of IVX-121 in June 2022, and positive six-month immunogenicity data from this trial in December 2022, we do not know whether our vaccine candidates will perform in current and future clinical trials as they have performed in these prior studies. For example, early stage clinical trials typically enroll a limited number of subjects. For these reasons and others, it is not uncommon to observe results in later clinical trials that are unexpected based on preclinical studies and early clinical trials. Many vaccine candidates fail in clinical trials despite very promising early results, and a number of companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier preclinical studies and clinical trials. Such setbacks may occur for many reasons, including, but not limited to: the fact that our vaccine candidates may fail to demonstrate sufficient immunogenicity, efficacy or safety, or may fail to demonstrate sufficient immunogenicity, efficacy or safety in certain subject subpopulations, which has not been observed in earlier trials due to limited sample size, lack of

analysis or otherwise; or our clinical trials may not adequately represent the subject populations the vaccine is intended to treat, whether due to limitations in our trial designs or otherwise, such as where one subject subgroup is overrepresented in the clinical trial; clinical sites and investigators may deviate from clinical trial protocols, and we may fail to detect any such deviations in a timely manner; subjects may fail to adhere to any required clinical trial procedures, and other errors in clinical trial performance or other unexpected setbacks or negative results may occur.

As a result, we cannot be certain that our ongoing and planned clinical trials will be successful. In particular, inadequate immunogenicity, efficacy or safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our vaccine candidates in those and other indications, all of which could have a material adverse effect on our business, financial condition and results of operations.

Any difficulties or delays in the commencement or completion, or the termination or suspension, of our current or planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue or adversely affect our commercial prospects.

Before obtaining marketing approval from regulatory authorities for the sale of our vaccine candidates, we must conduct extensive clinical trials to demonstrate the safety, purity, immunogenicity and efficacy of the vaccine candidates in humans. Before we can initiate clinical trials for our vaccine candidates, we must submit the results of preclinical studies to the FDA or comparable foreign regulatory authorities along with other information, including information about vaccine candidate chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND or similar regulatory filing required for allowance to proceed with clinical development. We are currently conducting a Phase 1 clinical trial of IVX-A12 in the United States. We are also conducting or planning to conduct clinical trials in additional jurisdictions outside the United States. The FDA or other regulatory authorities could require us to conduct additional preclinical studies or added clinical evaluation under any IND, CTA or similar regulatory filing, which may lead to delays and increase the costs of our preclinical and clinical development programs. In addition, even after commencing a clinical trial, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Any such delays in the commencement or completion of our planned or ongoing clinical trials for our vaccine candidates could significantly affect our product development timelines and product development costs.

We do not know whether our planned clinical trials will begin on time, or whether our planned and ongoing clinical trials will be completed on schedule, if at all. The commencement, data readouts, and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- inability to obtain regulatory authorizations to commence a trial or reach a consensus with regulatory authorities on trial design;
- the FDA or comparable foreign regulatory authorities disagreeing as to the implementation of our clinical trials;
- any failure or delay in reaching an agreement with clinical research organizations (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 identifying, recruiting and training suitable clinical investigators;
- challenges or delays in obtaining approval from one or more institutional review boards (IRBs) or ethics committees at clinical trial sites;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- major changes or amendments to the clinical trial protocol;
- clinical sites deviating from the trial protocol or dropping out of a trial;
- failure by our CROs to perform in accordance with good clinical practice (GCP) requirements or applicable regulatory guidelines in other countries;
- challenges in manufacturing sufficient quantities of a vaccine candidate or adjuvant for use in clinical trials, which could be impacted by COVID-19 outbreaks, supply chain disruption or other issues;
- subjects failing to enroll or remain in our trials at the rate we expect, or failing to return for post-treatment follow-up, including subjects failing to remain in our trials due to movement restrictions or heath reasons, or enrollment impacts otherwise resulting from COVID-19 outbreaks and the seasonal cycles associated with respiratory illnesses such as RSV and influenza;
- individuals choosing an alternative vaccine for the indication for which we are developing our vaccine candidates, or participating in competing clinical trials;

- lack of adequate funding to complete the clinical trial;
- subjects experiencing severe or serious unexpected vaccine-related adverse effects;
- occurrence of vaccine-related serious adverse events in trials of other protein-based vaccine candidates conducted by other companies that could be considered similar to our vaccine candidates;
- selection of clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data;
- transfer of manufacturing processes to larger-scale facilities operated by a contract manufacturing organization (CMO), delays or failure by our CMOs or us to make any necessary changes to such manufacturing process, or failure of our CMOs to produce clinical trial materials in accordance with current good manufacturing (cGMP) regulations or other applicable requirements or in a timely manner; and
- third parties being unwilling or unable to satisfy their contractual obligations to us in a timely manner.

In addition, disruptions caused by COVID-19 outbreaks may also increase the likelihood that we encounter such difficulties or delays in initiating, conducting or completing our planned clinical trials. Specific COVID-19 or future pandemic-related mandates, such as mask-wearing and limits to congregating, could also result in a diminished circulation of target respiratory viruses, which could result in challenges establishing efficacy in our planned late-stage clinical trials that have endpoints specific to rates of infection in placebo- versus vaccine- treated groups.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a vaccine, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries, as we plan to continue to do for our vaccine candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled subjects in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes and privacy regulations, and political and economic risks, including war, relevant to such foreign countries.

In addition, many of the factors that cause, or lead to, the termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a vaccine candidate. We may make formulation or manufacturing changes with respect to our vaccine candidates, in which case we may need to conduct additional preclinical studies to bridge our modified vaccine candidates to earlier versions. Any resulting delays to our clinical trials could shorten any period during which we may have the exclusive right to commercialize our vaccine candidates. In such cases, our competitors may be able to bring products to market before we do, and the commercial viability of our vaccine candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

We may find it difficult to enroll subjects in our clinical trials. If we encounter difficulties enrolling subjects in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Successful and timely completion of clinical trials will require that we identify and enroll a specified number of subjects for each of our clinical trials. We may not be able to initiate or continue clinical trials for our vaccine candidates if we are unable to identify and enroll a sufficient number of eligible subjects to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Subject enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the subject population, the severity of the disease under investigation, the proximity of subjects to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the ability to obtain and maintain informed consents, the risk that enrolled subjects will not complete a clinical trial, our ability to recruit clinical trial investigators with the appropriate competencies and experience, competing clinical trials and clinicians' and subjects' perceptions as to the potential advantages and risks of the vaccine candidate being studied in relation to other available vaccines, including any new products that may be approved for the indications we are investigating as well as any vaccine candidates under development. Across our ongoing and

anticipated clinical trials and target subjects, other vaccine companies targeting these same infections are recruiting clinical trial subjects from these target populations, which may make it more difficult to fully enroll our clinical trials.

In addition, the process of finding subjects may prove costly. The timing of our clinical trials depends, in part, on the speed at which we can recruit subjects to participate in our trials, as well as completion of required follow-up periods. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants as may the seasonal cycles associated with respiratory illnesses such as RSV and influenza and the impacts of potential COVID-19 outbreaks. If subjects are unwilling or unable to participate in our trials for any reason, including the existence of concurrent clinical trials for similar target populations, negative perceptions of vaccines generally or of any of our vaccine candidates in particular, the availability of approved or authorized vaccines, the effects of COVID-19 outbreaks, or the fact that enrolling in our trials would prevent subjects from taking a different vaccine, or we otherwise have difficulty enrolling a sufficient number of subjects, the timeline for recruiting subjects, conducting trials and obtaining regulatory approval of our vaccine candidates may be delayed. Our inability to enroll a specified number of subjects for any of our future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. In addition, we rely on, and will continue to rely on, CROs and clinical trial sites to ensure proper and timely conduct of our preclinical studies and clinical trials. Though we have entered into agreements governing their services, we will have limited influence over their actual performance.

We cannot assure you that our assumptions used in determining expected clinical trial timelines and our clinical development plans are correct, and flaws in such assumptions could result in the delay of completion of such trials beyond our expected timelines, in increased clinical development costs or decrease the likelihood of meeting clinical endpoints.

If the incidence rates of infection for the specific pathogens we are targeting are smaller than we believe they are, our clinical development may be adversely affected, and our business may suffer.

Our projections of both the number of people who have respiratory diseases, as well as the subset of people with these diseases who have the potential to benefit from immunization with our vaccine candidates, are based on our estimates. These estimates have been derived from a variety of sources, including scientific literature, epidemiologic surveys, and market research based on healthcare databases, and may prove to be incorrect or imprecise. In addition, precise incidence for all the respiratory conditions we aim to address with our vaccine candidates may vary from season to season. Further, new trials or information may change the estimated incidence of these diseases. Our planned clinical trial sizes for later stage efficacy trials are based on our current estimates for rates of infection for the specific pathogens targeted by our vaccine candidates. If our estimates are incorrect, this may impact the number of subjects that need to be recruited for our clinical trials, may result in us having to expand or repeat a clinical trial, or could impact the likelihood of success of our clinical development. In particular, the incidence rate of hMPV is uncertain. We are planning our own epidemiological assessments of hMPV and RSV infections in older adults prior to commencing our planned later stage clinical trials to inform our determination of the sample size of the patient population to be enrolled in the trial. If the outcome of that assessment is a lower incidence rate than we are currently anticipating, we may need to plan for a larger clinical trial, which would result in increased clinical development costs, or could encounter greater difficulty in meeting trial endpoints. In addition, the likely potential approval of GlaxoSmithKline and Pfizer's RSV vaccine candidates based on high levels of efficacy demonstrated in Phase 3 clinical studies could make our clinical trial recruitment more difficult and increase our clinical development costs. For example, the FDA or other regulatory agencies may request inclusion of licensed RSV vaccines in our clinical trials.

Use of our vaccine candidates could be associated with adverse side effects, adverse events or other safety risks, which could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon a vaccine candidate, limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition.

As is the case with biopharmaceuticals generally, it is likely that there may be adverse side effects associated with our vaccine candidates' use. We cannot provide assurance that our vaccine candidates will not have similar effects to other experimental or licensed vaccines as we are in the early stages of evaluating our vaccine candidates in clinical trials.

We will continue to monitor for expected and unexpected side effects in our clinical trials. Future results of our clinical trials could reveal a high and unacceptable severity and prevalence of expected or unexpected side effects. Vaccine-related side effects could affect subject recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Undesirable side effects caused by our vaccine candidates when used alone or in

combination with approved drugs, biologics or vaccines could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or lead to the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Any of these occurrences may harm our business, financial condition and prospects significantly.

Moreover, if our vaccine candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for the vaccine candidate if approved. We may also be required to modify our development and clinical trial plans based on findings after we commence clinical trials. Many compounds that initially showed promise in early-stage testing have later been found to cause side effects that prevented their further development. In addition, regulatory authorities may draw different conclusions or require additional testing to confirm these determinations.

We will also monitor in our clinical trials for less common adverse events of special interest to regulatory authorities, such as enhanced respiratory disease after vaccination. It is possible that as we test our vaccine candidates in larger, longer and more extensive clinical trials, or if the use of these vaccine candidates becomes more widespread following regulatory approval, more illnesses, injuries, discomforts and other adverse events than were observed in earlier trials, as well as new conditions that did not occur or went undetected, may be discovered. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition and prospects significantly.

In addition, if one or more of our vaccine candidates receives marketing approval, and we or others later identify undesirable side effects caused by such vaccine a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw, suspend or limit approvals of such vaccine or seek an injunction against its manufacture or distribution;
- we may be required to recall a vaccine or change the way such vaccine is administered to individuals;
- regulatory authorities may require additional warnings on the label, such as a “black box” warning or a contraindication;
- we may be required to implement a Risk Evaluation and Mitigation Strategy (REMS) or create a medication guide outlining the risks of such side effects for distribution to individuals;
- we may be required to change the way a vaccine is distributed or administered, conduct additional clinical trials or change the labeling of a vaccine or be required to conduct additional post-marketing studies or surveillance;
- we could be sued and held liable for harm caused to vaccine recipients;
- sales of the vaccine may decrease significantly or the vaccine could become less competitive; and
- our reputation may suffer.

Adverse events associated with vaccines developed by other companies that target the same indications as our vaccine candidates target, or that include antigens closely related to the antigens included in our vaccine candidates, may also negatively affect our prospects. For example, the FDA could require us to do additional testing or perform additional post-marketing studies to monitor the incidence of adverse events depending upon the adverse events associated with such other vaccines.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular vaccine candidate, if approved, and could significantly harm our business, results of operations and prospects.

As an organization, we have limited experience conducting clinical trials, and may be unable to successfully complete current and future clinical trials for any of our vaccine candidates.

We are conducting clinical trials for two of our vaccine candidates. Our other vaccine candidates are in the preclinical development stage. We will need to successfully complete our current and additional planned clinical trials in order to seek FDA or comparable foreign regulatory approval to market our vaccine candidates. Carrying out clinical trials and the submission of a successful BLA or other regulatory submission for marketing approval is a complicated process. In general, in order to proceed with clinical trials, we must receive allowance to proceed under INDs or comparable applications submitted to foreign regulatory authorities. We have limited experience as a company in conducting clinical trials and preparing, submitting and prosecuting regulatory filings. We also plan to conduct a number of clinical trials over the next several years, which may be a difficult process to manage with our limited resources and which may divert the

attention of management. We cannot be certain how many clinical trials of our vaccine candidates will be required or how such trials should be designed, or that we will not encounter material delays in our clinical development plans. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to regulatory submission and approval of any of our vaccine candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of vaccine candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in submitting BLAs for and commercializing our vaccine candidates.

We have licensed the rights in our technology for a limited number of infectious diseases in certain jurisdictions, which may limit our ability to obtain regulatory approval, commercialize our vaccine candidates, or expand our pipeline to fully realize the commercial potential of our VLP platform.

We have a prescribed list of infectious disease applications for which we have obtained licenses from UW to develop vaccine candidates using our VLP technology platform. Third parties may also have licensed or will license the same VLP technology from UW for use in infectious disease applications or jurisdictions where we do not have an exclusive license. Any adverse developments that occur during clinical trials related to these infectious disease applications conducted by third parties in other jurisdictions may result in delays, limitations or denials of regulatory approvals of our vaccine candidates, may cause regulators to require us to conduct additional clinical trials as a condition to marketing approval, may result in the withdrawal of any approvals of our vaccine candidates that we receive in the future, or may result in further restrictions on our ability to commercialize our vaccine candidates. Such adverse developments may also negatively impact the perception of our vaccine candidates, which may reduce the enrollment of subjects in our clinical trials or inhibit our ability to market our vaccine candidates in the future if approved. For example, SK Bioscience (SK) has launched a vaccine in South Korea that uses the same VLP technology that we have licensed from UW for our vaccine candidates. Any adverse developments related to its vaccine could negatively impact our vaccine candidates and perceptions of our VLP platform.

In addition, the expansion of our pipeline to target additional infectious diseases for which we do not currently have a license will require us to seek additional licenses, which could increase our costs. Failure to acquire such licenses would reduce the infectious diseases that we may target with the vaccine candidates that we develop, which would prevent us from realizing the full potential of our VLP technology platform.

Our vaccine candidates are subject to extensive regulation and compliance, which is costly and time consuming, and such regulation and compliance may cause unanticipated delays or prevent the receipt of the required approvals and licenses to commercialize our vaccine candidates.

The clinical development, manufacturing, labeling, packaging, storage, record-keeping, advertising, promotion, import, export, marketing, distribution and adverse event reporting, including the submission of safety and other information, of our vaccine candidates are subject to extensive regulation by the FDA in the United States and by comparable foreign regulatory authorities in foreign markets. In the United States, we are not permitted to market our vaccine candidates until we receive regulatory approval from the FDA, which is referred to as licensure. The process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the vaccine candidates involved, as well as the target indications and populations. Approval policies or regulations may change, and the FDA has substantial discretion in the vaccine approval process, including the ability to delay, limit or deny approval of a vaccine candidate for many reasons. Despite the time and expense invested in clinical development of vaccine candidates, regulatory approval is never guaranteed. Neither we nor any current or future collaborator is permitted to market any of our vaccine candidates in the United States until we receive approval of a BLA, or if applicable, an Emergency Use Authorization, from the FDA.

Prior to obtaining approval to commercialize a vaccine candidate in the United States or abroad, we or our collaborators must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such vaccine candidates are safe, pure and potent for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our vaccine candidates are promising, such data may not be sufficient to support approval by the FDA and comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities, as the case may be, may also require us to conduct additional preclinical studies or clinical trials for our vaccine candidates either prior to approval or post-approval, or may object to elements of our clinical development program.

The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a vaccine candidate for many reasons, including:

- such authorities may disagree with the design or implementation of our current or future collaborators' clinical trials;
- negative or ambiguous results from our clinical trials, or results may not otherwise meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval;
- serious and unexpected vaccine-related side effects may be experienced by participants in our clinical trials or by individuals using vaccines similar to our vaccine candidates;
- such authorities may not accept clinical data from trials that are conducted at clinical facilities or in countries where the standard of care is potentially different from those of their respective home countries;
- we or any of our current or future collaborators may be unable to demonstrate that a vaccine candidate is safe and effective, and that such vaccine candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- such authorities may not agree that the data collected from clinical trials of our vaccine candidates are acceptable or sufficient to support the submission of a BLA or other marketing application, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- such authorities may disagree regarding the formulation, labeling and/or the specifications of our vaccine candidates;
- approval may be granted only for indications that are significantly more limited than what we apply for and/or be subject to other significant restrictions on distribution and use;
- such authorities may find deficiencies in the manufacturing processes, approval policies or facilities of our third-party manufacturers with which we or any of our future collaborators contract for clinical and commercial supplies;
- regulations of such authorities may significantly change in a manner rendering our or any of our potential future collaborators' clinical data insufficient for approval; or
- such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission.

Of the large number of vaccines and biologics in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our vaccine candidates, which would significantly harm our business, results of operations and prospects.

With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed biopharmaceuticals may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new drugs based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals.

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

Because we have limited financial and managerial resources, we focus on specific vaccine candidates, development programs and indications. As a result, we may forgo or delay pursuit of opportunities with our vaccine candidates or other vaccine candidates that could have had greater technical and commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and vaccine candidates for specific indications may not yield any commercially viable vaccine candidates. If we do not accurately evaluate the commercial potential or target market for a particular vaccine candidate or lack the internal staffing and financial resources to develop the vaccine candidate ourselves, we may relinquish valuable rights to that vaccine candidate through collaborations, licenses and other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such vaccine candidate.

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

We are conducting and plan to conduct certain of our clinical trials for our vaccine candidates outside the United States, including the Phase 1/1b extension trial we are conducting in Belgium of IVX-121 in adults aged 60-75. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, and the study was not otherwise subject to an IND, the FDA will not accept the data as support for an application for marketing approval unless the study was conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many regulatory authorities outside the United States have similar requirements. In addition, trials conducted outside the United States are subject to the applicable local laws of the jurisdictions where the trials are conducted. There can be no assurance the FDA will accept data from clinical trials conducted outside of the United States. If the FDA does not accept data from our clinical trials of our vaccine candidates, it would likely result in the need for additional clinical trials, which would be costly and time consuming and delay or permanently halt our development of our vaccine candidates.

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

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

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

From time to time, we may publicly disclose interim, preliminary or topline data from our preclinical 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. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, interim, preliminary or topline results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline and preliminary 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, topline, interim and preliminary data should be viewed with caution until the final data are available. In addition, 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 subject enrollment continues and more clinical trial data become available. Adverse differences between interim, topline or preliminary data and final data could significantly harm our business prospects. Further, disclosure of such data by us could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular vaccine candidate or product and the value of our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, vaccine candidate or our business. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our vaccine candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Fast track designation by the FDA for IVX-A12 or our other vaccine candidates may not actually lead to a faster development or regulatory review or approval process.

We have been granted a fast track designation for IVX-A12 by the FDA and may seek fast track designations for other vaccine candidates in the future. The fast track program is intended to expedite or facilitate the process for reviewing new product candidates that meet certain criteria. Specifically, new drugs and biologics are eligible for fast track designation if they are intended, alone or in combination with one or more drugs or biologics, to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product candidate and the specific indication for which it is being studied. With regard to a fast track product candidate, the FDA may consider for review sections of the NDA or BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA or BLA, the FDA agrees to accept sections of the NDA or BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA or BLA.

Obtaining a fast track designation does not change the standards for product approval, but may expedite the development or approval process. Even though the FDA has granted such designation for IVX-A12, it may not actually result in faster clinical development or regulatory review or approval. Furthermore, such a designation does not increase the likelihood that IVX-A12 or any other vaccine candidate that may be granted fast track designation will receive marketing approval in the United States.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and other government agencies to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, a government agency's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the government agency's ability to perform routine functions. Average review times at the FDA and other government agencies have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new biologics or modifications to approved biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business.

Separately, in response to the global COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, any resurgence of COVID-19 or emergence of new variants may lead to further inspectional delays. Regulatory authorities outside the United States may adopt similar policy measures. If a prolonged government shutdown were to occur based on pandemic or other factors, or if global health considerations were to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct many of our preclinical studies and all of our clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, our development programs and our ability to seek or obtain regulatory approval for or commercialize our vaccine candidates may be delayed.

