SECURITIES AND EXCHANGE COMMISSION

# **FORM 10-K**

Annual report pursuant to section 13 and 15(d)

Filing Date: 2022-03-30 | Period of Report: 2021-12-31 SEC Accession No. 0000950170-22-005064

(HTML Version on secdatabase.com)

### **FILER**

### Icosavax, Inc.

CIK:1786255| IRS No.: 000000000 | State of Incorp.:DE | Fiscal Year End: 1231 Type: 10-K | Act: 34 | File No.: 001-40655 | Film No.: 22787425 SIC: 2836 Biological products, (no disgnostic substances) Mailing Address 1616 EASTLAKE AVE E, SUITE 208 SEATTLE WA 98102 Business Address 1616 EASTLAKE AVE E, SUITE 208 SEATTLE WA 98102 (206) 737-0085

### 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, 2021

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 (State or other jurisdiction of incorporation or organization) 82-3640549 (I.R.S. Employer Identification No.)

1616 Eastlake Avenue E., Suite 208 Seattle, Washington (Address of principal executive offices)

98102 (Zip Code)

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

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

	Trading	
Title of each class	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  $\Box$  No  $\blacksquare$ 

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act: Yes  $\Box$  No  $\square$ 

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  $\square$  No  $\square$ 

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  $\square$  No  $\square$ 

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

Large accelerated filer □ Non-accelerated filer ☑ Accelerated filer □ Smaller reporting company ☑ Emerging growth company

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

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

As of June 30, 2021, the last business day of the registrant's most recently completed second fiscal quarter, there was no established public trading market for the registrant's equity securities. The registrant's common stock began trading on the Nasdaq Global Select Market on July 29, 2021.

As of March 28, 2022, the registrant had 39,724,980 shares of common stock (\$0.0001 par value) outstanding.

### DOCUMENTS INCORPORATED BY REFERENCE

Certain sections of the registrant's definitive proxy statement for the 2022 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.

### TABLE OF CONTENTS

PART I Item 1. Item 1A. Item 1B. Item 2. Item 3. Item 4.	Business Risk Factors Unresolved Staff Comments Properties Legal Proceedings Mine Safety Disclosures	2 3 47 105 105 105 105
PART II Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity	<b>106</b>
Item 6. Item 7. Item 7A. Item 8. Item 9. Item 9A. Item 9B. item 9C.	[Reserved] Management's Discussion and Analysis of Financial Condition and Results of Operations Quantitative and Qualitative Disclosures About Market Risk Financial Statements and Supplementary Data Changes in and Disagreements with Accountants on Accounting and Financial Disclosure Controls and Procedures Other Information Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	107 108 116 118 142 142 142 142 142
PART III Item 10. Item 11. Item 12. Item 13. Item 14.	Directors, Executive Officers and Corporate Governance Executive Compensation Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters Certain Relationships and Related Transactions, and Director Independence Principal Accounting Fees and Services	<b>143</b> 143 143 143 143 143
PART IV Item 15. Item 16.	Exhibits, Financial Statement Schedules Form 10-K Summary Signatures	<b>144</b> 144 144 146

### 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, 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 impact of COVID-19 on our business, 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 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 for either RSV or hMPV, which are two common causes of pneumonia in older adults. We initiated a clinical trial of IVX-121 in September 2021, with interim topline data expected in the second quarter of 2022. Contingent on favorable results from the IVX-121 clinical trial and completion of Good Manufacturing Practices (cGMP) manufacturing of IVX-241, we plan to submit an investigational new drug application (IND) to the U.S. Food and Drug Administration (FDA) and, thereafter, initiate a clinical trial of our combination vaccine candidate, IVX-A12, in the second half of 2022.