We are dependent on third parties to conduct our preclinical studies and clinical trials for our vaccine candidates, and expect to rely on third parties for the conduct of any preclinical studies and clinical trials for our future vaccine candidates. Specifically, we have used and relied on, and intend to continue to use and rely on, medical institutions, clinical investigators, CROs and consultants to conduct our preclinical studies and clinical trials, in each case in accordance with our preclinical and clinical protocols and regulatory requirements. These CROs, investigators and other third parties play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. Though we carefully manage our relationships with our CROs, investigators and other third parties, 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 and prospects. Further, while we have and will have

agreements governing the activities of our third-party contractors, we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our preclinical studies and clinical trials are conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on our CROs and other third parties does not relieve us of our regulatory responsibilities. For example, toxicology studies of our vaccine candidates must be completed under GLP regulations and our or our CROs' failure to comply with these regulations may delay our ability to initiate clinical trials. In addition, we and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our vaccine candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs or trial sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Furthermore, our clinical trials must be conducted with vaccine candidates produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

There is no guarantee that any of our CROs, investigators or other third parties will devote adequate time and resources to our preclinical studies or clinical trials or perform as contractually required. If any of these third parties fails to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise performs in a substandard manner, our clinical trials may be extended, delayed or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting preclinical studies, clinical trials or other development activities that could harm our competitive position.

Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any BLA we submit. Any such delay or rejection could prevent us from commercializing our vaccine candidates.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach, and under other specified circumstances. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms or at all. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires our management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we work to carefully manage our relationships with our CROs, investigators and other third parties, 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 and prospects.

We rely on third parties for the manufacture of our vaccine candidates for preclinical and clinical development and expect to continue to do so for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of our vaccine candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate manufacturing facilities and have no plans to develop our own clinical or commercial-scale manufacturing capabilities. We rely, and will continue to rely, on third parties for the manufacture of our vaccine candidates and related raw materials for preclinical and clinical development, as well as for commercial manufacture if any of our vaccine candidates receive marketing approval. The facilities used by third-party manufacturers to manufacture our vaccine candidates must be approved by the FDA and any comparable foreign regulatory authority pursuant to inspections that will be conducted after we submit a BLA to the FDA or any comparable submission to a foreign regulatory authority. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP requirements for manufacture of products. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Furthermore, the process of manufacturing biologics is complex and highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, other supply disruptions and higher costs. If microbial, viral or other contaminations are discovered at the facilities of our third-party manufacturers, such

facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials, result in higher costs of drug product and adversely affect our business.

If our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or any comparable foreign regulatory authority, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If the FDA or any comparable foreign regulatory authority does not approve these facilities for the manufacture of our vaccine candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our vaccine candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of vaccine candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. Additionally, our third-party manufacturers may rely on single source suppliers for certain of the raw materials for our preclinical and clinical product supplies, or may otherwise encounter problems sourcing the supplies necessary for manufacturing our vaccine candidates or products, particularly in light of current supply chain disruption. If current or future suppliers are delayed or unable to supply sufficient raw materials to manufacture product for our preclinical studies and clinical trials, we may experience delays in our development efforts as materials are obtained or we locate and qualify new raw material manufacturers. In addition, supply chain challenges could impact the ability of our third-party manufacturers to meet agreed timelines. Delays at an intermediary manufacturer who is manufacturing materials that will be combined with other materials by a second manufacturer could cause delays with the second manufacturer, which could cause us to lose our manufacturing reservation, have to wait until another slot is available and potentially pay a postponement penalty.

Our or a third party's failure to execute on our manufacturing requirements on commercially reasonable terms and in compliance with cGMP or other regulatory requirements and on the necessary timeline could adversely affect our business in a number of ways, including:

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

In addition, we may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- breach of the manufacturing agreement by the third party;
- failure to manufacture our product according to our specifications, our schedule, or at all;
- misappropriation of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Our vaccine candidates and any products that we may develop may compete with other vaccine candidates and products for access to manufacturers and manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. In addition, the COVID-19 pandemic and supply chain and staffing shortages have reduced manufacturing capacity worldwide and limited access to materials needed to manufacture key components of our vaccine candidates. Further, certain of our in-license agreements require that vaccine products sold in the United States be substantially manufactured in the United States, which limits the number of manufacturers available to us. Increased competition amongst developers to access manufacturers and materials could increase the costs of, or otherwise limit our ability to, manufacture our vaccine candidates.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval, and any related remedial measures may be costly or time consuming to implement. We do not currently have arrangements in place for redundant supply or a second source for all required raw materials used in the

manufacture of our vaccine candidates. If our existing or future third-party manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all.

Our current and anticipated future dependence upon others for the manufacture of our vaccine candidates or products may adversely affect our ability to advance our vaccine candidates in clinical development, our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

We and our third-party manufacturers may face difficulty scaling up manufacturing capabilities which could delay our development timelines, or substantially increase our overall development costs.

As part of our development strategy, we plan to initiate scale-up of manufacturing process development activities to enable incorporation of final process changes early in the overall development cycle, and we have initiated such scale-up activities for IVX-A12. In addition, we intend to evaluate alternative manufacturing processes that we believe could reduce time from candidate selection to availability of clinical trial material, enable us to rapidly respond to annual strain changes as needed in our influenza program, and potentially make our VLP technology available as needed for future pandemics. However, we may face significant challenges in this scale-up of manufacturing capabilities and development of alternative manufacturing processes, including challenges with respect to large scale process development, analytical development and quality control testing, and manufacturing our vaccine candidates to our specifications and in a timely manner to support our preclinical and clinical trials. We may also face challenges in identifying and securing third-party manufacturers to support our manufacturing development activities and produce sufficient quantities at an acceptable cost. Delays in establishing and scaling up our manufacturing process, including any alternative manufacturing processes, and in securing third-party manufacturers may materially delay or disrupt our development efforts, and increase our overall development costs. In particular, if we are unable to develop faster alternative manufacturing processes, this will limit the prospects of any influenza or SARS-CoV-2 vaccine that we may develop.

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

Because we currently rely on third parties to manufacture our vaccine candidates and to perform quality testing, we must, at times, share our proprietary technology and confidential information, including trade secrets, with them. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements, and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are intentionally or inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets and despite our efforts to protect our trade secrets, a competitor's discovery of our proprietary technology and confidential information or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects.

We may seek to enter into collaborations, licenses and other similar arrangements and may not be successful in doing so, and even if we are, we may relinquish valuable rights and may not realize the benefits of such relationships.

We may seek to enter into collaborations, joint ventures, licenses and other similar arrangements for the development or commercialization of our vaccine candidates, due to capital costs required to develop or commercialize the vaccine candidate, manufacturing constraints or other strategic considerations. We may not be successful in our efforts to establish or maintain such collaborations for our vaccine candidates because our research and development pipeline may be insufficient, our vaccine candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our vaccine candidates as having the requisite potential to demonstrate safety and efficacy or significant commercial opportunity. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process can be time-consuming and complex. We may need to relinquish valuable rights to our future revenue streams, research programs, vaccine candidates or VLP platform, or grant licenses on terms that may not be favorable to us, as part of any such arrangement, and such arrangements may restrict us from entering into additional agreements with other potential collaborators. We cannot be certain that, following a collaboration, license or strategic transaction, we will achieve an economic benefit that justifies such transaction.

Even if we are successful in our efforts to establish such collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such collaborations if, for example, the development or approval of a vaccine candidate is delayed, the safety of a vaccine candidate is questioned or the sales of an approved vaccine candidate are unsatisfactory.

Collaborations involving our vaccine candidates would pose significant risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not pursue development and commercialization of any vaccine 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' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a vaccine candidate, repeat or conduct new clinical trials or require a new formulation of a vaccine candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, vaccines that compete directly or indirectly with our vaccine candidates if the collaborators believe that competitive vaccines are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- vaccine candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own vaccine candidates or drugs, which may cause collaborators to cease to devote resources to the commercialization of our vaccine candidates;
- a collaborator with marketing and distribution rights to one or more of our vaccine candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such vaccines;
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays in or termination of the research, development or commercialization of vaccine candidates, might lead to additional responsibilities for us with respect to vaccine candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- collaborators may not provide us with timely and accurate information regarding development, regulatory or commercialization status or results, which could adversely impact our ability to manage our own development efforts, accurately forecast financial results or provide timely information to our stockholders regarding our out-licensed vaccine candidates;
- if a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated; and
- collaborations may be terminated, including for the convenience of the collaborator, and, if terminated, we may find it more difficult to enter into future collaborations or be required to raise additional capital to pursue further development or commercialization of the applicable vaccine candidates.

Any termination of collaborations we enter into in the future, or any delay in entering into collaborations related to our vaccine candidates, could delay the development and commercialization of our vaccine candidates and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Commercialization of Our Vaccine Candidates

Even if we receive regulatory approval for any vaccine candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our vaccine candidates, if approved, could be subject to labeling and other restrictions on marketing or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our vaccine candidates, when and if any of them are approved.

Any regulatory approvals that we may receive for our vaccine candidates will require the submission of reports to regulatory authorities, subject us to surveillance to monitor the safety and efficacy of the product, 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 REMS as a condition of approval of our vaccine candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our vaccine candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and cGCP requirements for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our products, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- fines, restitutions, disgorgement of profits or revenues, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications submitted by us or suspension or revocation of approvals;
- warning letters, untitled letters, or adverse publicity requirements;
- product seizure or detention, or refusal to permit the import or export of our products; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our vaccine candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay marketing authorization of any vaccine candidates we develop. 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 be subject to enforcement action and we may not achieve or sustain profitability.

Our vaccine candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The Patient Protection and Affordable Care Act (as amended by the Health Care and Education Reconciliation Act, collectively, the ACA) includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a highly similar or "biosimilar" product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, the FDA may approve a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. We believe that any of our vaccine candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our vaccine

candidates to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated.

The commercial success of our vaccine candidates will depend upon the degree of market acceptance of such vaccine candidates by healthcare providers, vaccine recipients, healthcare payors and others in the medical community.

Our vaccine candidates may not be commercially successful. Even if any of our vaccine candidates receive regulatory approval, they may not gain market acceptance among healthcare providers, individuals within our target population, healthcare payors, national immunization technical advisory groups (NITAGs) or the medical community. The commercial success of any of our current or future vaccine candidates will depend significantly on the broad adoption and use of the resulting product by these individuals and organizations for approved indications. The degree of market acceptance of our products will depend on a number of factors, including:

- demonstration of clinical efficacy and safety compared to other more-established products;
- the indications for which our vaccine candidates are approved;
- any anti-vaccine sentiments within our targeted patient population;
- the limitation of our targeted population and other limitations or warnings contained in any FDA-approved labeling;
- acceptance of a competing vaccine for the relevant indication by healthcare providers and their patients;
- acceptance of, and preference for, a therapeutic that treats the condition our vaccine targets, by healthcare providers and their patients;
- the pricing and cost-effectiveness of our products, as well as the cost of vaccination with our products in relation to alternative treatments and therapies;
- our ability to obtain and maintain sufficient third-party coverage and adequate reimbursement from government healthcare programs, including Medicare and Medicaid, private health insurers and other third-party payors;
- receiving recommendations from U.S. Center for Disease Control's (CDC) Advisory Committee on Immunization Practices (ACIP), or other foreign NITAGs, for use, as well as placement of our vaccine candidates on national immunization programs, which may impact the likelihood of third-party coverage and extent of healthcare provider acceptance;
- the willingness of vaccine recipients to pay all, or a portion of, out-of-pocket costs associated with our products in the absence of sufficient third-party coverage and adequate reimbursement;
- any restrictions on the use of our products, and the prevalence and severity of any adverse effects;
- potential product liability claims;
- the timing of market introduction of our products as well as competitive vaccines;
- the effectiveness of our or any of our current or potential future collaborators' sales and marketing strategies; and
- unfavorable publicity relating to the product.

In the United States, the ACIP develops vaccine recommendations, and there are similar NITAG agencies in other jurisdictions around the world that develop vaccine recommendations. To develop its recommendations, the ACIP forms working groups that gather, analyze and prepare scientific information. The ACIP also considers many of the factors above, as well as myriad additional factors such as the value of vaccination for the target population regarding the outcomes, health economic data and implementation issues. The ACIP recommendations are also made within categories, such as in an age group or a specified risk group and vaccines that receive a preferred ACIP recommendation are generally widely adopted in the United States. We expect that other developers of RSV vaccine candidates that are in later stages of development will secure a recommendation from the ACIP. The failure of these developers to secure such an ACIP recommendation, or any limitations of any ACIP recommendations secured by these developers, may limit the market opportunity of our vaccine candidates or otherwise require us to seek an ACIP recommendation ourselves, which may cause us to expend additional time and/or resources. If any vaccine candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors or patients, we may not generate sufficient revenue from that product and may not become or remain profitable.

The successful commercialization of our vaccine candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our products could limit our ability to market those products and decrease our ability to generate revenue.

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most vaccine recipients to be able to afford prescription medications such as our vaccine candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third-party payors will have an effect on our ability to successfully commercialize those products. Accordingly, we will need to successfully implement a coverage and reimbursement strategy for any approved vaccine candidate. Even if we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that vaccine recipients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new vaccines will be covered. Some third-party payors may require pre-approval of coverage for new or innovative products before they will reimburse healthcare providers who use such products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our vaccine candidates. In addition, certain ACA marketplace and other private payor plans are required to include coverage for certain preventative services, including vaccinations recommended by the ACIP and on the CDC's National Immunization Program, without cost share obligations (i.e., co-payments, deductibles or co-insurance) for plan members. Children through 18 years of age without other health insurance coverage may be eligible to receive such vaccinations free-of-charge through the CDC's Vaccines for Children program. For Medicare beneficiaries, vaccines may be covered for reimbursement under either the Part B program or Part D depending on several criteria, including the type of vaccine and the beneficiary's coverage eligibility. If our vaccine candidates, if approved, are reimbursed only under the Part D program, healthcare providers may be less willing to use our products because of the claims adjudication costs and time related to the claims adjudication process and collection of co-payment associated with the Part D program.

Obtaining and maintaining reimbursement status is time consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of our products. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to set their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with the sale of any of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

We face significant competition, and if our competitors develop technologies or vaccine candidates more rapidly than we do or their technologies are more effective, our business and our ability to develop and successfully commercialize products may be adversely affected.

The biotechnology and biopharmaceutical industries are characterized by rapid advancing technologies, intense competition and a strong emphasis on proprietary and novel products and vaccine candidates. We compete with (i) developers of vaccine candidates using technologies other than VLP technologies that target the same or similar infectious diseases targeted by our vaccine candidates and (ii) other developers of VLP technologies. Our competitors have developed, are developing or may develop vaccine candidates or products that are competitive with our vaccine candidates. Any vaccine candidates that we successfully develop and commercialize will compete with existing vaccines and new vaccines that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the prevention of diseases for which we may attempt to develop vaccine candidates. In particular, there is intense competition in the VLP technology field and the RSV, influenza and COVID-19 vaccine fields. Our competitors include larger and better funded pharmaceutical, biopharmaceutical, biotechnological and vaccine companies. Moreover, we may also compete with universities and other research institutions who may be active in respiratory vaccine research and could be in direct competition with us. We also compete with these organizations to recruit management, scientists and clinical development personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, enrolling subjects for clinical trials and in identifying and in-licensing new vaccine candidates. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

A number of companies have initiated trials, announced plans to initiate trials, or completed trials, or are commercializing non-VLP vaccine candidates targeting RSV, hMPV, influenza and SARS-CoV-2. For example, GlaxoSmithKline, Pfizer, Bavarian Nordic, Janssen, and Moderna are currently developing vaccines against RSV for use in older adults, with several currently in Phase 3 trials, and GlaxoSmithKline and Pfizer are each expected to receive marketing approval in 2023. There are currently no combination RSV and hMPV vaccines in the clinic for older adults; however, Moderna has an RSV and hMPV combination vaccine in preclinical development for pediatric use and Sanofi has announced that it is exploring RSV monovalent and RSV and hMPV combination vaccines for older adults preclinically. Several companies such as Sanofi, GlaxoSmithKline and Seqirus are currently marketing influenza vaccines and/or running influenza clinical trials. Moderna, Pfizer/BioNTech, AstraZeneca, Janssen, and Novavax along with many other companies, are currently marketing COVID-19 vaccines. Some of these companies have announced plans to develop combination vaccines with other respiratory targets, including Moderna which is planning to combine SARS-CoV-2 with RSV and influenza antigens, and BioNTech/Pfizer and Novavax which have COVID-19/influenza combination vaccines in Phase 1 and Phase 2 clinical development, respectively. We also compete with companies that have developed, or are developing, VLP technologies or protein nanoparticle vaccines including Bavarian Nordic, SpyBiotech, VBI Vaccines, UVax Bio and ModeX. To the extent these companies develop vaccines or vaccine candidates that provide or have the potential to provide comparable or better efficacy than our vaccine candidates, these efforts could create competition for subject recruitment into our trials, require changes to our clinical trial designs and limit our commercial opportunity.

Many of our competitors have significantly greater financial, technical, clinical development, manufacturing, marketing, sales and supply resources or experience than we do. If we successfully obtain approval for any vaccine candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered, the extent to which vaccine recipients accept relatively new vaccines, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior vaccine alternatives, including by being more effective, safer, more convenient, less expensive or marketed and sold more effectively than any products we may develop. Competitive products approaches may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our vaccine candidates. We plan to pursue development of a combination RSV and hMPV vaccine candidate, and it takes significant manufacturing and development resources to develop combination candidates. Our competitors may have greater resources than we do, allowing them to advance combination candidates faster than we are able to or allowing them to advance additional combination vaccine candidates incorporating more pathogens in a single candidate. These combination candidates could limit the commercialization potential of our combination candidates. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected.

We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may need to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate product revenue.

We have no internal sales, marketing or distribution capabilities, nor have we commercialized a product. If any of our vaccine candidates ultimately receives regulatory approval, we must build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming. Alternatively, we may need to collaborate with third parties that have direct sales forces and established distribution systems, in lieu of or to augment our own sales force and distribution systems. We have no prior experience as a company in the marketing, sale and distribution of biopharmaceutical products and there are significant risks involved in building and managing of a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our vaccine candidates in foreign markets. We are not permitted to market or promote any of our vaccine candidates before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for any of our vaccine candidates. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, pricing and distribution of our vaccine candidates. If we obtain regulatory approval of our vaccine candidates and ultimately commercialize our products in foreign markets, we would be subject to additional risks and uncertainties, including:

- different regulatory requirements for approval of drugs in foreign countries;
- reduced protection for intellectual property rights;
- the existence of additional third-party patent rights of potential relevance to our business;
- pricing pressure from vaccine procurement organizations;
- determinations by NITAGs not to include our vaccine products in immunization schedules for our target patient population, older adults;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- compliance with export control and import laws and regulations;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is common;
- differing regulatory requirements with respect to manufacturing of vaccine products;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

Risks Related to Our Business Operations and Industry

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the timing and cost of, and level of investment in, research, development, regulatory approval and commercialization activities relating to our vaccine candidates, which may change from time to time;
- coverage and reimbursement policies with respect to our vaccine candidates, if approved, and potential future drugs that compete with our products;
- the cost of manufacturing our vaccine candidates, which may vary depending on the quantity of production and the terms of our agreements with third-party manufacturers;
- expenditures that we may incur to acquire, develop or commercialize additional vaccine candidates and technologies;
- the level of demand for any approved products, which may vary significantly;
- future accounting pronouncements or changes in our accounting policies; and
- the timing and success or failure of preclinical studies or clinical trials for our vaccine candidates or competing vaccine candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

We are dependent on the services of our management and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, as well as our senior scientists, clinical development and manufacturing personnel. For example, we have scientific, clinical and manufacturing personnel with significant and unique expertise in vaccines and related technologies. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our preclinical studies and clinical trials or the commercialization of our vaccine candidates. Although we have executed employment agreements or offer letters with these employees, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. In addition, we do not currently maintain “key person” life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

We will need to expand and effectively manage our managerial, technical, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. The competition for qualified personnel in the biotechnology field is currently particularly intense, and our future success depends upon our ability to attract, retain and motivate highly skilled biotechnology employees. We may not be successful in continuing to attract or retain qualified management and scientific, clinical and manufacturing personnel due to this intense competition for qualified personnel. The biotechnology industry has experienced a high rate of turnover of personnel in recent years. If we are not able to attract, integrate, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

We may encounter difficulties in managing our growth and expanding our operations successfully.

As we continue development and pursue the potential commercialization of our vaccine candidates, and function as a public company, we will need to expand our financial, development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. In addition,

we are in the process of building out a new facility that will house expanded laboratory operations and our corporate headquarters. We may encounter delays or quality or other issues as we build-out and transition to this new facility, and any such disruptions in our operations could result in delays in our research and development activities. We may also need to further expand our facilities, including laboratory operations, and may be unable to do so on commercially reasonable terms, or at all. Our future financial performance and our ability to develop and commercialize our vaccine candidates and to compete effectively will depend, in part, on our ability to manage current and future growth effectively.

Our business is subject to risks arising from COVID-19 outbreaks, and future pandemic and epidemic diseases.

The COVID-19 worldwide pandemic presented substantial public health and economic challenges and affected our employees, clinical trial subjects, physicians and other healthcare providers, communities and business operations, as well as the United States and global economies, financial markets, labor markets and supply chains. It is not possible at this time to estimate the impact that COVID-19 or other disease outbreaks could have on our business in the future, particularly as we advance our vaccine candidates through clinical development. Outbreaks of COVID-19, the measures taken by governmental authorities, any future pandemic or epidemic disease outbreaks, and any supply chain disruptions or staffing shortages, could disrupt the manufacture or shipment of our vaccine candidates for use in our research, preclinical studies and clinical trials, delay, limit or prevent our employees and CROs from continuing or timely advancing research and development activities, impede our clinical trial initiation and recruitment and the ability of subjects to continue in clinical trials, impede testing, monitoring, data collection and analysis and other related activities, any of which could delay our preclinical studies and clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition and results of operations. The COVID-19 pandemic and any future epidemic disease outbreaks could also potentially further affect the business of the FDA or other regulatory authorities, which could result in delays in meetings related to planned clinical trials or other regulatory matters.