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. We are conducting a Phase 1/2 clinical trial of our coronavirus disease 2019 (COVID-19) candidate IVX-411 in Australia and reported interim topline results for this clinical trial in March 2022. Overall, although an immune response was observed and the initial reactogenicity data were favorable, the level of immunogenicity response was below our expectations. We are conducting further analysis of the data and our IVX-411 vaccine candidate, including an investigation into the manufacture, shipment, and vaccine administration in the Phase 1/2 clinical trial. We will further evaluate our plans with respect to our current COVID-19 vaccine candidates based on the results of these efforts. We also have licensed the rights to develop and commercialize an influenza VLP vaccine from the University of Washington (UW) and have an emerging flu program.

### **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 and pneumonia in older adults. We initiated a Phase 1/1b clinical trial in September 2021 to assess the safety and immunogenicity of IVX-121 against RSV in adults aged 18-45 and 60-75. We expect to report interim topline data from this trial in the second quarter of 2022. Contingent on favorable results, we plan to combine IVX-121 with our hMPV VLP vaccine candidate, IVX-241, to produce our bivalent vaccine candidate, IVX-A12, and to advance this combination vaccine candidate into clinical development. We have completed our pre-IND meeting for the IVX-A12 combination bivalent RSV and hMPV VLP vaccine candidate and expect to begin our Phase 1 trial for IVX-A12 in the second half of 2022. We believe that a bivalent RSV and hMPV targeted VLP vaccine has the potential to provide a more optimal approach to preventing these two common causes of pneumonia, neither of which currently has an approved vaccine.

•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 SARS-CoV-2 and in influenza, and we have programs in both of these indications. We also plan to evaluate the development of VLP candidates for other indications with high unmet need, and 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 programs, we plan to identify and contract with large-scale commercial contract development and manufacturing organizations

early in the development process. We plan 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 and build the scale-up capability that is also needed for delivering on our vision of a pan-respiratory vaccine.

•Further optimizing our VLP platform technology. We intend to invest in process enhancements that we believe could enable a 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, 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.

•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 basis partnerships or strategic collaborations to accelerate development or commercialization in key regions with third parties who have complementary capabilities that allow us to enhance the value of our pipeline.

### **Our VLP Technology**

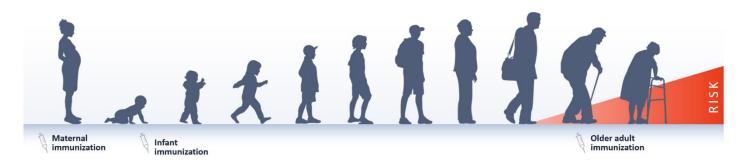
Our technology platform is based on the VLP approach to vaccine development, which we believe has been validated through the regulatory approvals and commercial success of third-party, naturally occurring VLP vaccines and has several benefits. These naturally occurring VLPs have shown the ability to 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 IPD) 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 other VLP technologies. Our licensed VLP technology utilizes a two-component 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 more 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.



### WANING IMMUNITY WITH TIME CREATES RISK FOR INFECTION AND HOSPITALIZATION



Our initial focus is on the development of vaccines to prevent respiratory disease and 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 RSV, hMPV, 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.

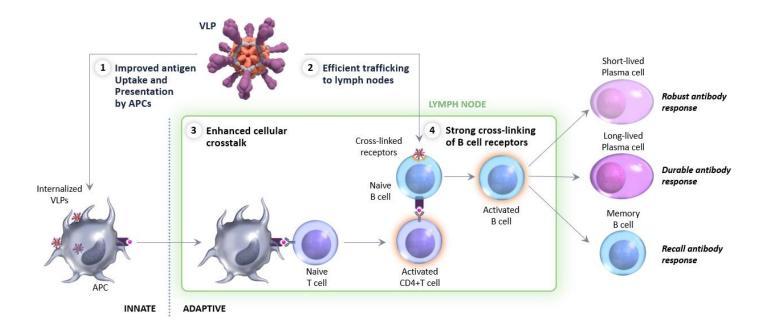
We predict that as more vaccines targeting the older adult community are developed, combination vaccines will become the preferred approach for older adults, similar to what has occurred with pediatric and young adult vaccines. We believe an early focus on combination vaccine candidates against respiratory 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 vaccines on the market (e.g., for HPV and HBV) and vaccines in development (e.g., for norovirus) that are based on 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 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 antigens.