The extent to which the COVID-19 pandemic or a future pandemic or epidemic may impact our business, including our preclinical studies, clinical trials, and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the geographic spread of variants, vaccine utilization, effectiveness and durability, business or supply chain disruptions and the effectiveness of actions taken in the United States and other countries to contain the spread of infection and otherwise address the particular pandemic or epidemic.

We are subject to various U.S. federal, state and foreign healthcare laws and regulations, which could increase compliance costs, and our failure to comply with these laws and regulations could harm our results of operations and financial condition.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers expose us to broadly applicable foreign, federal and state fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any products for which we obtain marketing approval. Such laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, in return for, either the referral of an individual or the purchase, lease, or order, or arranging for or recommending the purchase, lease, or order of any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;
- the federal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making or causing to be made a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or

covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services (CMS), information related to payments and other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse-midwives) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; some state laws that require biotechnology companies to report information on the pricing of certain drug products; and some state and local laws require the registration or pharmaceutical sales representatives.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare and privacy laws and regulations will involve ongoing substantial costs. It is possible that governmental authorities will conclude that our business practices 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 penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare program.

Recently enacted legislation, future legislation and healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize our vaccine candidates and may affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any vaccine candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the ACA was enacted in the United States. Among the provisions of the ACA of importance to our potential vaccine candidates, the ACA: established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expanded eligibility criteria for Medicaid programs; expanded the entities eligible for discounts under the 340B drug pricing program; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; implemented a new methodology by which the average manufacturer price under the Medicaid Drug Rebate Program is calculated for drugs that are inhaled, infused, instilled, implanted, or injected; established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA, and on June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden had issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, resulted in reductions to Medicare payments to providers, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. In addition, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, beginning January 1, 2024.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient assistance programs, and reform government program reimbursement methodologies for products. Most recently, the Inflation Reduction Act of 2022 included a number of significant drug pricing reforms, which include the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that requires manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers under Medicare Parts B and D to penalize price increases that outpace inflation, and a redesign of the Part D benefit, as part of which manufacturers are required to provide discounts on Part D drugs. Additional drug pricing proposals could appear in future legislation.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure and other transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our vaccine candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

We expect that the ACA, these new laws and other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our vaccine candidates, if approved.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. If we are found or alleged to have improperly promoted off-label uses, we may become subject to significant liability.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If any of our vaccine candidates are approved, and we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied

large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The government has also required companies to enter into consent decrees or imposed permanent injunctions under which specified promotional conduct is changed or curtailed.

In an effort to comply with applicable laws and regulations, including those governing the promotion of prescription products, we plan to implement compliance programs designed to actively identify, prevent and mitigate risk by implementing policies and systems. However, we cannot guarantee that these policies or systems will be sufficient or effective. If we were found to have promoted an approved vaccine product, if any, for off-label uses, we may be subject to significant liability, including significant civil and administrative financial penalties and other remedies as well as criminal penalties and other sanctions. Even if we successfully defend against any allegation of off-label promotion, a government investigation could negatively impact our business practices, harm our reputation, divert the attention of management and increase our expenses. Any of these outcomes could have a material adverse effect on our business, results of operations, financial condition and growth prospects.

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

We face an inherent risk of product liability as a result of the clinical trials of our vaccine candidates and will face an even greater risk if we commercialize our vaccine candidates. For example, we may be sued if our vaccine candidates allegedly cause injury or are found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the vaccine candidate, negligence, strict liability and a breach of warranties. Claims may be brought against us by clinical trial participants, vaccine recipients or others using, administering or selling products that may be approved in the future. Claims could also be asserted under state consumer protection acts.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease the commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of our management's time and our resources;
- substantial monetary awards to trial participants or vaccine recipients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant negative financial impact;
- the inability to commercialize our vaccine candidates; and
- a decline in our stock price.

Although we currently maintain clinical trial liability insurance coverage, we may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our vaccine candidates. Insurance coverage is increasingly expensive. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of our vaccine candidates. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

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

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include property, general liability, employment benefits liability, business automobile, workers' compensation, products liability, malicious invasion of our electronic systems, and clinical trials, and directors' and officers', employment practices and fiduciary liability insurance. We do not know, however, if we will be able to maintain

insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

We and any of our potential future collaborators will be required to report to regulatory authorities if any of our approved products cause or contribute to adverse medical events, and any failure to do so would result in sanctions that would materially harm our business.

If we or any of our potential future collaborators are successful in commercializing our products, the FDA and foreign regulatory authorities would require that we and such collaborators report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We and any of our potential future collaborators or CROs may fail to report adverse events within the prescribed timeframe. If we or any of our current or potential future collaborators or CROs fail to comply with such reporting obligations, the FDA or a foreign regulatory authority could take action, including criminal prosecution, the imposition of civil monetary penalties, seizure of our products or delay in approval or clearance of future products.

We and our service providers may be subject to a variety of privacy and data security laws and contractual obligations, which could increase compliance costs and actual or perceived failure to comply with them could subject us to potentially significant fines or penalties and otherwise harm our business.

The global data protection landscape is rapidly evolving, and we are or may become subject to state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal information. These laws and regulations may be subject to differing interpretations, creating potentially complex compliance issues for us and our service providers. Guidance on implementation and compliance practices is often updated or otherwise revised, which may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance and business.

In the United States, numerous federal and state laws and regulations, including health information privacy laws, data breach notification laws and consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators and third-party providers. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA.

In addition, certain state laws govern the privacy and security of health and other information in certain circumstances. These laws are evolving rapidly and may differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Further, we may also be subject to other state laws governing the privacy, processing and protection of personal information. By way of example, the California Consumer Privacy Act (CCPA), which went into effect on January 1, 2020, and provides California residents with individual privacy rights, including the right to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that has increased the likelihood of and risks associated with data breach litigation. Further, the California Privacy Rights Act (CPRA) generally went into effect on January 1, 2023 and significantly amends the CCPA. It imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It creates a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may also be required. Similar laws have passed in Virginia, Utah, Connecticut and Colorado, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or

other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Our operations abroad including our clinical trials may also be subject to increased scrutiny or attention from data protection authorities, and there are a wide variety of foreign privacy laws that may impact our operations, now or in the future. For example, in Europe, the GDPR imposes stringent requirements regarding the collection, use, disclosure, transfer or other processing of personal data of individuals within the EEA. Companies that must comply with the GDPR including us face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. The GDPR also confers, in certain circumstances, a private right of action to data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States; in July 2020, the Court of Justice of the European Union (CJEU) limited how organizations could lawfully transfer personal data from the EU/EEA to the United States by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on the use of standard contractual clauses (SCCs). In March 2022, the U.S. and EU announced a new regulatory regime intended to replace the invalidated regulations; however, this new EU-U.S. Data Privacy Framework has not been implemented beyond an executive order signed by President Biden on October 7, 2022 on Enhancing Safeguards for United States Signals Intelligence Activities. European court and regulatory decisions subsequent to the CJEU decision of July 16, 2020 have taken a restrictive approach to international data transfers. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Further, from January 1, 2021, we have had to comply with the GDPR and separately the UK GDPR, which together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR and has the ability to fine up to the greater of €20 million/£17 million or 4% of global turnover. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, update our data privacy and security policies and procedures, or in some cases, impact our ability to operate in certain jurisdictions. Failure or perceived failure by us or our collaborators and service providers to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our current or future collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and adversely affect our business, financial condition, results of operations and prospects. Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our information technology systems, or those of any of our service providers, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

We and our service providers maintain and will maintain a large quantity of sensitive information, including confidential business and health-related information in connection with our preclinical studies and planned clinical trials, and are subject to laws and regulations governing the privacy and security of such information. Our information technology systems and those of our third-party collaborators, service providers, vendors, contractors and consultants are vulnerable to attack, damage or interruption from computer viruses and malware (e.g., ransomware), natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, malicious code, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization.

Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the COVID-19 pandemic and the continued hybrid working environment, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. We may also experience security breaches that may remain undetected for an extended period. Any security breach or other incident, whether actual or perceived, could impact our reputation and/or operations, cause us to incur significant costs, including legal expenses, harm customer confidence, hurt our expansion into new markets, cause us to incur remediation costs, or cause us to lose existing customers. For example, the loss of clinical trial data from clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We also rely on third parties to manufacture our vaccine candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent any actual or perceived disruption or security breach affects our systems (or those of our third-party collaborators, service providers, vendors, contractors or consultants) or were to result in a loss of or accidental, unlawful or unauthorized access to, use of, release of, or other processing of personally identifiable information, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, the further development and commercialization of our vaccine candidates could be delayed.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, were such an event to occur and cause interruptions in our operations or result in the unauthorized disclosure of or access to personally identifiable information or individually identifiable health information, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. If our third-party vendors fail to protect their information technology systems and our confidential and proprietary information, we may be vulnerable to disruptions in service and unauthorized access to our confidential or proprietary information and we could incur liability and reputational damage. Some federal, state and foreign laws and regulations also include obligations for companies to notify individuals of security breaches involving particular categories of personally identifiable information. Such laws and regulations could expose us to litigation, as well as enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties, fines and significant legal liability, all of which could materially and adversely affect our business, results of operations or financial condition. Further, our insurance coverage may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.

Our business could be affected by litigation, government investigations and enforcement actions.

We currently operate in a number of jurisdictions in a highly regulated industry and we could be subject to litigation, government investigation and enforcement actions on a variety of matters in the United States. or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, false claims, privacy, anti-kickback, anti-bribery, securities, commercial, employment and other claims and legal proceedings which may arise from conducting our business. Any determination that our operations or activities are not in compliance with existing laws or regulations could result in the imposition of fines, civil and criminal penalties, equitable remedies, including disgorgement, injunctive relief and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations.

Legal proceedings, government investigations and enforcement actions can be expensive and time consuming. An adverse outcome resulting from any such proceeding, investigations or enforcement actions could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, healthcare debarment, injunctive relief, product recalls, reputational damage and modifications of our business practices, which could have a material adverse effect on our business and results of operations.

Our employees and independent contractors, including principal investigators, CROs, consultants and vendors, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees and independent contractors, including principal investigators, CROs, consultants and vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate: (i) the laws and regulations of the FDA and other similar regulatory requirements, including those laws that require the reporting of true, complete and accurate information to such authorities, (ii) manufacturing standards, including cGMP requirements, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad or (iv) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of intellectual property, products or technologies. Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of our management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits of the acquisition. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our vaccine candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our vaccine candidates may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our vaccine candidates, platform technology and other proprietary technologies we may develop. We seek to protect our proprietary position, in part, by exclusively licensing and filing company-owned patent applications in the United States and abroad relating to our vaccine candidates, VLP technology, manufacturing processes, and methods of use. If we or our principal licensor, UW, are unable to obtain or maintain patent protection, our business, financial condition, results of operations and prospects could be materially harmed.

Changes in either the patent laws or their interpretation in the United States and other jurisdictions may diminish our ability to protect our intellectual property, obtain, maintain and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our protection. We cannot predict whether the

patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection against competitors or other third parties.

The patent prosecution process is expensive, time-consuming, and complex, and we or our licensors may not be able to file, prosecute or maintain all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, third party collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in any of our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. This may result in us needing to obtain additional licenses, which could have a financial impact, or ceasing development of our candidates if not able to obtain additional necessary licenses.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our patent applications may not result in patents being issued which protect our vaccine candidates or proprietary technologies we may develop or which effectively prevent others from commercializing competitive technologies and products.

Moreover, the claim coverage in a patent application can be significantly reduced before the patent is granted. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Any patents issuing from our patent applications may be challenged, narrowed, circumvented or invalidated by third parties. Our competitors or other third parties may avail themselves of safe harbors under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) to conduct research and clinical trials. Consequently, we do not know whether our vaccine candidates and other proprietary technology will be protectable or remain protected by valid and enforceable patents. Even if a patent is granted, our competitors or other third parties may be able to circumvent the patent by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects. In addition, given the amount of time required for the development, testing and regulatory review of our vaccine candidates, patents protecting the vaccine candidates might expire before or shortly after such vaccine candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability and our patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party pre-issuance submission of prior art to the United States Patent and Trademark Office (USPTO) or become involved in opposition, derivation, revocation, reexamination, post-grant review, inter partes review, or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our vaccine programs and other proprietary technologies we may develop and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

Moreover, some of our owned and in-licensed patent rights may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patent rights, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of such patent rights in order to enforce such patent rights against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

We rely heavily on certain license agreements with UW and also depend on intellectual property licensed from other third parties, and these licensors may not always act in our best interest. If we fail to comply with our obligations under our intellectual property licenses, if the licenses are terminated, or if disputes regarding these licenses arise, we could lose significant rights that are important to our business.

We are dependent, in part, on patents, know-how and proprietary technology licensed from others. We are a party to a number of license agreements under which we are granted rights to intellectual property that are important to our business and we may enter into additional license agreements in the future. Our existing license agreements impose, and we expect that any future license agreements where we in-license intellectual property will impose on us, various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. Specifically, we are party to various option and license agreements with UW. See the descriptions of these agreements provided in the section of this Annual Report titled "Business—Material Agreements" for additional information on these agreements. These licenses and, if exercised, options impose various diligence, milestone payment, royalty, and other obligations on us, and any future license agreements we enter into may do the same. In addition, we rely on in-licensing antigens from third parties other than UW to combine with our VLP platform. If we fail to comply with our obligations under these agreements, or we are subject to bankruptcy-related proceedings, the licensor may have the right to terminate the license, in which event we would not be able to develop or market the products covered by the license. In addition, we may need to obtain additional licenses from our existing licensors and others to advance our research or allow commercialization of vaccine candidates we may develop. It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. In either event, we may be required to expend significant time and resources to redesign our technology, vaccine 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. If we are unable to do so, we may be unable to develop or commercialize the affected technology or vaccine candidates.

If we or our licensors fail to adequately protect our licensed intellectual property, our ability to commercialize vaccine candidates could suffer. We do not have complete control over the maintenance, prosecution and litigation of our in-licensed patents and patent applications and may have limited control over future intellectual property that may be in-licensed. For example, we cannot be certain that activities such as the maintenance and prosecution by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. It is possible that our licensors' infringement proceedings or defense activities may be less vigorous than had we conducted them ourselves, or may not be conducted in accordance with our best interests. Furthermore, there may be certain limitations to our right to enforce certain exclusively licensed patents, including, for example, the requirement that we obtain the licensor's consent prior to settling such lawsuits in a manner that would adversely affect the licensor's rights, and a general prohibition on enforcement against non-profit entities.

In addition, the agreements under which we license intellectual property or technology from third parties are 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 patents, know-how and proprietary technology, or increase what we believe to be our financial or other obligations under the relevant agreement. Disputes that may arise between us and our licensors regarding intellectual property subject to a license agreement could include disputes regarding:

- 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 licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our vaccine candidates and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected technology or vaccine candidates. As a result, any termination of or disputes over our intellectual property licenses could result in the loss of our ability to develop and commercialize our vaccine candidates, or we could lose other significant

rights, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Furthermore, our licensed patent rights are or may be subject to retained or reserved rights by the licensor or one or more third parties. For example, UW retained rights to conduct academic research for itself and other rights necessary for UW to comply with its obligations to BMGF, which funded in part the research resulting in certain of our licensed patent rights and technology under the UW agreements. Further, because our licensed patent rights allow the licensor to continue their research on the licensed technology, a licensor may develop new inventions that we may want to license in the future. Any such licenses provided to us will increase our costs. Alternatively, if a licensor does not provide us with a license, we may be limited in our ability to develop competitive vaccine candidates in the future.

Intellectual property discovered through government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for United States-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-United States manufacturers.

We have in-licensed certain patents and patent applications that were generated through the use of United States government funding or grants, and we may acquire or license in the future intellectual property rights that have been generated through the use of United States government funding or grants. Pursuant to the Bayh-Dole Act of 1980, the United States government has certain rights in inventions developed with government funding. These United States government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the United States government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third-party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). If the United States government exercises its march-in rights in our current or future intellectual property rights that are generated through the use of United States government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the United States government for the exercise of such rights. The United States government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the United States government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for United States industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for United States industry may limit our ability to contract with non-United States product manufacturers for products covered by such intellectual property. Any failure by us to comply with federal regulations regarding intellectual property rights that were developed through the use of United States government funding could have a material adverse effect on our business, financial condition, results of operations, and prospects.

For example, because the research resulting in certain of our licensed patent rights and technology under the UW agreements and the agreement with the National Institutes of Health was funded in whole or in part by the United States government, the United States government has certain rights to such patent rights and technology, including a non-exclusive license authorizing the government to use the invention for non-commercial purposes and march-in rights, and impose certain reporting and domestic manufacturing requirements. These rights apply to IVX-121, IVX-241, and IVX-A12 and may permit the United States government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to United States industry. In addition, our rights in such inventions are and may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations and prospects.

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

Competitors may infringe, misappropriate, or violate our intellectual property rights or those of our licensors. To prevent infringement, misappropriation, violation, or unauthorized use, we and/or our licensors may be required to file infringement claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we own or license is not valid, is unenforceable and/or is not infringed. If we or any of our licensors or potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at our vaccine candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent litigation, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such vaccine candidate. In addition, if the breadth or strength of protection provided by our patents and patent applications or those of our licensors is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize current or future vaccine candidates. Such a loss of patent protection would have a material adverse impact on our business. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1).

In addition, we may in the future choose to challenge the patentability of claims in a third-party's patent by requesting that the USPTO review the patent claims in re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). We may in the future choose to challenge third party patents in patent opposition proceedings in the EPO or another foreign patent office. Even if successful, the costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO, or other patent office we may be exposed to litigation by the third party alleging that the relevant patent may be infringed by our vaccine candidates.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Filing, prosecuting and defending patents on our vaccine candidates and/or VLP technology in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our intellectual property in and into the United States or other jurisdictions. Competitors may use our intellectual property in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. 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. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, some jurisdictions, such as Europe, Japan and China, may have a higher standard for patentability than in the United States, including, for example, the requirement of claims having literal support in the original patent filing and the limitation on using supporting data that is not in the original patent filing. Under those heightened patentability requirements, we may not be able to obtain sufficient patent protection in certain jurisdictions even though the same or similar patent protection can be secured in the United States and other jurisdictions.

Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual

property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

In 2012, the European Patent Package, or EU Patent Package, regulations were passed with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court, or UPC, for litigation involving European patents. Implementation of the EU Patent Package will likely occur in the first half of 2023. Under the UPC, all European patents, including those issued prior to ratification of the European Patent Package, will by default automatically fall under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain pan-European injunctions. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. Under the EU Patent Package as currently proposed, we will have the right to opt our patents out of the UPC over the first seven years of the court's existence, but doing so may preclude us from realizing the benefits of the new unified court.

Many countries 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 are 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.

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

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and applications. In certain circumstances, we rely on our licensors to pay these fees due to U.S. and non-U.S. patent agencies. The USPTO and various non-U.S. patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. For example, due to the sanctions imposed by the United States on Russia as a result of the conflict in Ukraine, it is not possible to pay fees on Russian patents and the future of such patents is uncertain. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act (the America Invents Act) enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This requires us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (i) file any patent application related to our vaccine programs and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our patent applications.

The America Invents Act also included a number of significant changes that affected the way patent applications are prosecuted and also affect patent litigation. These include allowing third party submission of prior art to the USPTO during

patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Any of these factors could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of patents issuing from those patent applications, and have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. 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. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once 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 that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

Issued patents covering our vaccine candidates and VLP technology could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

If we initiated legal proceedings against a third party to enforce a patent covering our vaccine candidates or VLP technology, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of a patent before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of or amendment to our patents in such a way that they no longer cover our vaccine candidates or VLP technology. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our licensing partners and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our vaccine candidates. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

Patent terms may be inadequate to protect the competitive position of our vaccine candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional or international patent application filing date. Various extensions may be available, including by patent term adjustment (PTA) due to delays at the USPTO. Conversely, patent terms may be reduced by a terminal disclaimer that is necessary to overcome a double patenting rejection during patent prosecution. Such a terminal disclaimer could obviate any extension or adjustment that may be available. Irrespective of whether extensions are available, the life of a patent, and the protection it affords, is limited. Even if patents covering our vaccine candidates are obtained, once the patent has expired, we may be vulnerable to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new vaccine candidates, patents protecting such vaccine candidates might expire before or shortly after such vaccine candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension for our vaccine candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any vaccine candidate we have or may develop, one or more of our patents issuing from our U.S. patent applications may be eligible for limited patent term extension under the 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 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. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as in Europe under Supplemental Protection Certificate. However, we may not be granted an extension for various reasons, including 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 failing to satisfy other applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patent rights, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our vaccine candidates and other proprietary technologies we may develop. Litigation may be necessary to defend against these and other claims challenging inventorship or our patent rights, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our vaccine candidates and other proprietary technologies we may develop. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for our vaccine candidates and proprietary technologies, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information and to maintain our competitive position. We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, third-party collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

We may be subject to claims that third parties have an ownership interest in our trade secrets. For example, we may have disputes arise from conflicting obligations of our employees, consultants or others who are involved in developing our vaccine candidate. Litigation may be necessary to defend against these and other claims challenging ownership of our trade secrets. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable trade secret rights, such as exclusive ownership of, or right to use, trade secrets that are important to our vaccine programs and other proprietary technologies we may develop. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products and vaccine candidates.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of our current and future products and vaccine candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending patent application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products or vaccine candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products. Further, we may need to share our proprietary information, including trade secrets, with our current and future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Some of our employees, consultants and advisors are currently or were previously employed at universities, including UW, or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors 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 individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or 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, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

Third-party claims of intellectual property infringement, misappropriation or other violations against us or our potential future collaborators could be expensive and time consuming and may prevent or delay the development and commercialization of our vaccine candidates and other proprietary technologies.

Our commercial success depends in part on our ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. As discussed above, recently, due to changes in U.S. law referred to as patent reform, new procedures including inter partes review and post-grant review have also been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our patents in the future.

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are commercializing or plan to commercialize our vaccine candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our vaccine candidates, proprietary technologies and commercializing activities may give rise to claims of infringement of the patent rights of others. We cannot assure you that our vaccine candidates or proprietary technologies will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued for which a third party, such as a competitor in the fields in which we are developing our vaccine candidates, might accuse us of infringing. It is also possible that patents owned by third parties of which we are

aware, but which we do not believe we infringe or that we believe we have valid defenses to any claims of patent infringement, could be found to be infringed by us. It is not unusual that corresponding patents issued in different countries have different scopes of coverage, such that in one country a third-party patent does not pose a material risk, but in another country, the corresponding third-party patent may pose a material risk to our vaccine candidates. As such, we monitor third-party patents in the relevant pharmaceutical markets. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that we may infringe.

Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing the infringing products or technologies. In addition, we may be required to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties and/or redesign our infringing products or technologies, which may be impossible or require substantial time and monetary expenditure. Further, we cannot predict whether any required license would be available at all or whether it would be available on commercially reasonable terms. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product or be forced to cease some aspect of our business operations as a result of actual or threatened patent infringement claims.

Even if resolved in our favor, the foregoing proceedings could be very expensive, particularly for a company of our size, and time-consuming. Such proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such proceedings adequately. Further, some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

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

Our registered or unregistered trademarks or trade names may be opposed, challenged, infringed, circumvented, invalidated, cancelled, or declared generic or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to such rejections, we may be unable to overcome them. 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, which may not survive such proceedings. Moreover, any name we may propose to use with our vaccine candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or an equivalent administrative body in a foreign jurisdiction objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our

efforts to enforce or protect our proprietary rights related to trademarks, trade names, domain name or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our vaccine candidates or utilize similar technology but that are not covered by the claims of the patents that we license or may own;
- we might not have been the first to make the inventions covered by our current or future patent applications;
- we might not have been the first to file patent applications covering our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our current or future patent applications will not lead to issued patents;
- any patent issuing from our current or future patent applications may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- 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;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file for patent protection in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property.

Should any of the foregoing occur, it could adversely affect our business, financial condition, results of operations and prospects.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

The growth of our business may depend in part on our ability to acquire, in-license or use third-party proprietary rights. For example, our vaccine candidates may require specific formulations to work effectively and efficiently, we may develop vaccine candidates containing our compounds and pre-existing pharmaceutical compounds, which could require us to obtain rights to use intellectual property held by third parties. For example, we may find from our preclinical or clinical trials that our vaccine candidates achieve improved efficacy through combination with proprietary adjuvants. We may not be able to achieve long-term access to these adjuvants or may be only able to do so under unfavorable terms. This could limit the effectiveness of our vaccine candidates if we are unable to obtain access to these adjuvants or could impact our potential profitability and prospects if we can only obtain access under unfavorable terms. In addition, with respect to any patents we may co-own with third parties, we may require licenses to such co-owners interest to such patents. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Were that to happen, we may need to cease use of the compositions or methods covered by those third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on those intellectual property rights, which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, which means that our competitors may also receive access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Additionally, we may collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution’s rights in technology resulting from the collaboration. Even if we hold such an option, we may be unable to negotiate a license from the institution within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program.

The licensing and acquisition of third-party intellectual property rights is a competitive area, 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 vaccine candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. There can be no assurance that we will be able to successfully complete these types of negotiations and ultimately acquire the rights to the intellectual property surrounding the additional vaccine candidates that we may seek to develop or market. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of certain programs and our business financial condition, results of operations and prospects could suffer.

Risks Related to Our Common Stock

The trading price of the shares of our common stock could be highly volatile, and purchasers of our common stock could incur substantial losses.

Our stock price is likely to be volatile. The stock market in general and the market for stock of biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price at which they paid. The market price for our common stock may be influenced by those factors discussed in this "Risk Factors" section and many others, including:

- results of our preclinical studies and clinical trials, and the results of trials of our competitors or those of other companies in our market sector;
- our ability to enroll subjects in our future clinical trials;
- regulatory approval of our vaccine candidates, or limitations to specific label indications or target populations for its use, or changes or delays in the regulatory review process;
- regulatory developments in the United States and foreign countries;
- changes in the structure of healthcare payment systems;
- the success or failure of our efforts to develop, acquire or license additional vaccine candidates;
- innovations, clinical trial results, product approvals and other developments regarding our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- manufacturing, supply or distribution delays or shortages;
- any changes to our relationship with any manufacturers, suppliers, collaborators or other strategic partners;
- achievement of expected product sales and profitability;
- variations in our financial results or those of companies that are perceived to be similar to us;
- market conditions in the biopharmaceutical sector and issuance of securities analysts' reports or recommendations;
- trading volume of our common stock;
- an inability to obtain additional funding;
- sales of our stock by insiders and stockholders;
- general economic, industry, geopolitical and market conditions events or factors, many of which are beyond our control, such as the COVID-19 pandemic, the military conflict between Russia and Ukraine, inflation and interest rate changes, and financial institution instability;
- additions or departures of key personnel;
- intellectual property, product liability or other litigation against us;
- changes in our capital structure, such as future issuances of securities and the incurrence of additional debt; and
- changes in accounting standards, policies, guidelines, interpretations or principles.

In addition, in the past, stockholders have initiated class action lawsuits against biopharmaceutical companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert our management's attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

An active, liquid and orderly market for our common stock may not be maintained.

We can provide no assurance that we will be able to maintain an active trading market for our common stock. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies using our shares as consideration, which, in turn, could materially adversely affect our business.

Our executive officers, directors and principal stockholders, if they choose to act together, will continue to have the ability to significantly influence all matters submitted to stockholders for approval.

As of December 31, 2022, our executive officers, directors and greater than 5% stockholders, in the aggregate, owned approximately 26% of our outstanding common stock. As a result, such persons, acting together, will have the ability to significantly influence all matters submitted to our board of directors or stockholders for approval, including the appointment of our management, the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

We do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation, if any, in the price of our common stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

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

Sales of a substantial number of shares of our common stock by our executive officers, directors and principal stockholders in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities.

We are an emerging growth company and a smaller reporting company, and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the completion of our IPO. However, if certain events occur prior to the end of such five-year period, including if we become a “large accelerated filer”, as defined under the Exchange Act, our annual gross revenues exceed $1.235 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. 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:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002 (Sarbanes-Oxley);
- 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, unless the SEC determines the new rules are necessary for protecting the public;

- 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 cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Provisions in our governing documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could significantly reduce the value of our shares to a potential acquiror or delay or prevent changes in control or changes in our management without the consent of our board of directors. The provisions in our charter documents include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors, unless the board of directors grants such right to the stockholders, to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the required approval of at least 66-2/3% of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;
- the required approval of at least 66-2/3% of the shares entitled to vote to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- an exclusive forum provision providing that the Court of Chancery of the State of Delaware will be the exclusive forum for certain actions and proceedings;
- the requirement that a special meeting of stockholders may be called only by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

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

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided, that, this provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, our amended and restated certificate of incorporation also provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. By agreeing to this provision, however, stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provisions in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

General Risk Factors

We incur significant 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, we incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, Sarbanes-Oxley, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of Sarbanes-Oxley, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory "say on pay" voting and "pay versus performance" disclosure requirements that will apply to us when we cease to be an emerging growth company. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

The rules and regulations applicable to public companies have increased and may continue to increase our legal and financial compliance costs and to make some activities more time consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, in recent periods obtaining director and officer liability insurance has become more expensive, and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

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

The global credit and financial markets have from time to time experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, inflation, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflict between Russia and Ukraine, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. More recently, the closures of Silicon Valley Bank (SVB) and Signature Bank and their placement into receivership with the Federal Deposit Insurance Corporation (FDIC) created bank-specific and broader financial institution liquidity risk and concerns. Although the Department of the Treasury, the Federal Reserve, and the FDIC jointly released a statement that depositors at SVB and Signature Bank would have access to their funds, even those in excess of the standard FDIC insurance limits, under a systemic risk exception, future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages, impair the ability of companies to access near-term working capital needs, and create additional market and economic uncertainty. The biotech sector has experienced particular volatility in the past year. There can be no assurance that future credit and financial market instability and a deterioration in confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, liquidity shortages, volatile business environment or continued unpredictable and unstable market conditions. If the equity and credit markets deteriorate, or if adverse developments are experienced by financial institutions, it may cause short-term liquidity risk and also make any necessary debt or equity financing more difficult, more costly, more onerous with respect to financial and operating covenants and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, financial institutions, manufacturers and other partners may be adversely affected by the foregoing risks, which could directly affect our ability to attain our operating goals on schedule and on budget.

Our portfolio of investments or bank deposits may be subject to market, interest and credit risk that may reduce their value and adversely affect our business, results of operations and financial condition.

The value of our investments may decline due to increases in interest rates, downgrades of the bonds and other securities included in our commercial money market account portfolio and instability in the global financial markets that reduces the liquidity of securities included in our portfolio. In addition, the closure of SVB and Signature Bank and the appointment of FDIC as receiver created bank-specific and broader financial institution liquidity risk and concerns. Although the Department of the Treasury, the Federal Reserve, and the FDIC jointly released a statement that depositors at SVB and Signature Bank would have access to their funds, even those in excess of the standard FDIC insurance limits, under a systemic risk exception, future adverse developments with respect to specific financial institutions or the broader financial services industry may impair our ability to access capital needed to support near-term working capital needs, whether from our existing investment and deposit accounts and credit facilities or otherwise, and may lead to market-wide liquidity shortages and create additional market and economic uncertainty. Furthermore, a possible recession, rising inflation, and the ongoing COVID-19 pandemic has and may continue to adversely affect the financial markets in some or all countries worldwide. Each of these events may cause us to record charges to reduce the carrying value of our investment portfolio or sell investments for less than our acquisition cost. Although we attempt to mitigate these risks through diversification of our investments, the value of our investments may nevertheless decline, and our ability to fund our near-term and long-term working capital needs to support our business and clinical development plans may be adversely affected. In addition, any decline in available funding or access to our cash and liquidity resources could also result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us, because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of our management's attention and resources, which could harm our business.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We could face criminal liability and other serious consequences for violations, which could harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls and anti-corruption and anti-money laundering laws and regulations, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, CROs, contractors and other collaborators and partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, CROs, contractors and other collaborators and partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Furthermore, U.S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments, and persons targeted by U.S. sanctions. U.S. sanctions that have been or may be imposed as a result of military conflicts in other countries may impact our ability to continue activities at future clinical trial sites within regions covered by such sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. These export and import controls and economic sanctions could also adversely affect our supply chain.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We rely on third-party manufacturers to produce our vaccine candidates. Our ability to obtain clinical supplies of our vaccine candidates could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption. In addition, our corporate headquarters is located in Seattle, Washington, near earthquake faults and fire zones, and the ultimate impact on us of being located near earthquake faults and fire zones and being consolidated in a certain geographical area is unknown. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

We and any of our third-party manufacturers or suppliers may use potent chemical agents and hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.

We and any of our third-party manufacturers or suppliers and current or potential future collaborators will use biological materials, potent chemical agents and may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety of the environment. Our operations and the operations of our third-party manufacturers and suppliers also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. 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. Although we maintain workers'

compensation insurance for certain costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for toxic tort claims that may be asserted against us in connection with our storage or disposal of biologic, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations, which have tended to become more stringent over time. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects.

Our ability to use net operating loss carryforwards and other tax attributes may be limited in connection with our initial public offering or other ownership changes.

We have incurred substantial losses during our history, do not expect to become profitable in the near future and may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire (if at all). At December 31, 2022, we had federal and state net operating loss (NOL) carryforwards of approximately $76.2 million and $30.8 million, respectively.

Federal NOL carryforwards generated after January 1, 2018 may be carried forward indefinitely. The deductibility of federal NOL carryforwards may be limited. In addition, our NOL carryforwards are subject to review and possible adjustment by the Internal Revenue Service (IRS) and state tax authorities.

Under Section 382 of the Internal Revenue Code (the Code), our federal NOL carryforwards may be or become subject to an annual limitation in the event we have had or have in the future certain cumulative changes in the ownership of our company. An “ownership change” pursuant to Section 382 of the Code generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company’s stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. We have not yet determined the amount of the cumulative change in our ownership resulting from our initial public offering or other transactions, or any resulting limitations on our ability to utilize our NOL carryforwards and other tax attributes. However, we believe that our ability to utilize our NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes, including potential changes in connection with our initial public offering. If we earn taxable income, such limitations could result in increased future income tax liability to us and our future cash flows could be adversely affected. We have recorded a full valuation allowance related to our NOL carryforwards and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

Changes in tax law may materially adversely affect our financial condition, results of operations and cash flows.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, or interpreted, changed, modified or applied adversely to us, any of which could adversely affect our business operations and financial performance. In particular, the U.S. government may enact significant changes to the taxation of business entities including, among others, an increase in the corporate income tax rate and the imposition of minimum taxes or surtaxes on certain types of income. The likelihood of these changes being enacted or implemented is unclear. We are currently unable to predict whether such changes will occur. If such changes are enacted or implemented, we are currently unable to predict the ultimate impact on our business. We urge our investors to consult with their legal and tax advisors with respect to any changes in tax law and the potential tax consequences of investing in our common stock.

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

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. If one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

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

Pursuant to Section 404 of Sarbanes-Oxley, our management is required to report upon the effectiveness of our internal control over financial reporting. When we lose our status as an "emerging growth company" and do not otherwise qualify as a "smaller reporting company", our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we may need to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begin its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Item 1B. Unresolved Staff Comments

None

Item 2. Properties

Our corporate headquarters is located at 1930 Boren Avenue in Seattle, Washington, where we lease 25,253 square feet of laboratory and office space pursuant to a lease agreement that commenced in October 2022 and will expire in December 2027, which may be extended at our option for five additional years at a fair market rent rate set based on comparable laboratory and research space in the premises and in the Seattle market.

Item 3. Legal Proceedings

We are not currently subject to any material legal proceedings. From time to time, we may be involved in legal proceedings or subject to claims incident to the ordinary course of business. Regardless of the outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

Item 4. Mine Safety Disclosures

Not Applicable.

PART II

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

Market Information

Our common stock is listed on the Nasdaq Global Market under the symbol "ICVX."

Holders of Common Stock

As of March 21, 2023, we had approximately 33 stockholders of record. This number was derived from our shareholder records and does not include beneficial owners of our common stock whose shares are held in the name of various dealers, clearing agencies, banks, brokers and other fiduciaries.

Securities Authorized for Issuance Under Equity Compensation Plans

Information about securities authorized for issuance under our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Recent Sales of Unregistered Securities

None.

Use of Proceeds

On July 28, 2021, our registration statement on Form S-1 (File No. 333- 257733) was declared effective by the SEC for our IPO. At the closing of the offering on August 2, 2021, we sold 13,953,332 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 1,819,999 additional shares, at an initial public offering price of $15.00 per share and received gross proceeds of $209.3 million, which resulted in net proceeds to us of approximately $190.7 million, after deducting underwriting discounts and commissions of approximately $14.7 million and offering-related transaction costs of approximately $4.0 million. None of the expenses associated with the initial public offering were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates, or to our affiliates. Jefferies LLC, Cowen and Company, LLC and Evercore Group L.L.C. acted as joint book-running managers for the offering.

As of December 31, 2022, we have not used any of the proceeds from our IPO. There has been no material change in the planned use of proceeds from our initial public offering from that described in the Prospectus dated July 28, 2021 filed pursuant to Rule 424(b) under the Securities Act with the SEC on July 30, 2021.

Issuer Repurchases of Equity Securities

None.

Item 6. [Reserved]

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

The following discussion and analysis should be read in conjunction with our financial statements and related notes included elsewhere in this Annual Report. This discussion and analysis and other parts of this Annual Report contain forward-looking statements based upon current beliefs, plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth in the section titled "Risk Factors" and elsewhere in this Annual Report. You should carefully read the "Risk Factors" section of this Annual Report to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section titled "Forward-Looking Statements and Market Data."

Overview

We are a biopharmaceutical company leveraging our innovative virus-like particle (VLP) platform technology to develop vaccines against infectious diseases, with an initial focus on life-threatening respiratory diseases. Our VLP platform technology is designed to enable multivalent, particle-based display of complex viral antigens, which we believe will induce broad, robust, and durable protection against the specific viruses targeted. Our pipeline includes vaccine candidates targeting some of the most prevalent viral causes of pneumonia. We are developing these candidates for older adults, a patient population with high unmet need. Our lead vaccine candidate IVX-A12 is a bivalent candidate, or a mixture of two different VLP candidates. IVX-A12 combines IVX-121, a vaccine candidate designed to target respiratory syncytial virus (RSV), and IVX-241, a vaccine candidate designed to target human metapneumovirus (hMPV). There are currently no vaccines approved that target both RSV and hMPV, which are two common causes of pneumonia in older adults.

As part of our IVX-A12 development plan, we are also conducting a clinical trial of IVX-121 and in June 2022, we announced positive topline interim results from our Phase 1/1b clinical trial of IVX-121 in young and older adults. These topline interim data showed that IVX-121 was generally well-tolerated across all dosage groups and induced a robust immune response, consistent across both young and older adult groups, and including at the lowest non-adjuvanted dose tested. In December 2022, we reported positive six-month IVX-121 immunogenicity data, demonstrating a sustained nAb response against RSV in young and older adults, lasting for at least six months after a single administration of IVX-121. We are also conducting a Phase 1b extension study for IVX-121, in which a subset of older adults from the Phase 1b cohort will be followed out to 12 months to assess durability of response. Twelve-month IVX-121 immunogenicity data is expected in mid-2023.

In August 2022, we submitted an investigational new drug application (IND) for IVX-A12 to the U.S. Food and Drug Administration (FDA). We received allowance from the FDA and in October 2022, we initiated a Phase 1 clinical trial of IVX-A12, with topline interim data expected in the second quarter of 2023. In February 2023, we announced that the FDA granted IVX-A12 fast track designation for the prevention of disease caused by RSV and hMPV in older adults aged 60 or older.

We are developing additional vaccine candidates as part of our strategy to develop combination VLP vaccines targeting the viral causes of pneumonia in older adults, including influenza and SARS-CoV-2. In the future we may also develop candidates in other areas of unmet need where VLP vaccines have the potential to offer differentiated benefits.

We commenced our operations in 2017 and have devoted substantially all of our resources to date to organizing and staffing our company, business planning, raising capital, in-licensing intellectual property rights, developing vaccine candidates, scaling up manufacturing of vaccine candidates, and preparing for and conducting preclinical studies and clinical trials. Our operations to date have been funded primarily through the sale and issuance of convertible preferred stock and our common stock, generating net proceeds of $349.6 million. As of December 31, 2022, we had cash, cash equivalents, restricted cash, and short-term investments of $219.4 million.

We have incurred significant operating losses since inception. Our net losses for the years ended December 31, 2022 and 2021 were $91.8 million and $67.0 million, respectively. As of December 31, 2022, we had an accumulated deficit of $185.8 million. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical development activities, other research and development activities, and capital expenditures. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate our expenses will increase substantially as we seek to advance our vaccine candidates through preclinical and clinical development, expand our research and development activities, develop new vaccine candidates, complete clinical trials,

seek regulatory approval and, if we receive regulatory approval, commercialize our products, as well as hire additional personnel, and protect our intellectual property.

Based on our current operating plan, we believe that our existing cash, cash equivalents, restricted cash, and short-term investments will be sufficient to fund our operations through at least 2024. We have never generated any revenue from product sales and do not expect to generate any revenues from product sales unless and until we successfully complete development of and obtain regulatory approval for our vaccine candidates, which will not be for several years, if ever. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from sales of our vaccine candidates, if ever, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potential collaborations, licenses, and other similar arrangements. However, we may not be able to raise additional funds or enter into such other arrangements when needed or on favorable terms, or at all. If we are unable to raise additional capital or enter into such arrangements when needed, we could be forced to delay, limit, reduce or terminate our research and development programs or future commercialization efforts, or grant rights to develop and market our vaccine candidates to third parties where we might otherwise prefer to develop and market such vaccine candidates ourselves.

Components of Results of Operations

Grant Revenue

To date, we have not generated any revenues from the commercial sale of approved products, and we do not expect to generate revenues from the commercial sale of our vaccine candidates for at least the foreseeable future, if ever. For the years ended December 31, 2022 and 2021, revenue was derived from the September 2020 grant agreement (the Grant Agreement) with the Bill & Melinda Gates Foundation (BMGF), pursuant to which BMGF awarded a grant totaling up to $10.0 million, in support of our development of our former IVX-411 COVID-19 vaccine for pandemic use. The Grant Agreement terminated in accordance with its terms on March 31, 2022.

Operating Expenses

Research and Development

Research and development expenses consist primarily of external and internal costs related to the development of vaccine candidates. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

External costs include:

- expenses incurred in connection with research, laboratory consumables and preclinical studies;
- expenses incurred in connection with conducting clinical trials and site payments for time and pass-through expenses and expenses incurred under agreements with CROs, other vendors, or service providers engaged to conduct our trials;
- expenses incurred in connection with manufacturing of our vaccine candidates and related intermediates under agreements with contract development and manufacturing organizations or other service providers;
- the cost of consultants engaged in research and development related services and the cost to manufacture vaccine candidates for use in our preclinical studies and clinical trials;
- costs related to regulatory compliance; and
- the cost of annual license fees and milestone payments under our license agreements.