The robust response to VLPs is 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 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 thought 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 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 \$5.7 billion in 2021 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.

VLP-based vaccines have also induced cross-protective immune responses against related virus strains not included in the vaccine. This result was believed to be due to antibody responses against subdominant epitopes that only provoke an immune response when presented to the immune system in a multivalent form. Cross-protective immune responses have been seen in clinical and post-marketing surveillance data from approved HPV vaccines, Phase 2 data from the Takeda/HilleVax norovirus VLP candidate, as well as preclinical data with influenza vaccines using our two-component VLP platform.

### Limitations of Current 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 not all pathogens have protective antigens that

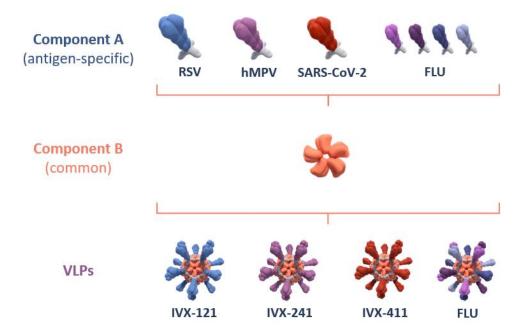
naturally form VLPs, this limits the specific pathogens that can be targeted with this approach. Several developers have and are currently utilizing various other approaches to develop and manufacture VLP-based vaccines. One approach is to use proteins from viruses that naturally form VLPs (e.g., tobacco 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—Two-Component Computationally Designed VLP Technology

We believe that our two-component VLP platform technology, licensed from the UW, retains the benefits of the naturally occurring VLPs while potentially overcoming the constraints and limitations seen in other VLP technologies to date. Our platform is based on technology developed by researchers at the UW IPD, who pioneered a computationally designed VLP system with potential to address a wide range of vaccine targets.

Our licensed VLP technology encompasses VLPs formed from two protein components that are separately produced using traditional recombinant protein manufacturing techniques. 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 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 VLP.

We are focusing our current development efforts on a single 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.

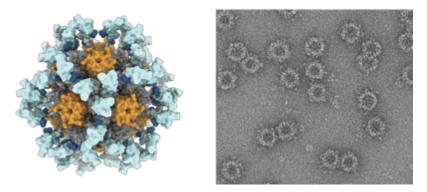


Component A and Component B are expressed and purified separately prior to assembly. Upon mixture, the two protein components self-assemble into an icosahedral VLP displaying 20 copies of a trimeric antigen, such as RSV or



hMPV, or 60 copies of a monomeric antigen, such as the RBD antigen in the SARS-CoV-2 vaccine candidate, as illustrated below.

#### SARS-CoV-2 VLP Vaccine Candidate



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 support the potential of our platform to generate VLPs that induce high nAb levels, durable immunogenicity and cross-protection against related viral strains.

•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 two-component technology facilitates the use of standard, scalable recombinant protein 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**

Prior to COVID-19, the global vaccine market was estimated to be over \$50 billion in 2020 and was anticipated to grow to over \$100 billion by 2027. Over \$12.5 billion in 2020 was from vaccines for influenza and pneumococcus, two of the leading causes of pneumonia. Vaccines against COVID-19 have grown the vaccine market considerably in 2021 with estimated sales of over \$60 billion. The future endemic market is estimated by market research firms to stabilize at up to \$20 billion per year. While mRNA vaccines have contributed largely to the COVID vaccine market, recombinant, conjugate and subunit vaccines, which include VLP-based vaccines, make up over 50% of the non-COVID vaccine market. Prior to the COVID-19 pandemic, the global vaccine market was expected to grow rapidly at a compound annual growth rate of 10% between 2019 and 2027. The increased awareness of infectious diseases and importance of vaccines driven by the COVID-19 pandemic is likely to increase vaccine utilization further, particularly for respiratory viruses.