Internal costs include:

- employee-related expenses, including salaries, related benefits, travel and stock-based compensation expenses for employees engaged in research and development functions; and
- facilities, depreciation and other expenses, which include allocated expenses for rent and maintenance of facilities, insurance, laboratory consumables and supplies.

Research and development activities are central to our business model. There are numerous factors associated with the successful development and regulatory approval of any of our vaccine candidates, including future trial design and various regulatory requirements, as well as the safety, immunogenicity and efficacy of our vaccine candidates, which cannot be determined with accuracy at this time. We may never succeed in obtaining regulatory approval for any of our vaccine candidates. Vaccine 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. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our vaccine candidates. In addition, we cannot forecast which vaccine candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. However, we expect that our research and development expenses will increase substantially in connection with our planned preclinical and clinical development activities in the near term and in the future.

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

- the number and scope of preclinical and regulatory filing-enabling studies;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible subjects;
- the number of subjects that participate in the trials;
- the number of doses evaluated in the trials;
- the costs and timing of manufacturing our vaccine candidates;
- the drop-out or discontinuation rates of clinical trial subjects;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of subject participation in the trials and follow-up;
- the phase of development of the vaccine candidate;
- the impact of any interruptions to our operations or to those of the third parties with whom we work due to COVID-19 outbreaks and any other future pandemic and epidemic disease and any associated supply chain disruption and staffing shortages; and
- the immunogenicity, efficacy and safety profile of our vaccine candidates.

General and Administrative

General and administrative expenses consist of personnel-related costs, including salaries, payroll taxes, employee benefits, and stock-based compensation charges for personnel in executive, finance and other administrative functions. Other significant costs include facility-related costs, legal fees relating to intellectual property and corporate matters, professional fees for accounting and consulting services, and insurance costs. We anticipate that our general and administrative expenses will increase substantially for the foreseeable future to support our continued research and development activities, pre-commercial preparation activities for our vaccine candidates, and, if any vaccine candidate receives marketing approval, commercialization activities. We also anticipate increased expenses related to audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums, and investor relations costs associated with operating as a growing public company.

Change in Fair Value of Derivative Liability

We issued a convertible promissory note in August 2020. We bifurcated certain embedded features that were required to be accounted for separately as a single derivative liability. The initial recognition of the fair value of the derivative resulted in a reduction to the carrying value of the convertible promissory note, a discount which is then amortized to interest expense over the term of the note. We adjusted the carrying value of the derivative liability to its estimated fair value at each reporting date, with any related changes in fair value recorded as change in fair value of derivative liability in our statements of operations and comprehensive loss. The convertible promissory note converted into 2,805,850 shares of our Series B-2 convertible preferred stock in March 2021.

Prior to the conversion of the convertible promissory note into our Series B-2 convertible preferred stock in March 2021, the fair value of the derivative liability was estimated using a scenario-based analysis comparing the probability-weighted present value of the convertible promissory note payoff at maturity with and without the bifurcated features, considering possible outcomes available to the noteholders, including various financing dissolution scenarios.

Loss on Extinguishment of Convertible Promissory Note

We recorded a loss on extinguishment of convertible promissory note of $0.8 million during the year ended December 31, 2021 in connection with the conversion of our convertible promissory note issued in August 2020. See Note 7 to the audited financial statements included elsewhere in this Annual Report for more information on this transaction.

Interest and Other Income (Expense)

Interest income consists of interest income earned on short-term investments in debt securities and interest-bearing demand accounts.

Interest expense consisted of interest on our outstanding convertible promissory note at a per annum interest rate of 6.0% and non-cash interest expense related to discount amortization prior to its conversion into shares of our Series B-2 convertible preferred stock in March 2021.

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2021

The following table summarizes our results of operations for the years ended December 31, 2022 and 2021 (in thousands):

	Year Ended December 31,		
	2022	2021	Change
Grant revenue	$ 582	$ 7,802	$ (7,220)
Operating expenses:			
Research and development	65,410	38,776	26,634
General and administrative	30,230	34,887	(4,657)
Total operating expenses	95,640	73,663	21,977
Loss from operations	(95,058)	(65,861)	(29,197)
Other income (expense)			
Change in fair value of embedded derivative liability	—	(205)	205
Loss on extinguishment of convertible promissory note	—	(754)	754
Interest and other	3,300	(151)	3,451
Total other income (expense)	3,300	(1,110)	4,410
Net loss	$ (91,758)	$ (66,971)	$ (24,787)

Grant Revenue

We recognized revenue from the Grant Agreement of $0.6 million for the year ended December 31, 2022 compared to $7.8 million for the year ended December 31, 2021. We had received the full $10.0 million in funding under the Grant Agreement as of December 31, 2021, and through December 31, 2022, we have recognized $10.0 million in revenue since the inception of the Grant Agreement.

Research and Development Expenses

Research and development expenses were $65.4 million for the year ended December 31, 2022, compared to $38.8 million for the year ended December 31, 2021. The increase of $26.6 million was due to a $7.5 million increase in direct costs related to clinical development, $6.9 million increase in direct costs related to manufacturing and preclinical development, a $5.4 million increase related to non-cash stock-based compensation expense, a $5.1 million increase in personnel related expenses due to increased headcount to support our development activities, and a $1.7 million increase in other expenses primarily related to facilities costs.

We track outsourced development, outsourced personnel costs and other external research and development costs of specific programs. We do not track our internal research and development costs, which include but are not limited to personnel and facilities costs, on a program-by-program basis.

Research and development expenses are summarized by program in the table below (in thousands):

	Year Ended December 31,	
	2022	2021
RSV-hMPV	$ 27,640	$ 12,484
SARS-CoV-2	8,334	13,487
Internal costs and unallocated research and development expense	29,436	12,805
Total research and development expense	$ 65,410	$ 38,776

General and Administrative Expenses

General and administrative expenses were $30.2 million for the year ended December 31, 2022, compared to $34.9 million for the year ended December 31, 2021. The decrease of $4.7 million consisted of lower non-cash stock-based compensation expense of $12.7 million, due to $21.0 million recognized in 2021 for the modification of stock options accelerated in connection with the death of our former Chairman, partially offset by increased personnel-related expenses of $3.1 million, increased other expenses of $2.1 million primarily related to facilities costs, increased professional services including audit and legal fees of $1.6 million, and increased insurance costs of $1.2 million.

Other Income (Expense)

Other income (expense) was income of $3.3 million for the year ended December 31, 2022, compared to expense of $1.1 million for the year ended December 31, 2021. The $4.4 million change was the result of net interest income of $3.3 million in 2022 compared to net interest expense of $0.2 million in 2021, a loss on extinguishment of convertible promissory note of $0.8 million in 2021, and a loss recognized on the change in fair value of derivative liability of $0.2 million in 2021.

Liquidity and Capital Resources

We have incurred significant operating losses since our inception and anticipate we will continue to incur significant operating losses for the foreseeable future as we continue to develop our current and future vaccine candidates, and may never become profitable. Since our inception, we have funded our operations primarily through the sale of our convertible preferred stock and common stock.

In August 2022, we entered into the Equity Distribution Agreement with Oppenheimer & Co. Inc. (the Agent), pursuant to which we may offer and sell shares of our common stock having an aggregate offering price of up to $150 million from time to time, in “at the market” offerings through the Agent. Sales of the shares of common stock, if any, will be made at prevailing market prices at the time of sale, or as otherwise agreed with the Agent. During the three months ended December 31, 2022, we sold and issued 980,000 shares of common stock under the Equity Distribution Agreement, resulting in net cash proceeds of $9.4 million.

In August 2021, we completed our IPO with the sale of 13,953,332 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 1,819,999 additional shares, at an IPO price of $15.00 per share with net proceeds of $190.7 million. Prior to our IPO, we had funded our operations primarily through the sale of convertible preferred stock and had previously raised $149.5 million in net proceeds.

As of December 31, 2022, we had cash, cash equivalents, restricted cash, and short-term investments of $219.4 million and an accumulated deficit of $185.8 million.

Funding Requirements

Based on our current operating plan we believe that our existing cash, cash equivalents, restricted cash, and short-term investments will be sufficient to meet our anticipated operating expenses and capital expenditures through at least 2024. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources

sooner than we expect. Additionally, the process of testing vaccine candidates in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain.

Our future capital requirements will depend on many factors, including:

- the initiation, type, number, scope, results, costs and timing of, our ongoing and planned clinical trials and preclinical studies or clinical trials of other potential vaccine candidates we may choose to pursue in the future, including feedback received from regulatory authorities;
- the costs and timing of manufacturing for current or future vaccine candidates, including commercial scale manufacturing if any vaccine candidate is approved;
- the costs, timing and outcome of regulatory review of current or future vaccine candidates;
- any delays and cost increases that may result from COVID-19 outbreaks or supply chain and staffing issues;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our business grows, including additional executive officers and clinical development personnel;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements;
- the timing and amount of the milestone or other payments we must make to current and future licensors;
- the costs and timing of establishing or securing sales and marketing capabilities if a current or future vaccine candidate is approved;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors; and
- costs associated with any products or technologies that we may in-license or acquire.

Our existing cash, cash equivalents, restricted cash, and short-term investments will not be sufficient to complete development of IVX-A12, an influenza vaccine candidate, a bivalent SARS-CoV-2 candidate, or any other future vaccine candidate. Accordingly, we will be required to obtain further funding to achieve our business objectives.

Until such time, if ever, as we can generate substantial product revenues to support our cost structure, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potential collaborations, licenses, and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or vaccine candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings 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 our vaccine candidates to third parties where we might otherwise prefer to develop and market such vaccine candidates ourselves.

Cash Flows

The following table sets forth a summary of the net cash flow activity for each of the periods set forth below (in thousands):

	Year Ended December 31,	
	2022	2021
Net cash (used in) provided by		
Operating activities	$ (61,675)	$ (38,540)
Investing activities	(169,449)	(1,006)
Financing activities	10,307	304,772
Net change in cash, cash equivalents, and restricted cash	$ (220,817)	$ 265,226

Operating Activities

Net cash used in operating activities for the year ended December 31, 2022 was $61.7 million, consisting primarily of our net loss incurred during the period of $91.8 million adjusted for $22.0 million of non-cash expenses and $8.1 million for net changes in operating assets and liabilities. Non-cash expenses consisted primarily of $21.7 million in stock-based compensation expense. The net change in operating assets and liabilities primarily consisted of $4.6 million in proceeds from a lease incentive, $2.8 million increase in accounts payable and accrued and other current liabilities, a $1.3 million decrease in prepaids and other current assets, and a $0.6 million decrease in deferred revenue.

Net cash used in operating activities for the year ended December 31, 2021 was $38.5 million, consisting primarily of our net loss incurred during the period of $67.0 million adjusted for $30.3 million of non-cash charges and $(1.9) million for net changes in operating assets and liabilities. Non-cash charges consisted primarily of $29.0 million in stock-based compensation expense inclusive of $21.0 million in expense related to the modification of options accelerated in connection with the death of our former Chairman, $0.8 million loss on extinguishment of convertible promissory note, $0.3 million non-cash interest expense, and $0.2 million of non-cash expense recognized related to the change in fair value of the derivative liability. The net change in operating assets and liabilities consisted of a $5.2 million increase in prepaids and other current assets, a $5.1 million increase in accounts payable and accrued and other current liabilities, and a $1.8 million decrease in deferred revenue.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2022 was $169.4 million, consisting of purchases of short-term investments of $221.1 million and $11.1 million of purchases of property and equipment, offset by $62.8 million of maturities of short-term investments.

Net cash used in investing activities for the years ended December 31, 2021 was $1.0 million for purchases of property and equipment.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2022 was $10.3 million, consisting of $9.4 million in net proceeds from the issuance of common stock, and $0.9 million of proceeds from exercises of stock options.

Net cash provided by financing activities for the year ended December 31, 2021 was $304.8 million consisting of $190.7 million in net proceeds related to the issuance of common stock in connection with the IPO in August 2021, $92.6 million in net proceeds related to the issuance of Series B-1 convertible preferred stock in March 2021, $21.0 million in net proceeds related to the issuance of Series A-1 convertible preferred stock in February 2021, and $0.4 million proceeds from exercises of stock options, including early exercises.

Contractual Obligations and Commitments

As we describe in Note 8 to the audited financial statements included elsewhere in this Annual Report, we have a lease agreement for corporate office and laboratory space in Seattle, Washington. The lease agreement expires in December 2027 and provides for a one-time option to extend for a period of five additional years. The monthly base rent will be $0.2 million for the first year, beginning in October 2022, and will increase by 3.0% per year over the initial term. In addition, we are obligated to pay for common area maintenance and other costs. The lease agreement provides us with an allowance for tenant improvements of $5.3 million that is reimbursed to us as construction of improvements occurs. Through December 31, 2022, we have received $4.6 million of the tenant improvement allowance. Under the terms of the lease agreement, we are required to maintain a standby letter of credit of $1.1 million at the execution of the lease agreement, reduced to $0.9 million at October 2023, and further reduced to $0.7 million at October 2024.

Under our license agreements, we have milestone payment obligations that are contingent upon the achievement of specified development, regulatory, and commercial sales milestones and are required to make certain royalty payments in connection with the sale of products developed under the agreements. As of December 31, 2022, we are unable to estimate the timing or likelihood of achieving the milestones or making future product sales and, therefore, any related payments are not reflected as contractual obligations herein. See the descriptions of these agreements provided in the section of this Annual Report titled "Business—Material Agreements" for additional information on these license agreements.

We enter into contracts in the normal course of business for contract research services, contract manufacturing services, professional services and other services and products for operating purposes. These contracts generally provide for termination after a notice period, and, therefore, are cancelable contracts and not included as contractual obligations herein.

Critical Accounting Policies and Significant Judgments and Estimates

Our financial statements are prepared in accordance with generally accepted accounting principles in the United States (GAAP). The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, costs, and expenses and the disclosure of contingent assets and liabilities in our financial statements and accompanying notes. We base our estimates and assumptions on historical experience and other factors that we believe to be reasonable under the circumstances. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience, known trends and events, and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our audited financial statements included elsewhere in this Annual Report, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Accrued Research and Development Expenses

We are required to estimate our obligations for expenses incurred under contracts with vendors, consultants and CROs, in connection with conducting research and development activities. The financial terms of these contracts vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. We reflect research and development expenses in our financial statements by recognizing those expenses in the periods in which services and efforts are expended. We account for these expenses according to the progress of the preclinical study or clinical trial as measured by the timing of various aspects of the study, trial or related activities. We determine accrual estimates through review of the underlying contracts along with preparation of financial models taking into account discussions with research and other key personnel as to the progress of studies or trials, or other services being conducted. During the course of a study or trial, we adjust our rate of expense recognition if actual results differ from our estimates.

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

JOBS Act and Smaller Reporting Company

As an emerging growth company under the JOBS Act, we can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. We intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of Sarbanes-Oxley. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of the consummation of our IPO, (ii) the last day of the fiscal year in which we have total annual gross

revenue of at least $1.235 billion, (iii) the first day of the fiscal year in which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of the prior year, or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Recent Accounting Pronouncements

See Note 2 to our audited financial statements included elsewhere in this Annual Report for recent accounting pronouncements.

Item 7a. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

Our cash, cash equivalents, and restricted cash consist of cash in readily available checking accounts and money market funds. Our short-term investments consist of investments in debt securities that have maturities of less than one year. As a result, the fair value of our portfolio is relatively insensitive to interest rate changes.

Foreign Currency Exchange Risk

We are exposed to market risk related to changes in foreign currency exchange rates. We contract with vendors that are located outside the United States, and certain invoices are denominated in foreign currencies. We are subject to fluctuations in foreign currency exchange rates in connection with these arrangements. To date, we have not experienced any material effects from foreign currency exchange rate fluctuations.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and research and development contract costs. We do not believe inflation has had a material effect on our results of operations during the periods presented in our financial statements included elsewhere in this Annual Report.

Item 8. Financial Statements and Supplementary Data

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of
Icosavax, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Icosavax, Inc. (the Company) as of December 31, 2022 and 2021, the related statements of operations and comprehensive loss, 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 financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its 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

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

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

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

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2019.

Seattle, Washington
March 30, 2023

ICOSAVAX, INC.

Balance Sheets

(in thousands, except share and par value data)

	December 31,	
	2022	**2021**
Assets		
Current assets:		
Cash and cash equivalents	$ 58,846	$ 279,082
Restricted cash	1,061	1,642
Short-term investments	159,461	—
Prepaid expenses and other current assets	4,545	5,829
Total current assets	223,913	286,553
Right-of-use assets – operating leases	3,247	—
Property and equipment, net	11,517	1,076
Total assets	$ 238,677	$ 287,629
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,892	$ 3,899
Accrued and other current liabilities	8,759	4,757
Current portion of operating lease liabilities	2,137	—
Deferred revenue	—	582
Total current liabilities	13,788	9,238
Operating lease liabilities, net of current portion	6,658	—
Other noncurrent liabilities	69	171
Total liabilities	20,515	9,409
Commitments and contingencies *(Note 2)*		
Stockholders' equity:		
Common stock, $0.0001 par value; 500,000,000 authorized at December 31, 2022 and 2021; 41,177,706 and 39,429,103 shares issued as of December 31, 2022 and 2021, respectively; 41,095,564 and 39,175,279 shares outstanding as of December 31, 2022 and December 31, 2021, respectively	6	5
Additional paid-in capital	404,386	372,284
Accumulated other comprehensive loss	(403)	—
Accumulated deficit	(185,827)	(94,069)
Total stockholders' equity	218,162	278,220
Total liabilities and stockholders' equity	$ 238,677	$ 287,629

See accompanying notes to financial statements

ICOSAVAX, INC.

Statements of Operations and Comprehensive Loss
(in thousands, except share data)

	Year Ended December 31,	
	2022	**2021**
Grant revenue	$ 582	$ 7,802
Operating expenses:		
Research and development	65,410	38,776
General and administrative	30,230	34,887
Total operating expenses	95,640	73,663
Loss from operations	(95,058)	(65,861)
Other income (expense):		
Change in fair value of embedded derivative liability	—	(205)
Loss on extinguishment of convertible promissory note	—	(754)
Interest and other	3,300	(151)
Total other income (expense)	3,300	(1,110)
Net loss	$ (91,758)	$ (66,971)
Other comprehensive loss:		
Unrealized losses on available-for-sale debt securities	(403)	—
Comprehensive loss	$ (92,161)	$ (66,971)
Net loss per share, basic and diluted	$ (2.31)	$ (3.73)
Weighted-average common shares outstanding, basic and diluted	39,725,131	17,965,894

See accompanying notes to financial statements

ICOSAVAX, INC.

Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)

(in thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance at December 31, 2020	32,198,879	$ 30,062	2,639,026	$ 2	$ 393	$ -	$ (27,098)	$ (26,703)
Issuance of Series A-1 convertible preferred stock for cash of $0.9615 per share net of $0.1 million of issuance costs	21,944,874	21,004	—	—	—	—	—	—
Issuance of Series B-1 convertible preferred stock for cash of $2.82172 per share net of $0.3 million of issuance costs	32,958,612	92,630	—	—	—	—	—	—
Issuance of Series B-2 convertible preferred stock from convertible note	2,805,850	7,917	—	—	—	—	—	—
Initial public offering, net of issuance costs of $18.6 million	—	—	13,953,332	1	190,736	—	—	190,737
Conversion of convertible preferred stock into common stock	(89,908,215)	(151,613)	21,634,898	2	151,611	—	—	151,613
Shares released from restriction upon vesting of early-exercised stock options	—	—	344,179	—	203	—	—	203
Exercise of common stock options	—	—	117,745	—	98	—	—	98
Vesting of shares of restricted common stock	—	—	469,493	—	—	—	—	—
Issuance of common stock for Employee Stock Purchase Plan	—	—	16,606	—	212	—	—	212
Stock-based compensation	—	—	—	—	29,031	—	—	29,031
Net loss and comprehensive loss	—	—	—	—	—	—	(66,971)	(66,971)
Balance at December 31, 2021	—	$ —	39,175,279	$ 5	$ 372,284	$ -	$ (94,069)	$ 278,220
Issuance of common stock	—	—	980,000	1	9,412	—	—	9,413
Shares released from restriction upon vesting of early-exercised stock options	—	—	171,682	—	102	—	—	102
Exercise of common stock options	—	—	395,050	—	585	—	—	585
Vesting of shares of restricted common stock	—	—	302,281	—	—	—	—	—
Issuance of common stock for Employee Stock Purchase Plan	—	—	71,272	—	309	—	—	309
Stock-based compensation	—	—	—	—	21,694	—	—	21,694
Other comprehensive loss	—	—	—	—	—	(403)	—	(403)
Net loss	—	—	—	—	—		(91,758)	(91,758)
Balance at December 31, 2022	—	$ —	41,095,564	$ 6	$ 404,386	$ (403)	$ (185,827)	$ 218,162

See accompanying notes to financial statements

ICOSAVAX, INC.

Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2022	**2021**
Operating activities:		
Net loss	$ (91,758)	$ (66,971)
Adjustments to reconcile net loss to cash used in operating activities:		
Stock-based compensation	21,694	29,031
Depreciation	860	82
Non-cash lease expense	983	—
Amortization of premiums and discounts on short-term investments	(1,528)	—
Non-cash interest expense	—	264
Change in fair value of embedded derivative liability	—	205
Loss on extinguishment of convertible promissory note	—	754
Changes in operating assets and liabilities:		
Prepaids and other current assets	1,284	(5,167)
Accounts payable	(1,195)	1,839
Accrued and other current liabilities	4,002	3,225
Deferred revenue	(582)	(1,802)
Proceeds from lease incentive	4,565	—
Net cash used in operating activities	(61,675)	(38,540)
Investing activities:		
Purchases of property and equipment	(11,113)	(1,006)
Purchases of short-term investments	(221,086)	—
Maturities of short-term investments	62,750	—
Net cash used in investing activities	(169,449)	(1,006)
Financing activities:		
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	113,634
Proceeds from initial public offering, net of offering costs	—	190,738
Proceeds from issuance of common stock, net of issuance costs	9,413	—
Proceeds from exercise of stock options, including early exercise	894	400
Net cash provided by financing activities	10,307	304,772
Net increase (decrease) in cash, cash equivalents, and restricted cash	(220,817)	265,226
Cash, cash equivalents, and restricted cash at beginning of period	280,724	15,498
Cash, cash equivalents, and restricted cash at end of period	$ 59,907	$ 280,724
Supplemental disclosure of noncash activities		
Conversion of preferred stock to common stock	$ —	$ 151,613
Purchases of property and equipment included in accounts payable and accrued liabilities	$ 330	$ 142
Right-of-use assets and lease liabilities recognized upon commencement of lease	$ 3,370	$ —

See accompanying notes to financial statements

NOTES TO FINANCIAL STATEMENTS

1. Description of Business

Organization

Icosavax, Inc. (the “Company”) was incorporated in the state of Delaware on November 1, 2017, and is located in Seattle, Washington. The Company is focused on the research and development of vaccines against infectious diseases. The Company was founded on computationally designed virus-like particle technology, exclusively licensed for a variety of infectious disease indications from the Institute for Protein Design at the University of Washington.

The Company’s business involves inherent risks. These risks include, among others, dependence on key personnel, licensors and third-party service providers, patentability of the Company’s products and processes, the immunogenicity, efficacy and safety of the Company’s vaccine candidates and the potential of the Company's novel vaccine technology platform. In addition, any of the Company’s vaccine candidates, and the Company's vaccine technology platform, could become obsolete or diminished in value by discoveries and developments at other organizations.

In July 2021, the Company effected a 1-for-4.1557 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for each series of the Company’s convertible preferred stock. Accordingly, all share and per share amounts for all periods presented in the accompanying financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split and adjustment of the convertible preferred stock conversion ratios.

On August 2, 2021, the Company completed its initial public offering (“IPO”) pursuant through which it issued 12,133,333 shares of its common stock at a public offering price of $15.00 per share, and on August 2, 2021, the Company sold an additional 1,819,999 shares pursuant to the exercise by the underwriters of their option to purchase additional shares. The Company received net proceeds from its IPO, inclusive of the exercise by the underwriters of their option to purchase additional shares, of $190.7 million, after deducting underwriting discounts and commissions and offering expenses. Upon the closing of the IPO, all 89,908,215 shares of the then outstanding convertible preferred stock automatically converted into 21,634,898 shares of common stock.

Liquidity

The Company had an accumulated deficit of $185.8 million, cash, cash equivalents, and short-term investments of $218.3 million, and restricted cash of $1.1 million at December 31, 2022.

Management believes the Company has sufficient capital to execute its strategic plan and fund operations through at least the next twelve months from the date these financial statements are issued.

The Company has devoted substantially all of its resources to organizing and staffing the Company, business planning, raising capital, in-licensing intellectual property rights, developing vaccine candidates, scaling up manufacturing of vaccine candidates, and preparing for and conducting preclinical studies and clinical trials. The Company has a limited operating history, and the sales and income potential of its business is unproven. The Company has incurred net losses and negative cash flows from operating activities since its inception and expects to continue to incur net losses into the foreseeable future as it continues the development of its vaccine candidates. From inception to December 31, 2022, the Company has funded its operations primarily through the sale of its convertible preferred stock and common stock.

As the Company continues to pursue its business plan, it expects to finance its operations through equity offerings, debt financings or other capital sources, including potential strategic collaborations, licenses, and other similar arrangements. However, there can be no assurance that any additional financing or strategic transactions will be available to the Company on acceptable terms, if at all. If events or circumstances occur such that the Company does not obtain additional funding, it may need to delay, reduce or eliminate its product development or future commercialization efforts, which could have a material adverse effect on the Company’s business, results of operations or financial condition. The accompanying financial statements do not include any adjustments that might be necessary if the Company were unable to continue as a going concern.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”). Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Updates (“ASU”) promulgated by the Financial Accounting Standards Board (“FASB”).

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported balances of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Estimates are used for, but not limited to, stock-based compensation, derivative liability, the timing of research and development accruals, and income taxes. Although these estimates are based on the Company’s knowledge of current events and actions it may undertake in the future, actual results may materially differ from these estimates and assumptions.

Concentration of Credit Risk

Financial instruments which potentially subject the Company to significant concentration of credit risk consist of cash and cash equivalents, restricted cash, and short-term investments. The Company is exposed to credit risk from its deposits of cash in excess of amounts insured by the Federal Deposit Insurance Corporation. The Company maintains insured cash sweep accounts where balances are maintained in interest bearing demand accounts. The Company has not realized any losses on these deposits, and management believes that the Company is not exposed to significant credit risk due to the financial positions of the respective depository institutions in which those deposits are held, and its short-term investments are in high credit quality securities including U.S. Treasury and U.S. Agency securities, commercial paper, and highly rated corporate debt securities.

Cash and Cash Equivalents and Restricted Cash

Cash and cash equivalents consists of deposits with commercial banks in checking and interest-bearing accounts, highly rated money market funds, and all highly liquid investments with an original maturity of 90 days or less at the time of purchase. At December 31, 2022 and 2021, restricted cash includes cash deposited in a collateral account to support a letter of credit issued as security for the Company's operating lease to rent office and laboratory space in Seattle, Washington. At December 31, 2021, restricted cash also includes payments received under the Grant Agreement (as defined in Note 4) with the Bill & Melinda Gates Foundation (“BMGF”).

Investments

Investments include U.S. Treasury and U.S. Agency securities, commercial paper, and corporate debt securities with a final maturity of each security of less than one year. These investments are classified as available-for-sale debt securities, which are recorded at fair value based on quoted prices in active markets. The Company classifies investments maturing within one year of the reporting date as short-term investments.

The Company periodically evaluates whether declines in the fair values of its investments below their amortized cost basis are other-than-temporary. This evaluation considers qualitative and quantitative factors regarding the severity and duration of the unrealized loss as well as the Company’s ability and intent to hold the investment until a forecasted recovery occurs, including whether the Company has plans to sell the security or whether it is more likely than not the Company will be required to sell any investment before recovery of its amortized cost basis. Factors considered include quoted market prices, recent financial results and operating trends, implied values from any recent transactions or offers of investee securities, credit quality of debt instrument issuers, other publicly available information that may affect the value of the investments, duration and severity of the decline in value, and the Company’s strategy and intentions for holding the investment.

If the estimated fair value of a debt security is below its amortized cost basis, the Company evaluates whether credit losses exist for the related securities. Credit-related losses are recognized as an allowance for credit losses on the balance sheet with a corresponding adjustment recognized in net loss. Unrealized gains and losses that are unrelated to credit deterioration are reported in other comprehensive loss. The Company recognizes purchase premiums and discounts as interest income using the interest method over the terms of the securities. Realized gains and losses and

declines in fair value deemed to be other-than-temporary are reflected in the statements of operations and comprehensive loss using the specific-identification method.

Fair Value of Financial Instruments

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value, and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability.

The carrying amounts of prepaid expenses and other assets, accounts payable, and accrued and other current liabilities are considered to be representative of their respective fair values due to their short maturities.

Property and equipment, net

Property and equipment, net is stated at cost, net of accumulated depreciation and is depreciated using the straight-line method over the estimated useful lives of the assets, generally two to five years, while leasehold improvements are depreciated over the shorter of their estimated useful lives or the related lease term.

Impairment of Long-Lived Assets

The Company regularly reviews the carrying value and estimated lives of its long-lived assets, including property and equipment to determine whether indicators of impairment may exist which warrant adjustments to carrying values or estimated useful lives. Should an impairment exist, the impairment loss would be measured based on the excess over the carrying amount of the asset's fair value. The Company has not recognized any impairment losses from inception through December 31, 2022.

Derivative Liability, Convertible Notes Discount and Amortization

The Company's convertible note (see Note 7) had conversion and redemption features that met the definition of an embedded derivative and were therefore subject to bifurcation and derivative accounting. The initial recognition of the fair value of the derivative resulted in a discount to the convertible note, with a corresponding derivative liability. The discount to the convertible note was amortized using the effective interest method. The amortization of the discount is included in interest and other expense in the statements of operations and comprehensive loss. The derivative liability related to these features was recorded at estimated fair value and remeasured on a recurring basis. Any changes in fair value were reflected as change in fair value of derivative liability in the statements of operations and comprehensive loss at each reporting date while such instruments were outstanding. The derivative liability was settled in March 2021 upon conversion of the underlying convertible note into Series B convertible preferred stock, resulting in a loss on extinguishment of convertible promissory note.

Leases

At the inception of a contractual arrangement, the Company determines whether the contract contains a lease by assessing whether there is an identified asset and whether the contract conveys the right to control the use of the identified asset in exchange for consideration over a period of time. If both criteria are met, the Company records the associated lease liability and corresponding right-of-use ("ROU") asset upon commencement of the lease using the implicit rate or a discount rate based on a credit-adjusted secured borrowing rate commensurate with the term of the lease. The Company additionally evaluates leases at their inception to determine if they are to be accounted for as an operating lease or a finance lease. A lease is accounted for as a finance lease if it meets one of the following five criteria: the lease has a purchase option that is reasonably certain of being exercised, the present value of the future cash flows is substantially all of the fair market value of the underlying asset, the lease term is for a significant portion of the remaining economic life of the underlying asset, the title to the underlying asset transfers at the end of the lease term, or if the underlying asset is of such a specialized nature that it is expected to have no alternative uses to the lessor at the end of the term. Leases that do not meet the finance lease criteria are accounted for as an operating lease. Operating lease assets represent a right to use an underlying asset for the lease term and operating lease liabilities represent an obligation to make lease payments arising from the lease. Operating lease liabilities with a term greater than one year and their corresponding ROU assets are recognized on the balance sheet at the commencement date of the lease based on the present value of lease payments over the expected lease term. Certain adjustments to the ROU asset may be required for items such as initial direct costs paid or incentives received. As the Company's leases do not typically provide

an implicit rate, the Company utilizes the appropriate incremental borrowing rate, determined as the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term and in a similar economic environment. Lease cost is recognized on a straight-line basis over the lease term and variable lease payments are recognized as operating expenses in the period in which the obligation for those payments is incurred. Variable lease payments primarily include common area maintenance, utilities, real estate taxes, insurance, and other operating costs that are passed on from the lessor in proportion to the space leased by the Company. The Company has elected the practical expedient to not separate lease and non-lease components.

Liability for Early Exercise of Stock Options

Certain individuals were granted the ability to early exercise their stock options. The shares of common stock issued from the early exercise of unvested stock options are restricted and continue to vest in accordance with the original vesting schedule. The Company has the option to repurchase any unvested shares at the original purchase price upon any voluntary or involuntary termination. The shares purchased by the employees and non-employees pursuant to the early exercise of stock options are not deemed, for accounting purposes, to be outstanding until those shares vest. The cash received in exchange for exercised and unvested shares related to stock options granted is recorded as a liability for the early exercise of stock options on the accompanying balance sheets and will be reclassified as common stock and additional paid-in capital as the shares vest. Unvested shares issued under early exercise provisions subject to repurchase by the Company totaled 82,142 and 253,824 shares as of December 31, 2022 and 2021, respectively. As of December 31, 2022 and 2021, the Company recorded $0.1 million and $0.2 million respectively, related to shares issued with repurchase rights as other noncurrent liabilities in the accompanying balance sheets.

Commitments and Contingencies

The Company recognizes a liability with regard to loss contingencies when it believes it is probable a liability has been incurred, and the amount can be reasonably estimated. If some amount within a range of loss appears at the time to be a better estimate than any other amount within the range, the Company accrues that amount. When no amount within the range is a better estimate than any other amount the Company accrues the minimum amount in the range.

In the event the Company becomes subject to claims or suits arising in the ordinary course of business, the Company would accrue a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

The Company has not recorded any such liabilities at either December 31, 2022 or 2021.

Grant Revenue

The Company’s revenue consists of revenue under its prior Grant Agreement with BMGF (see Note 4). The Company was reimbursed for certain costs that support development activities, including the Company’s clinical trial notification (“CTN”) preparations for and planned first-in-human Phase 1/2 clinical trial of the Company's former IVX-411 SARS-CoV-2 vaccine in Australia. The Company’s Grant Agreement did not provide a direct economic benefit to BMGF. Rather, the Company entered into an agreement with BMGF to make a certain amount of any resulting vaccine available and accessible at affordable pricing to people in certain low- and middle-income countries. The Company assessed this cost reimbursement agreement to determine if the agreement should be accounted for as an exchange transaction or a contribution. Such an agreement is accounted for as a contribution if the resource provider does not receive commensurate value in return for the assets transferred. Contributions are recognized as grant revenue when all donor-imposed conditions have been met.

Accrued Research and Development Expense

The Company is required to estimate its obligation for expenses incurred under contracts with vendors, consultants, and contract research organizations, in connection with conducting research and development activities. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. The Company reflects research and development expenses in its financial statements by recognizing those expenses in the periods in which services and efforts are expended. The Company accounts for these expenses according to the progress of the preclinical study or clinical trial, as measured by the timing of various aspects of the study, trial or related activities. The Company determines accrual estimates through review of the underlying contracts along with preparation of financial models taking into account discussions with research and other key personnel and third-party service providers as to the progress of studies or trials, or other services being conducted. To date, the Company has had no material differences between its estimates of such expenses and the amounts actually incurred. During the course of a study or trial, the Company adjusts

its expense recognition if actual results differ from its estimate. Nonrefundable advance payments for goods and services, including fees for process development or manufacturing and distribution of clinical supplies that will be used in future research and development activities, are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

Research and Development

Research and development costs are expensed as incurred and consist primarily of external and internal costs related to the development of vaccine candidates, including salaries and benefits, stock-based compensation, facilities and depreciation, contracted research, consulting arrangements, and other expenses incurred to sustain the Company's research and development programs.

Interest Income

Interest income consists of interest income earned on short-term investments in debt securities and interest bearing demand accounts.

Stock-Based Compensation

Stock-based compensation expense represents the cost of the grant date fair value of employee, officer, director and non-employee stock option grants, estimated in accordance with the applicable accounting guidance, recognized on a straight-line basis over the vesting period. The vesting period generally approximates the expected service period of the awards. The Company recognizes forfeitures as they occur.

The fair value of restricted stock units ("RSUs") is based on the closing price of the Company's common stock on the grant date. The fair value of stock options is estimated using the Black-Scholes option pricing model. The Black-Scholes option pricing model uses inputs which are assumptions that generally require judgment. These assumptions include:

- ***Fair Value of Common Stock***. The grant date fair value of the Company's common stock is determined based on its closing price.
- ***Expected Term***. The expected term represents the period that the options granted are expected to be outstanding. The expected term of stock options issued is determined using the simplified method (based on the average of the vesting term and the original contractual term) as the Company has concluded that its stock option exercise history does not provide a reasonable basis upon which to estimate expected term.
- ***Expected Volatility***. Given the Company's limited historical stock price volatility data, the Company derived the expected volatility from the average historical volatilities over a period approximately equal to the expected term of comparable publicly traded companies within the Company's peer group that were deemed to be representative of future stock price trends as the Company has limited trading history for its common stock. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.
- ***Risk-Free Interest Rate***. The risk-free interest rate is based on the U.S. Treasury zero-coupon issues in effect at the time of grant for periods corresponding with the expected term of the options.
- ***Expected Dividend Yield***. The Company has never paid dividends on its common stock and does not anticipate paying any dividends in the foreseeable future. Therefore, the Company used an expected dividend yield of zero.

Significant changes to the key assumptions underlying the factors used could result in different fair values of stock options at each valuation date.

Income Taxes

The Company accounts for income taxes under 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 financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-

planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

As of December 31, 2022 and 2021, the Company maintained valuation allowances against its deferred tax assets as the Company concluded it had not met the “more likely than not” to be realized threshold. Changes in the valuation allowance when they are recognized in the provision for income taxes may result in a change in the estimated annual effective tax rate.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability. As of December 31, 2022, the Company had no accrued interest or penalties.

Comprehensive Loss

Comprehensive loss comprises net loss and certain changes in equity excluded from net loss. For the year ended December 31, 2022, other comprehensive loss included unrealized losses on the Company's short-term investments in available-for-sale debt securities. The Company’s comprehensive loss was the same as its reported net loss for the year ended December 31, 2021.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock and common stock equivalents outstanding for the period. Common stock equivalents are only included when their effect is dilutive. The Company’s potentially dilutive securities include outstanding stock options and restricted stock units under the Company’s equity incentive plan and have been excluded from the computation of diluted net loss per share as they would be anti-dilutive to the net loss per share. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company’s net loss position.

The following tables summarize the computation of the basic and diluted net loss per share (in thousands, except share and per share data):

	Year Ended December 31,	
	2022	2021
Numerator:		
Net loss	$ (91,758)	$ (66,971)
Denominator:		
Weighted-average common shares outstanding, basic and diluted	39,725,131	17,965,894
Net loss per share, basic and diluted	$ (2.31)	$ (3.73)

The following table sets forth the outstanding potentially dilutive securities that have been excluded in the calculation of diluted net loss per share because their inclusion would be anti-dilutive.

	Year Ended December 31,	
	2022	2021
Common stock options and restricted stock units	9,387,963	6,591,727
ESPP shares	66,488	16,606
Unvested common stock	82,142	253,824
Total	9,536,593	6,862,157

Segments

The Company has determined that it operates and manages one operating segment, which is the business of researching and developing vaccines against infectious diseases. The Company's chief operating decision maker, its chief executive officer, reviews financial information on an aggregate basis for the purpose of allocating resources. All assets of the Company are located in the United States.

Recent Accounting Pronouncements

Recently Adopted Accounting Standards

In December 2019, the FASB issued ASU 2019-12, Income Taxes—Simplifying the Accounting for Income Taxes ("ASU 2019-12"). The new guidance simplifies the accounting for income taxes by removing several exceptions in the current standard and adding guidance to reduce complexity in certain areas, such as requiring that an entity reflect the effect of an enacted change in tax laws or rates in the annual effective tax rate computation in the interim period that includes the enactment date. The new standard is effective for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022 for all non-public entities, with early adoption permitted, and is effective for fiscal years beginning after December 15, 2020, including interim periods within those annual periods for public entities. Early adoption is permitted. The Company adopted ASU 2019-12 on January 1, 2021 and the standard did not have a material impact on its financial statements and related disclosures.

Recently Issued Accounting Standards

In June 2016, the FASB issued ASU 2016-13, Financial Instruments: Credit Losses (Topic 326) as clarified in ASU 2019-04, ASU 2019-05, and ASU 2020-02 ("ASU 2016-13"). The objective of the standard is to provide information about expected credit losses on financial instruments at each reporting date and to change how other-than-temporary impairments on investment securities are recorded. ASU 2016-13 will become effective beginning January 1, 2023, with early adoption permitted. The adoption of ASU 2016-13 did not have a material impact on the Company's financial condition, results of operations, cash flows, and financial statement disclosures.

3. Fair Value Measurements

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1—Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2—Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability.

Level 3—Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e. supported by little or no market activity).

No transfers between levels have occurred during the periods presented.

The Company measures the fair value of money market funds and U.S. Treasury securities based on quoted prices in active markets for identical securities. The Company measures the fair value of U.S. Agency securities, corporate debt securities and commercial paper based on recent trades of securities in inactive markets or based on quoted prices of similar instruments in active markets and other significant inputs derived from or corroborated by observable market data.

The following table summarizes, by major security type, the Company's cash, cash equivalents, and investments that are measured at fair value on a recurring basis by level within the fair value hierarchy as of December 31, 2022 (in thousands):

	Fair Value Hierarchy Level	December 31, 2022			
		Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Assets:					
Cash and cash equivalents:					
Cash	Level 1	$ 23,376	$ —	$ —	$ 23,376
Money market funds	Level 1	35,470	—	—	35,470
Total cash and cash equivalents		58,846	—	—	58,846
Investments:					
U.S. Treasury securities	Level 1	82,277	3	(331)	81,949
U.S. Agency securities	Level 2	14,044	28	—	14,072
Corporate debt securities and commercial paper	Level 2	63,543	—	(103)	63,440
Total investments		159,864	31	(434)	159,461
Total assets measured at fair value on a recurring basis		$ 218,710	$ 31	$ (434)	$ 218,307

As of December 31, 2021, the Company considered the carrying amounts of cash and cash equivalents to be representative of their respective fair values due to their short maturities.

All investments held as of December 31, 2022 were classified as available-for-sale debt securities and had contractual maturities within one year. There were no realized gains or losses on these securities for the year ended December 31, 2022. The aggregate fair value of available-for-sale debt securities in an unrealized loss position as of December 31, 2022 was $90.3 million. The Company evaluated its investments for other-than-temporary impairment and considered the decline in market value for the securities to be temporary in nature. It is not more likely than not that the Company will be required to sell the investments, and the Company does not intend to do so prior to recovery of the amortized cost basis.

As further described in Note 7, the Company issued a convertible promissory note in August 2020. The convertible promissory note contained certain features that met the definition of a derivative and were required to be bifurcated. The Company accounted for these as a single derivative comprising all the features requiring bifurcation. The fair value of the derivative liability was estimated using a scenario-based analysis comparing the probability-weighted present value of the convertible promissory note payoff at maturity with and without the bifurcated features. The Company considered possible outcomes available to the noteholders, including various financing dissolution scenarios. In addition, the probabilities applied to various scenarios, the key unobservable inputs are the time to liquidity for each scenario, and the discount rate.