Prior to the COVID-19 pandemic, lower respiratory infection (LRI), including pneumonia, was the leading cause of death and hospitalization from infections and the fourth highest cause of death globally. Older adults are particularly susceptible to respiratory pathogens and it is estimated that prior to COVID-19, 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 the UW.

- \* Icosavax does not plan to pursue the IVX-121 RSV monovalent candidate as a standalone candidate for RSV in older adults and plans to transition development to the IVX-A12 bivalent RSV/hMPV candidate following Phase 1. The RSV antigen incorporated into IVX-121 is licensed from the National Institutes of Health; key mutations in the hMPV antigen incorporated into IVX-A12 are licensed from the National Institute of Health (NIH) and the University of Texas at Austin (UT).
- <sup>^</sup> Icosavax has 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. As part of our ongoing response to emerging variants, we have initiated preclinical development of a potential Omicron VLP vaccine candidate for evaluation as a possible back-up in COVID-19 or incorporation as a possible component of a multivalent COVID-19 candidate.

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. The COVID-19 pandemic has increased awareness of the impact of LRIs on older adult mortality and morbidity with over 75% of the 934,000 deaths in the United States in people over the age of 65 attributable to LRIs as of February 19, 2022. Even 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, including RSV and hMPV. 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. We have licensed a prefusion stabilized form of the RSV F antigen, DS-Cav1, from the NIH that has been demonstrated in clinical trials

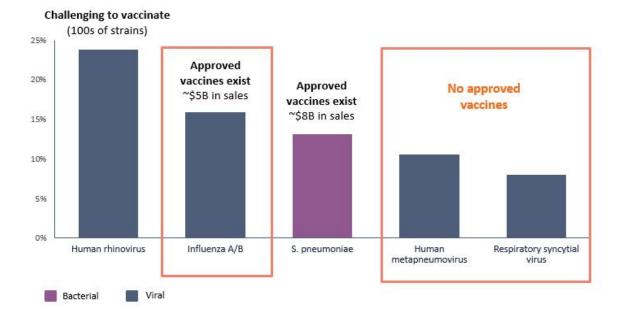
conducted by the NIH to be a robust immunogen. An initial clinical trial with DS-Cav1 showed an induction of nAb titers much higher than had previously been seen with other postfusion vaccine approaches to RSV. We have incorporated

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 UT. We have been assessing 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. We also plan to conduct a Phase 2 clinical trial to evaluate the optimal ratio of IVX-121 to IVX-241 in humans. 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 also plan to assess in clinical trials.

We initiated clinical development of IVX-A12 with a clinical trial of IVX-121. We initiated a Phase 1/1b clinical trial in September 2021 to assess the safety and immunogenicity of IVX-121 in adults aged 18-45 and 60-75. We expect to report interim topline data from this trial in the second quarter of 2022. Assuming favorable results, we plan to submit an IND to the FDA and thereafter initiate a Phase 1 clinical trial of IVX-A12 to assess its safety and immunogenicity in healthy younger and older adults. We have completed our pre-IND meeting for the IVX-A12 combination bivalent RSV and hMPV VLP vaccine candidate and we expect to begin our Phase 1 trial for IVX-A12 in the second half of 2022. We believe that a bivalent VLP vaccine targeting RSV and hMPV is an optimal approach to prevent these two common causes of pneumonia, neither of which has an approved vaccine to date.