The following table summarizes information about the significant unobservable inputs used in the fair value measurements for the derivative liability:

	March 19, 2021
Probability of financing	100%
Probability of dissolution	—
Time to liquidity (years)	—
Discount rate	7.6%

The Company adjusted the carrying value of the derivative liability within the convertible promissory note to the estimated fair value at each reporting date, with any related increases or decreases in the fair value recorded as change in fair value of derivative liability in the statements of operations and comprehensive loss. For the year ended December 31, 2021, the Company recognized $0.2 million of other income in the statements of operations and comprehensive loss related to increases in the fair value of the embedded derivative liability.

On March 19, 2021, in connection with the closing of the Series B convertible preferred stock financing, the convertible promissory note (including accrued interest) and derivative liability converted into 2,805,850 shares of Series B-2 convertible preferred stock. As a result of the conversion, the Company recorded a loss on extinguishment of convertible promissory note of $0.8 million of other expense in the statements of operations and comprehensive loss for the year ended December 31, 2021, which included the derecognition of unamortized debt issuance costs.

The following table provides a reconciliation of the fair value of the derivative liability using Level 3 significant unobservable inputs (in thousands):

	Derivative Liability
Fair value at December 31, 2020	$ (1,604)
Change in fair value of embedded derivative liability	(205)
Reclassification of derivative liability into convertible preferred stock resulting from conversion of convertible promissory note	1,809
Fair value at December 31, 2021	$ —

4. Grant Agreement

Bill & Melinda Gates Foundation Grant Agreement

In support of the Company's development of its former IVX-411 COVID-19 vaccine for pandemic use, in September 2020, the Company entered into the grant agreement (the "Grant Agreement") with the Bill & Melinda Gates Foundation ("BMGF"), under which it was awarded a grant totaling up to $10.0 million (the "Grant"). The Grant supported development activities related to IVX-411, including the Company's regulatory filing preparations and its Phase 1/2 clinical trial of IVX-411. The Grant Agreement terminated in accordance with its terms on March 31, 2022. Concurrent with and in connection with the Grant Agreement, the Company entered into a Global Access Commitments Agreement ("GACA") with BMGF. Under the terms of the GACA, among other things, the Company agreed to make a certain amount of its IVX-411 COVID-19 vaccine available and accessible at affordable pricing to people in certain low- and middle-income countries, if the vaccine was commercialized. The Company discontinued its IVX-411 program in July 2022.

Payments received in advance that were related to future performance were deferred and recognized as revenue when the research and development activities were performed. Cash payments received under the Grant Agreement were restricted as to their use until eligible expenditures were incurred.

At December 31, 2022, the Company had no restricted cash and no deferred revenue, and at December 31, 2021, had $0.6 million of restricted cash and deferred revenue, representing funds received from BMGF and the Company's estimate of costs to be reimbursed and revenue to be recognized, respectively, in the next twelve months under the Grant Agreement.

The Company received no funding from BMGF during the year ended December 31, 2022. During the year ended December 31, 2021, the Company received $6.0 million in funding from BMGF.

During the years ended December 31, 2022 and 2021, the Company recognized revenue from the Grant Agreement of $0.6 million and $7.8 million, respectively. The Company had received the full $10.0 million in funding under the Grant Agreement as of December 31, 2021, and through December 31, 2022, the Company has recognized $10.0 million in revenue since the inception of the Grant Agreement.

5. Balance Sheet Details

Property and equipment, net, consists of the following (in thousands):

	As of December 31,	
	2022	2021
Laboratory equipment	$ 2,192	$ 856
Leasehold improvements	9,660	—
Office furniture and equipment	608	—
Construction in progress	—	303
Property and equipment, cost	12,460	1,159
Accumulated depreciation	(943)	(83)
Property and equipment, net	$ 11,517	$ 1,076

Depreciation expense was $0.9 million for the year ended December 31, 2022, and $0.1 million for the year ended December 31, 2021.

Accrued and other current liabilities consist of the following (in thousands):

	As of December 31,	
	2022	2021
Taxes payable	$ 80	$ —
Accrued paid time off	664	342
Accrued bonus	3,135	2,216
Other accrued liabilities	4,512	1,977
Accrued 401k	324	156
ESPP liability	44	66
Total accrued and other current liabilities	$ 8,759	$ 4,757

6. License Agreements

License Agreement with the National Institutes of Health

The Company is a party to a non-exclusive patent license agreement (as amended, the “NIH Agreement”) with a U.S. government entity, the National Institutes of Health, represented by National Institute of Allergy and Infectious Disease (“NIAID”), which was originally entered into in June 2018. Under the NIH Agreement, the Company obtained a non-exclusive, worldwide, royalty-bearing, sublicensable license under certain NIAID patent rights, and transfer of know-how and biological materials for use in adjuvanted or non-adjuvanted vaccines for the prevention, cure, or treatment of RSV and metapneumovirus (hMPV) infection in humans.

Under the NIH Agreement, the Company is required to use commercially reasonable efforts to meet certain specified development, sales and regulatory milestones related to the licensed products within specified time periods. In consideration of the rights granted to the Company under the NIH Agreement, the Company paid a licensing fee upon execution of the NIH Agreement of $100,000, and will pay annual minimum royalty payments starting in the second year after the initial sale of each licensed product which can be credited against any earned royalties due for sales made in the year. The Company is obligated to pay aggregate potential milestone payments of up to $8.6 million with respect to future development and commercial milestones. Additionally, the Company has agreed to pay a tiered royalty of a low single digit percentage on net sales of all products applicable to the license. Additional royalties would be due in connection with sublicenses. The Company’s royalty obligations continue for each licensed product for so long as licensed patent rights exist and have not expired, been revoked, lapsed, or held unenforceable.

The NIH Agreement will terminate upon the last expiration of the patent rights or the Company may terminate the entirety of the agreement upon discontinuation of development or sales of licensed products and provision of written notice thereof to NIH.

The Company incurred fees associated with the license, recorded as research and development expenses, of $0.1 million during the year ended December 31, 2022, and $0.2 million during the year ended December 31, 2021.

License Agreements with University of Washington

License Agreement with respect to RSV and Other Pathogens

The Company is a party to an exclusive license agreement with the University of Washington (“UW”), originally entered into in June 2018 (as amended, the “UW 2018 Agreement”). Under the UW 2018 Agreement, UW granted the Company an exclusive, worldwide, royalty-bearing, sublicensable license under certain UW patents to make, use, sell, offer to sell, import, and otherwise exploit any product covered by the licensed patents, or licensed products, for the prophylactic and/or therapeutic treatment of RSV infection, hMPV infection and eight other infectious diseases. UW also granted the Company a non-exclusive, worldwide license under certain know-how related to the licensed patents. The licensed patents and know-how generally relate to computationally designed nanoparticles and vaccines based upon such designs, and relate to the Company’s proprietary two-component virus-like-particle technology as well as certain one-component virus-like-particle technology. The Company’s rights and obligations under the UW 2018 Agreement are subject to certain U.S. government rights, certain global access commitment rights for humanitarian purposes to BMGF, certain rights to Howard Hughes Medical Institute ("HHMI"), and certain other limited rights retained by UW. The Company issued 192,276 shares of common stock on August 1, 2018 in exchange for the UW 2018 Agreement’s exclusive license.

Under the UW 2018 Agreement, the Company is required to use commercially reasonable efforts to meet certain specified development, regulatory and sales milestones related to the licensed products within specified time periods. In consideration of the rights granted to the Company under the UW 2018 Agreement, the Company is required to pay an

annual maintenance fee in the mid four figures starting in 2020. Additionally, the Company is required to pay minimum annual royalties following the first year after commercial sale of each licensed product. There are milestone payments due upon the completion of certain development, regulatory, and commercial milestones for licensed products in the future. The aggregate potential milestone payments for future development, regulatory, and sales-based milestones are $1.35 million per indication, up to a maximum of $12.2 million in total milestone payments. Additionally, the Company has agreed to pay a royalty of a low single digit percentage on net sales of all licensed products. Additional royalties would be due in connection with sublicenses. The Company's royalty obligations continue for each licensed product for so long as licensed patent rights exist and have not expired, been revoked, lapsed, or held unenforceable.

Unless terminated earlier, the UW 2018 Agreement will remain in effect until all licensed patent rights have terminated and all obligations due to UW have been fulfilled. The last-to-expire licensed patent, if issued, is expected to expire in 2042, subject to any adjustment or extension of patent term that may be available. UW can terminate the UW 2018 Agreement if the Company breaches or fails to perform one of its material duties under the UW 2018 Agreement and the Company is unable to remedy the default within an agreed upon time period that can be extended by UW. The Company may terminate the UW 2018 Agreement at will with prior written notice to UW.

Option and License Agreement with Respect to COVID-19

The Company is also a party to an option and license agreement, originally entered into in July 2020 (as amended, the "UW 2020 Agreement"). Under the UW 2020 Agreement, UW granted the Company a non-exclusive, worldwide (excluding South Korea), sublicensable license under certain UW patents to make, use, sell, offer to sell, import, or otherwise exploit any product covered by the licensed patents for the prophylactic and/or therapeutic treatments of SARS-CoV-2 infection. Under an option exercised by the Company, UW granted the Company an exclusive license under the licensed patents for the United States, Canada, Mexico, and Europe (including Switzerland and the United Kingdom) starting in 2025. UW also granted the Company a non-exclusive, worldwide license under certain know-how related to the licensed patents. The licensed patents and know-how generally relate to computationally designed nanoparticles and vaccines based upon such designs. The Company's rights and obligations under the UW 2020 Agreement are subject to certain U.S. government rights, certain global access commitment rights for humanitarian purposes to BMGF, certain rights to HHMI, and certain other limited rights retained by UW.

Under the UW 2020 Agreement, the Company is required to use commercially reasonable efforts to meet certain specified development, regulatory and sales milestones related to the licensed products within specified time periods. The Company has agreed to pay a royalty of a low single digit percentage on net sales of all products applicable to the license. However, the Company will not be required to pay royalties on net sales of any licensed product under the UW 2020 Agreement if the Company is required to pay royalties on net sales under the UW 2018 Agreement. Additional royalties would be due in connection with sublicenses and milestones. The Company's royalty obligations continue for each licensed product for so long as licensed patent rights exist and have not expired, been revoked, lapsed, or held unenforceable.

Unless terminated earlier, the UW 2020 Agreement will remain in effect until all licensed patent rights have terminated and all obligations due to UW have been fulfilled. The last-to-expire licensed patent, if issued, is expected to expire in 2041, subject to any adjustment or extension of patent term that may be available. UW can terminate the UW 2020 Agreement if the Company breaches or fails to perform one of its material duties under the UW 2020 Agreement and the Company is unable to remedy the default within an agreed upon time period that can be extended by UW. The Company may terminate the UW 2020 Agreement at will with prior written notice to UW.

During the year ended December 31, 2022, the Company incurred fees associated with the 2018 and 2020 Agreements, recorded as research and development expenses, of $0.5 million. During the year ended December 31, 2021, the Company incurred fees associated with the 2018 and 2020 Agreements of $0.2 million.

License Agreement with Respect to Influenza

The Company is a party to a license agreement with UW ("UW Flu License Agreement") entered into in September 2021. Pursuant to the UW Flu License Agreement, UW granted the Company a non-exclusive, worldwide, royalty-bearing, sublicensable (subject to certain restrictions) license under certain UW patents to make, use, sell, offer to sell, import, and otherwise exploit any product covered by the licensed patents ("Licensed Flu Products"), for the prophylactic and/or therapeutic treatment of influenza. UW also granted the Company a non-exclusive, worldwide license to use certain know-how related to the licensed patents. The licensed patents and know-how generally relate to computationally designed nanoparticles and vaccines based upon such designs, and relate to the Company's proprietary two-component virus-like-particle technology and nanoparticle-based influenza virus vaccines. The United States federal government and HHMI

have similar rights under the UW Flu License Agreement and the UW 2018 Agreement described above in “License Agreement with respect to RSV and Other Pathogens".

The Company is obligated to use commercially reasonable efforts to commercialize Licensed Flu Products, and to initiate a clinical trial with respect to such Licensed Flu Products by a specified date in 2025. If the Company is unable to initiate a clinical trial by the specified date and cannot agree with UW to modify such obligation or does not cure by meeting such obligation, then UW may terminate the UW Flu License Agreement.

Under the UW Flu License Agreement, the Company paid UW a one-time upfront license fee, and after September 2023 and for the remainder of the term of the UW Flu License Agreement, the Company is required to pay tiered minimum annual fees ranging from the mid four figures to the mid five figures, with such fees creditable against royalty payments. The Company is required to pay UW up to an aggregate of $6.4 million for payments related to development and commercial milestones. The Company is also required to pay UW a fixed, low single-digit percentage royalty on net sales of Licensed Flu Products by the Company and its sublicensees, subject to certain reductions if the Company is required to pay for third-party intellectual property rights in order to commercialize the Licensed Flu Products. The Company is not obligated to pay duplicate royalties on net sales of any Licensed Flu Products if the Company is already required to pay a royalty on such net sales under the UW 2018 Agreement and the UW 2020 Agreement.

Unless terminated earlier, the UW Flu License Agreement will remain in effect until all licensed patent rights have expired and all obligations due to UW have been fulfilled. The last-to-expire licensed patent, if issued, is expected to expire in 2041, subject to any adjustment or extension of patent term that may be available. UW can terminate the UW Flu License Agreement if the Company breaches or fails to perform one of its material duties under the UW Flu License Agreement and is unable to remedy the default within an agreed upon time period that can be extended by UW. The Company can terminate the UW Flu License Agreement at will with prior written notice to UW.

During the year ended December 31, 2022, the Company incurred fees associated with the UW Flu License Agreement, recorded as research and development expenses, of $0.2 million. During year ended December 31, 2021, the Company incurred fees associated with the UW Flu License Agreement of $0.1 million.

License Agreement with the University of Texas

The Company is a party to an exclusive patent license agreement with the University of Texas at Austin (“UT”) with respect to its hMPV antigen utilized in the IVX-A12 program (the “UT Agreement”). The UT Agreement was entered into in June 2021. Under the UT Agreement, UT granted the Company an exclusive, worldwide, royalty-bearing, sublicensable license under certain patent rights, to use licensed know-how for prevention, cure, amelioration or treatment of respiratory disease caused by hMPV infection in all vaccine fields, excluding up to one mRNA-based vaccine.

The Company is obligated to pay aggregate potential milestone payments of up to $4.6 million with respect to future development and commercial milestones.

Unless terminated earlier, the UT Agreement will remain in effect until all the licensed patent rights have expired. The Company may terminate the UT Agreement with prior written notice to UT. UT may terminate the UT Agreement in whole or in part, or narrow the vaccine field, reduce the territory, or convert the license from exclusive to non-exclusive if the Company: (i) fails to meet its payment obligations, (ii) commits an uncured breach, (iii) commits three or more cured breaches within a specified time period, (iv) challenges the validity, enforceability, or scope of the licensed patent rights, or (v) undergoes certain insolvency-related events.

During the year ended December 31, 2022, the Company incurred fees associated with the UT Agreement of $0.1 million, recorded as research and development expenses. During year ended December 31, 2021, the Company incurred a negligible amount in fees associated with the UT Agreement.

7. Convertible Promissory Note

In August 2020, the Company issued a $6.5 million convertible promissory note (“Convertible Promissory Note”). The Convertible Promissory Note accrued interest at a rate of 6% a year with maturity date two years from issuance.

The Convertible Promissory Note could be converted or redeemed as follows (i) automatically converted in a qualified Series B financing transaction from which the Company would receive total gross proceeds of not less than $5.0 million at a conversion price equal to 85% of the per share price paid by investors for such securities, (ii) automatically converted upon initial public offering at a conversion price equal to 85% of the per share price off common stock in the initial public offering, (iii) optionally converted into Series A-3 preferred stock if a change in control, initial public offering, or

qualified Series B financing had not occurred prior to the maturity date at a price equal to an amount determined by dividing $140 million by the fully diluted capitalization of the Company at the time of conversion, or (iv) repaid upon a change in control for an amount equal to the issue price plus accrued and unpaid interest or an amount as would have been payable if the noteholders had optionally converted into shares of Series A-3 preferred stock. The Convertible Promissory Note was converted in March 2021 in connection with the Series B financing.

The Convertible Promissory Note was accounted for in accordance with ASC 470-20, *Debt with Conversion and Other Options* ("ASC 470-20") and ASC 815-15, *Derivatives and Hedging - Embedded Derivatives* ("ASC 815-15"). Under ASC 815-15, an embedded feature is required to be bifurcated if all three conditions are met: (1) economic characteristics and risks of the embedded derivative are not clearly and closely related to the economic characteristics and risks of the host contract, (2) the hybrid instrument is not remeasured at fair value under otherwise applicable GAAP with changes in fair value reported in earnings as they occur, and (3) a separate instrument which the same terms as the embedded derivative would be considered a derivative instrument subject to derivative accounting (the initial net investment for the hybrid instrument should not be considered to be the initial net investment for the embedded derivative. The Company bifurcated certain features that were required to be accounted separately for as a single embedded derivative. The initial fair value of this derivative of $1.8 million was recorded as a liability, and as a reduction to the carrying value of the Convertible Promissory Note. The Company also incurred a negligible amount of issuance costs related to the Convertible Promissory Note, which were also recorded as a reduction to the Convertible Promissory Note on the balance sheet.

The debt discount comprised the initial fair value of the derivative liability and the issuance costs, and was amortized using the effective interest method over the two-year contractual term of the Convertible Promissory Note and presented as a direct reduction of the debt liability. The debt discount was being amortized at an effective interest rate of 23.8%.

Interest expense incurred in connection with the Convertible Promissory Note consisted of the following (in thousands):

	Year Ended December 31, 2021
Coupon interest at 6%	$ 86
Accretion of discount and amortization of issuance costs	177
Total interest expense on Convertible Promissory Note	$ 263

On March 19, 2021, in connection with the closing of the Series B convertible preferred stock financing, the Convertible Promissory Note (including accrued interest) and derivative liability converted into 2,805,850 shares of Series B-2 convertible preferred stock at an issuance price of $2.39846 per share. As a result of the conversion, the Company recorded a loss on extinguishment of convertible promissory notes of $0.8 million of other expense in the statements of operations and comprehensive loss for the year ended December 31, 2021, which included the unamortized debt issuance costs.

8. Leases

In January 2020, and amended in March 2020, the Company entered into a 12-month lease agreement with renewal options for office and laboratory space in Seattle, Washington. The lease was terminated in June 2022. The lease agreement was considered short-term and therefore, no right-of-use asset or lease liability was recorded.

In December 2021, the Company entered into a lease agreement for corporate office and laboratory space in Seattle, Washington. The Company took possession of certain leased space at various dates in January 2022 and March 2022. The lease agreement expires in December 2027 and provides for a one-time option to extend for a period of five additional years. The lease agreement provides the Company with an allowance for tenant improvements of $5.3 million that is reimbursed to the Company as construction of improvements occurs. Through December 31, 2022, the Company received $4.6 million of the tenant improvement allowance. The monthly base rent will be $0.2 million for the first year, beginning in October 2022, and will increase by 3.0% per year over the initial term. In addition, the Company is obligated to pay for common area maintenance and other costs. Under the terms of the lease agreement, the Company is required to maintain a standby letter of credit of $1.1 million at the execution of the lease agreement, reduced to $0.9 million in October 2023, and further reduced to $0.7 million in October 2024. In June 2022, the Company took possession of temporary office and laboratory space under a short-term lease that terminated in September 2022.

Classification of ROU assets and lease liabilities and the weighted-average remaining lease term and discount rate associated with operating leases are as follows (in thousands):

	As of December 31, 2022
ROU assets:	
ROU assets - operating leases	$ 3,247
Lease liabilities:	
Current portion of operating lease liabilities	2,137
Noncurrent portion of operating lease liabilities	6,658
Total lease liabilities	$ 8,795
Weighted-average remaining lease term (in years):	
Operating leases	5.0
Weighted-average discount rate:	
Operating leases	8.0%

The components of lease costs are as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Operating lease costs	$ 983	$ —
Variable lease costs	144	—
Short-term lease costs	728	396
Total lease costs	$ 1,855	$ 396

The maturities of lease liabilities and reconciliation to the present value of lease liabilities are as follows (in thousands):

	As of December 31, 2022
2023	$ 2,137
2024	2,201
2025	2,267
2026	2,335
2027	2,405
Total undiscounted lease payments	11,345
Less: lease incentives	(530)
Less: imputed interest	(2,020)
Total lease liabilities	8,795
Less: current lease liabilities	(2,137)
Lease liabilities, net of current portion	$ 6,658

9. Convertible Preferred Stock and Stockholders' Equity

Convertible Preferred Stock

In connection with the Company's IPO in August 2021, all outstanding shares of the convertible preferred stock were converted into common stock as discussed below. No convertible preferred stock was outstanding as of December 31, 2022 or December 31, 2021.

In February 2021, the Company triggered a milestone closing associated with its Series A-1 convertible preferred stock resulting in the issuance of 21,944,874 shares.

In March 2021, before the Company effected a 1-for-4.1557 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for each series of the Company's convertible preferred stock in July 2021, the Company entered into a convertible preferred stock purchase agreement for the issuance of 35,764,462 shares of Series B convertible preferred stock, $0.0001 par value per share, of which 32,958,612 shares of Series B-1 and 2,805,850 shares of Series B-2 were issued. The Series B convertible preferred stock financing resulted in net cash proceeds of $92.7 million, net of $0.35 million in issuance costs from the sale of 32,958,612 shares of Series B-1 convertible preferred stock at a price of $2.82172 per share. In addition, the Convertible Promissory Note of $6.5 million that the Company issued in August 2020, including accrued interest as of the date of

conversion of $0.2 million, was converted into 2,805,850 shares of Series B-2 convertible preferred stock on March 19, 2021 at 85% of the offering's share price.

Prior to its conversion into common stock in connection with the Company's IPO in August 2021, the Company's convertible preferred stock was classified as temporary equity on the Company's balance sheets in accordance with authoritative guidance. In connection with the Company's IPO, all outstanding shares of the convertible preferred stock converted into 21,634,898 shares of common stock and the related carrying value was reclassified to common stock and additional paid-in capital. There were no shares of convertible preferred stock outstanding as of the closing of the IPO.

On August 2, 2021, the Company amended and restated its certificate of incorporation to authorize 500,000,000 shares of common stock and 50,000,000 shares of preferred stock, which shares of preferred stock are currently undesignated. The Company does not have any outstanding preferred stock as of December 31, 2022.

Common Stock

As of December 31, 2022 and 2021, of the 500,000,000 authorized shares of common stock, 41,177,706 and 39,429,103 shares were issued, respectively. As of December 31, 2022 and December 31, 2021, shares outstanding, which excludes common stock issued from the early exercise of unvested stock options, were 41,095,564 and 39,175,279, respectively.

On August 15, 2022, the Company entered into an Equity Distribution Agreement (the "Equity Distribution Agreement") with Oppenheimer & Co. Inc. (the "Agent"), pursuant to which the Company may offer and sell shares of the Company's common stock having an aggregate offering price of up to $150.0 million from time to time, in "at the market" offerings through the Agent. Sales of the shares of common stock, if any, will be made at prevailing market prices at the time of sale, or as otherwise agreed with the Agent. The Agent will receive a commission from the Company of up to 3.0% of the gross proceeds of any shares of common stock sold under the Equity Distribution Agreement. The Company is not obligated to sell, and the Agent is not obligated to buy or sell, any shares of common stock under the Equity Distribution Agreement. During the three months ended December 31, 2022, the Company sold and issued 980,000 shares of common stock under the Equity Distribution Agreement, resulting in net cash proceeds of $9.4 million, net of $0.6 million in issuance costs.

Equity Incentive Plans

In 2017, the Company established a stock option plan (the "2017 Plan") under which incentives may be granted to officers, employees, directors, consultants and advisors. Awards under the 2017 Plan may consist of restricted stock and incentive and non-qualified stock options to purchase shares of common stock of the Company.

During 2021, the Company's stockholders approved the 2021 Incentive Plan (the "2021 Plan"), which became effective in July 2021. The 2021 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock, dividend equivalents, RSUs and other stock or cash-based awards. The number of shares of the Company's common stock initially reserved for issuance under the 2021 Plan was 4,600,000 shares; plus the shares of common stock remaining available for issuance under the 2017 Plan as of the effective date of the 2021 Plan, as well as any shares subject to outstanding awards under the 2017 Plan as of the effective date of the 2021 Plan that become available for issuance under the 2021 Plan thereafter in accordance with its terms. The number of shares initially available for issuance increases annually on January 1 of each calendar year beginning in 2022 and ending in and including 2031, equal to the lesser of (A) 5% of the shares outstanding on the final day of the immediately preceding calendar year and (B) a smaller number of shares as determined by the Company's board of directors. The reserve for the 2021 Plan increased by 2,058,885 shares effective January 1, 2023. No more than 50,000,000 shares of common stock may be issued under the 2021 Plan upon the exercise of incentive stock options.

The 2021 Plan is administered by the Board of Directors of the Company or a committee appointed by the Board of Directors, which determines the types of awards to be granted, including the number of shares subject to the awards, the exercise price and the vesting schedule. All option and service-based RSU awards are subject to a time-based vesting period which will generally be four years. Performance-based RSU awards are subject to vesting conditions based on the achievement of specified milestones related to development of vaccine candidates. Certain option and RSU awards provide for accelerated vesting if there is a change in control or if other contractually specified contingencies are met.

The term of stock options granted under the 2021 Plan cannot exceed ten years (or five years in the case of incentive stock options granted to certain significant stockholders). Options shall not have an exercise price less than 100% of the fair market value of the Company's common stock on the grant date (or 110% in the case of incentive stock

options granted to certain significant stockholders), except with respect to certain substitute awards granted in connection with a corporate transaction.

Common stock reserved for future issuance consisted of the following:

	As of December 31, 2022
Common stock options and restricted stock units granted and outstanding	9,387,963
Shares available for issuance under the equity incentive plans	2,409,593
Shares available for issuance under the 2021 Employee Stock Purchase Plan	706,413
Total common stock reserved for issuance	12,503,969

A summary of the status of the options issued under the Company's equity incentive plans as of December 31, 2022, and information with respect to the changes in options outstanding is as follows (in thousands, except share and per share data):

	Options Outstanding	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at December 31, 2021	6,591,727	$ 8.04		
Granted	3,112,560	9.66		
Exercised	(395,050)	1.48		
Forfeited	(377,233)	10.91		
Expired	(547,014)	5.32		
Balance at December 31, 2022	8,384,990	$ 9.00	8.72	$ 20,499
Vested and expected to vest as of December 31, 2022	8,384,990	$ 9.00	8.72	$ 20,499
Vested and exercisable at December 31, 2022	2,219,625	$ 8.06	8.31	$ 5,636

Exercisable options in the table above reflect the number of options vested as of the date reported. Options that were granted under the 2017 Plan permitted early exercise. Cash received for early exercise of unvested options is recognized as an other noncurrent liability in the accompanying balance sheet and totaled $0.1 million at December 31, 2022.

The aggregate intrinsic value in the table above is calculated as the difference between the exercise price of the underlying options and the fair value of the Company's common stock for all options that were in-the-money as of December 31, 2022. The aggregate intrinsic value of options exercised during the years ended December 31, 2022 and 2021 was $5.1 million and $1.0 million, respectively.

The weighted-average grant date fair value of options granted during the years ended December 31, 2022 and 2021 was $7.33 and $8.52 per share, respectively.

A summary of the status of RSUs issued under the Company's equity incentive plans as of December 31, 2022, and information with respect to the changes in RSUs outstanding is as follows:

	Service-based RSUs		Performance-based RSUs	
	Units	Weighted Average Grant-Date Fair Value	Units	Weighted Average Grant-Date Fair Value
Nonvested at December 31, 2021	388,500	$ 25.96	—	$ —
Granted	906,271	$ 12.25	60,000	$ 18.74
Vested	(278,281)	$ 11.34	(24,000)	$ 10.91
Forfeited	(49,517)	$ 16.45	—	$ —
Nonvested at December 31, 2022	966,973	$ 17.81	36,000	$ 3.08
Expected to vest at December 31, 2022	966,973	$ 17.81	—	$ —

The total fair value of RSUs vested during the year ended December 31, 2022 was $1.6 million. No RSUs vested during the year ended December 31, 2021. The weighted-average grant date fair value of RSUs granted during the year ended December 31, 2021 was $25.96 per share.

Employee Stock Purchase Plan

During 2021, the Company's stockholders approved the 2021 Employee Stock Purchase Plan (the "ESPP"), which became effective in July 2021. The ESPP permits eligible employees who elect to participate in an offering under the ESPP to have up to 15% of their eligible earnings withheld, subject to certain limitations, to purchase shares of common stock pursuant to the ESPP. The price of common stock purchased under the ESPP is equal to 85% of the lower of the fair market value of the common stock at the commencement date of each offering period or the relevant date of purchase. The number of shares of common stock initially reserved for issuance under the ESPP was 400,000 shares. The number of shares of common stock reserved for issuance under the ESPP increased on January 1, 2022 and will increase each January 1 thereafter through January 1, 2031, in an amount equal to the lower of (1) 1% of the aggregate number of shares of common stock of the Company outstanding on the final day of the immediately preceding calendar year and (2) such smaller number of shares of common stock as determined by the Board, provided that no more than 15,000,000 shares of our common stock may be issued under the ESPP. The reserve for the ESPP increased by 411,777 shares effective January 1, 2023. During the year ended December 31, 2022, 71,272 shares were purchased by employees under the ESPP, and during the year ended December 31, 2021, 16,606 shares were purchased by employees under the ESPP. Stock-based compensation expense related to the ESPP for the years ended December 31, 2022 and 2021 was $0.3 million and $0.1 million, respectively.

Stock-Based Compensation Expense

Stock-based compensation expense for all equity awards and the ESPP, has been reported in the statements of operations and comprehensive loss as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Research and development	$ 8,123	$ 2,710
General and administrative	13,571	26,321
Total	$ 21,694	$ 29,031

The Company recognizes compensation expense for options and RSU awards based on their grant date fair value. The compensation expense is recognized over the requisite service period on a straight-line basis.

The fair value of RSUs is equal to the closing stock price on the date of grant. The fair value of each stock option granted was estimated using the Black-Scholes option pricing model. The assumptions used in the Black-Scholes option pricing model to estimate the fair value of the stock option grants issued during years ended were as follows:

	Year Ended December 31,	
	2022	2021
Risk-free rate of interest	1.43%-4.15%	0.63%-1.34%
Expected term (years)	5.27 - 6.08 years	5.77 - 6.08 years
Expected stock price volatility	89.3% - 118.1%	84.2% - 90.9%
Dividend yield	0%	0%

As of December 31, 2022, the unrecognized compensation cost related to outstanding stock options and RSU awards was $43.4 million and $14.1 million, respectively, and is expected to be recognized as expense over a weighted-average period of approximately 2.68 years.

On August 4, 2021, as a result of the death of Tadataka (Tachi) Yamada, M.D., the Company's former Chairman, the Company's Board of Directors decided to accelerate the vesting of all of Dr. Yamada's previously unvested stock options as of the date of his death. The Company accelerated the vesting of 611,639 stock options, with exercise prices ranging from $0.83 to $5.90 per share, resulting in incremental non-cash, stock-based compensation of $21.0 million being recorded in 2021 as general and administrative expense.

10. Income Taxes

The reconciliations of the U.S. statutory federal income tax rates to the Company's effective tax rates were as follows:

	Year Ended December 31,	
	2022	2021
U.S. federal statutory income tax rate	21.0%	21.0%
Adjustments for the tax effects of:		
State income taxes, net of federal tax	1.1	1.0
Other permanent differences	0.4	(0.4)
Research and development tax credits	3.4	3.1
Research and development credit permanent adjustment	—	(0.6)
Stock-based compensation	(2.2)	(1.6)
Uncertain tax positions	(0.9)	(0.8)
Change in valuation allowance	(22.8)	(21.7)
Effective income tax rate	—%	—%

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The significant components of our deferred tax assets and liabilities are as follows (in thousands):

	As of December 31,	
	2022	2021
Deferred tax assets		
Net operating loss carryforwards	$ 17,304	$ 12,623
Capitalized research and development	11,731	—
Research and development credits	4,599	2,349
Deferred revenue	—	126
Operating lease liabilities	1,951	—
Stock-based compensation	2,203	5,192
Other	712	533
Total deferred tax assets	38,500	20,823
Deferred tax liabilities		
Property and equipment	(1,135)	—
Right-of-use assets – operating leases	(720)	—
Other	(269)	(280)
Total deferred tax liabilities	(2,124)	(280)
Less: valuation allowance	(36,376)	(20,543)
Net deferred tax assets	$ —	$ —

The Tax Cuts and Jobs Act enacted in December 2017 contained a provision that requires the capitalization of Section 174 costs incurred in years beginning on or after January 1, 2022. Section 174 costs are expenditures which represent research and development costs that are incident to the development or improvement of a product, process, formula, invention, computer software, or technique. This provision changes the treatment of Section 174 costs such that the expenditures are no longer allowed as an immediate deduction but rather must be capitalized and amortized. The Company has included the impact of this provision, which results in a deferred tax asset of approximately $11.7 million as of December 31, 2022.

Due to the uncertainty surrounding the realization of deductible tax attributes in future tax returns, the Company has recorded a valuation allowance against its net deferred tax assets as of December 31, 2022 and 2021. Utilization of the net operating loss carryforwards is dependent on future taxable income. As such, realization is not assured, and a valuation allowance has been established.

The valuation allowance for deferred tax assets was approximately $36.4 million as of December 31, 2022, an increase of $15.8 million during the year ended December 31, 2022. The Company has total net operating loss carryforwards for U.S. federal income tax and state purposes of approximately $76.2 million and $30.8 million, respectively, as of December 31, 2022 which begin to expire in 2037 and 2035, respectively. Federal net operating losses generated after January 1, 2018 will be carried forward indefinitely. The Company has federal research and development tax credit carryforwards of approximately $5.9 million as of December 31, 2022, which begin to expire in 2037. Additionally, the Company has state research and development credit carryforwards of approximately $0.3 million as of December 31, 2022, which begin to expire in 2032. The operating loss carryforwards and research and development tax credits may be limited due to a change in control in the Company's ownership as defined by the Internal Revenue Code Sections 382 and 383.

The Company files federal and state income tax returns. The Company is not currently under examination but is open to audit by the I.R.S. and state tax authorities for tax years beginning in 2017. The resolutions of any examinations are not expected to be material to these financial statements. As of December 31, 2022, there are no penalties or accrued interest recorded in the financial statements.

A reconciliation of the beginning and ending amount of unrecognized tax benefits for uncertain tax positions were as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Unrecognized tax benefits, beginning of year	$ 758	$ 263
Additions based on tax positions relating to current year	775	495
Additions based on tax positions relating to prior year	14	—
Unrecognized tax benefits, end of year	$ 1,547	$ 758

The Company does not believe it is reasonably possible that its unrecognized tax benefits will change materially in the next twelve months.

11. Employee Savings Plan

The Company has a defined contribution 401(k) savings plan for those employees who meet minimum eligibility requirements. Under the terms of the plan, eligible employees may contribute up to 90% of their annual compensation to the plan, subject to Internal Revenue Service limitations. The Company may also, at its sole discretion, make contributions to the plan. The Company contributed $0.1 million to the plan during the year ended December 31, 2022. The Company did not make any contributions to the plan during 2021.

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

None.

Item 9A. Controls and Procedures

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Annual Report. Based on such evaluation, our principal executive officer and principal financial officer have concluded that as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) and Rule 15d-15(f) under the Exchange Act as of the end of the period covered by this Annual Report. Our internal control over financial reporting is a process designed by, or under the supervision of, our principal executive officer and principal financial officer to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP.

Our internal control over financial reporting includes those policies and procedures that:

(i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;

(ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

(iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. 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. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2022. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) Internal Control-Integrated Framework (2013). Based on our assessment using those criteria, our management has concluded that, as of December 31, 2022, our internal control over financial reporting was effective.

Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of our registered public accounting firm due to an exemption provided by the JOBS Act for "emerging growth companies" and our status as a non-accelerated filer under the Exchange Act.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting 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.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information required by this item and not set forth below will be set forth in the sections titled *"Election of Directors* and *Executive Officers"* contained in our definitive Proxy Statement to be filed with the Commission within 120 days after the conclusion of our year ended December 31, 2022 (the Proxy Statement) pursuant to General Instructions G(3) of Form 10-K and is incorporated herein by reference.

We have adopted a Code of Business Conduct and Ethics that applies to all officers, directors and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or person performing similar functions. A current copy of the Code of Business Conduct and Ethics is available on the Corporate Governance section of our website at https://investors.icosavax.com/. If we make any substantive amendments to the Code of Business Conduct and Ethics or grants any waiver from a provision of the Code of Business Conduct and Ethics to any executive officer or director that are required to be disclosed pursuant to SEC rules, we will promptly disclose the nature of the amendment or waiver on our website or in a current report on Form 8-K.

Item 11. Executive Compensation

The information required by this item will be set forth in our Proxy Statement in the section titled *"Executive and Director Compensation"* contained in our Proxy Statement and is incorporated herein by reference.

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

Information required by this item will be set forth in the sections titled *"Security Ownership of Certain Beneficial Owners and Management"* and *"Executive and Director Compensation"* contained in our Proxy Statement and is incorporated herein by reference.

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

Information required by this item will be set forth in the sections titled *"Certain Related-Person Transactions"* and *"Information Regarding the Board of Directors and Corporate Governance"* contained in our Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

Information required by this item will be set forth in the section titled *"Ratification of Selection of Independent Registered Public Accounting Firm"* contained in our Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits, and Financial Statement Schedules

1. All financial statements

The financial statements of Icosavax, Inc., together with the report thereon of Ernst & Young LLP, an independent registered public accounting firm, are included in this Annual Report beginning on page 99.

2. Financial Statement schedules

None.

3. Exhibits

A list of exhibits is set forth on the Exhibit Index immediately preceding the signature page of this Annual Report and is incorporated herein by reference.

Item 16. Form 10-K Summary

None.

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation	8-K	8/2/2021	3.1	
3.2	Amended and Restated Bylaws	8-K	8/2/2021	3.2	
4.1	Specimen stock certificate evidencing the shares of common stock	S-1/A	7/22/2021	4.1	
4.2	Amended and Restated Investors' Rights Agreement, dated March 19, 2021, by and among the Registrant and certain of its stockholders	S-1/A	7/22/2021	4.2	
4.3	Description of Registered Securities	10-K	3/30/2022	4.3	
10.1#	Icosavax, Inc. 2021 Incentive Award Plan, form of stock option agreement thereunder, and form of restricted stock unit agreement	S-1/A	7/22/2021	10.2	
10.2#	Icosavax, Inc. 2021 Employee Stock Purchase Plan	S-1/A	7/22/2021	10.3	
10.3#	Icosavax, Inc. Annual Bonus Plan	10-Q	5/16/2022	10.1	
10.4#	Amended and Restated Employment Letter Agreement, dated July 22, 2021, by and between Adam Simpson and the Registrant	S-1/A	7/22/2021	10.12	
10.5#	Amended and Restated Employment Letter Agreement, dated July 22, 2021, by and between Douglas Holtzman, Ph.D. and the Registrant	S-1/A	7/22/2021	10.13	
10.6#	Amended and Restated Employment Letter Agreement, dated July 22, 2021, by and between Niranjan Kanesa-Thasan, M.D. and the Registrant	S-1/A	7/22/2021	10.14	
10.7#	Amended and Restated Employment Letter Agreement, dated July 22, 2021, by and between Cassia Cearley and the Registrant	S-1/A	7/22/2021	10.15	
10.8#	Amended and Restated Employment Letter Agreement, dated July 22, 2021, by and between Thomas J. Russo and the Registrant	S-1/A	7/22/2021	10.17	
10.9#	Employment Letter Agreement, dated August 9, 2021, by and between Elizabeth Bekiroglu and the Registrant	10-Q	11/15/2021	10.10	
10.10#	Form of Indemnification Agreement for Directors and Officers	S-1	7/7/2021	10.18	
10.11†	Exclusive License Agreement, dated June 29, 2018, between the Registrant and University of Washington, as amended	S-1	7/7/2021	10.19	

10.12†	License and Exclusive Option Agreement, dated July 2, 2020, between the Registrant and University of Washington, as amended	S-1	7/7/2021	10.20	
10.13†	Non-Exclusive Patent License Agreement, dated June 28, 2018, between the Registrant and National Institute of Allergy and Infectious Diseases, as amended	S-1	7/7/2021	10.21	
10.14†	Patent License Agreement, dated June 2, 2021, between the Registrant and the University of Texas at Austin	S-1	7/7/2021	10.24	
10.15†^	Lease Agreement, dated December 15, 2021, by and between Boren Lofts Owner (DE) LLC	10-K	3/30/2022	10.18	
10.16†	Non-Exclusive License Agreement, dated September 16, 2021, by and between the University of Washington and the Registrant	10-K	3/30/2022	10.19	
10.17†	Amendment No. 3 to Exclusive License Agreement, effective as of June 3, 2022 between the University of Washington and the Registrant	10-Q	8/15/2022	10.1	
10.18	Equity Distribution Agreement, dated August 15, 2022 by and between the Registrant and Oppenheimer & Co. Inc.	S-3	8/16/2022	1.2	
23.1	Consent of Independent Registered Public Accounting Firm				X
31.1	Certification of Chief Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				X
31.2	Certification of Chief Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				X
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document				X
101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document				X
101.LAB	Inline XBRL Taxonomy Label Linkbase Document				X
101.PRE	Inline XBRL Presentation Linkbase Document				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				X

# Indicates management contract or compensatory plan.

† Portions of this exhibit have been omitted for confidentiality purposes.

* This certification is deemed not filed for purpose of section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

^ Certain exhibits and schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant hereby undertakes to furnish supplementally a copy of any omitted exhibit or schedule upon request by the SEC.

SIGNATURES

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

ICOSAVAX, INC.

Date: March 30, 2023

By: /s/ Adam Simpson
Adam Simpson
Chief Executive Officer and Director

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

SIGNATURE	TITLE	DATE
/s/ Adam Simpson Adam Simpson	Chief Executive Officer and Director (principal executive officer)	March 30, 2023
/s/ Thomas Russo, CFA Thomas Russo, CFA	Chief Financial Officer (principal financial and accounting officer)	March 30, 2023
/s/ Mark McDade Mark McDade	Chairman	March 30, 2023
/s/ Peter Kolchinsky, Ph.D. Peter Kolchinsky, Ph.D.	Director	March 30, 2023
/s/ Heidi Kunz Heidi Kunz	Director	March 30, 2023
/s/ John Shiver, Ph.D. John Shiver, Ph.D.	Director	March 30, 2023
/s/ Ann M. Veneman Ann M. Veneman	Director	March 30, 2023
/s/ James Wassil James Wassil	Director	March 30, 2023

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