### IVX-A12 Market Opportunity

Marketed vaccines for pneumococcus and influenza, two major causes of pneumonia, had an estimated combined annual 2020 global revenue of \$13 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 \$8 billion in 2020 and is projected to grow to around \$13.5 billion in 2030. The influenza market size is challenging to estimate due to the number of marketed vaccines worldwide but was estimated to be around \$4.5 billion in 2020 and is projected to grow to around \$8 billion by 2027. 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 75% in the 2020-2021 season. Pneumococcal vaccine uptake is also estimated to be around 70% in adults over 65 years of age. Pneumovax23, a pneumococcal 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 for RSV or 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) guidelines. 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. This applied to both monovalent (RSV only) and combination vaccines that incorporate an RSV component. The quantitative survey results suggested that policy recommendations were likely to drive immediate vaccine utilization of an RSV vaccine. In addition, survey results 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.

### IVX-121—RSV VLP Vaccine Candidate

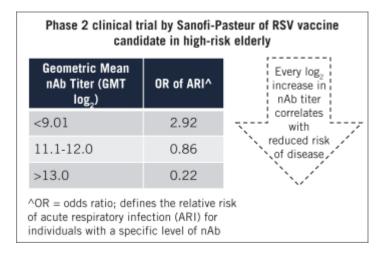
### Overview of RSV

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

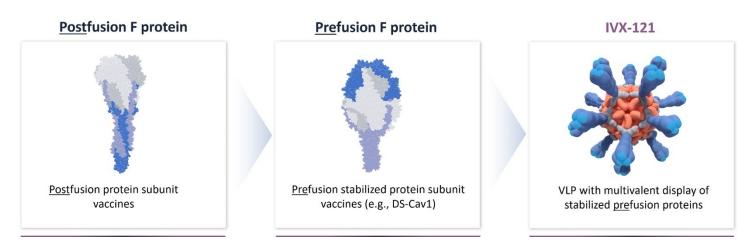
### Prefusion RSV-F Protein-Based Vaccines May Generate Higher Neutralizing Antibody Titers than Postfusion Vaccines

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 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, and RSV-F is the focus of most RSV vaccine development efforts. 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.

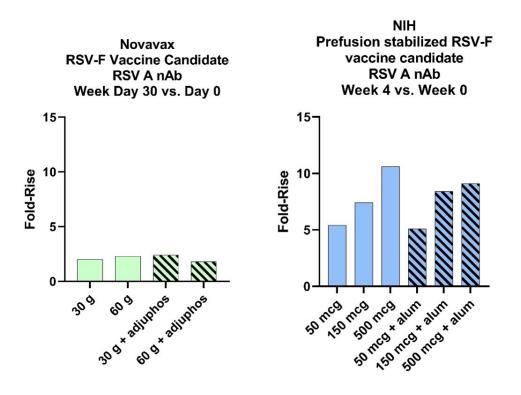


We believe that multivalent, particle-based display of the DS-Cav1 antigen has the potential to improve antigen presentation and B cell receptor cross-linking as has been observed with other VLPs. In addition, we have observed that the fusion of DS-Cav1 to the assembly domain of Component A of the VLP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

### Clinical Proof-of-Concept of RSV Prefusion Vaccine from the NIH

The NIH conducted a Phase 1 trial of DS-Cav1 in healthy volunteers to evaluate dose, safety, tolerability and immunogenicity of the stabilized RSV prefusion subunit protein vaccine alone or with aluminum hydroxide (alum), a commonly used aluminum salt adjuvant. Adjuvants can be used to induce a stronger immune response in people vaccinated. Aluminum salts are a widely used adjuvant in human vaccines and pose a low safety risk to humans based on hundreds of studies conducted to date with aluminum salt adjuvanted vaccines. In the NIH trial, 95 healthy adult subjects 18-50 years of age were vaccinated with formulations of DS-Cav1 with or without alum at dose levels of 50, 150, or 500 micrograms of prefusion antigen. Subjects received intramuscular vaccinations at day 0 and at week 12. Published results demonstrated that a single immunization resulted in a 5.1 to 10.6-fold increase in nAb titers from baseline to week 4 against RSV/A, as illustrated in the figure on the right below. A second immunization did not impact long-term neutralization. Although NIH's trial did not include a head-to-head comparison against other RSV vaccine candidates, the increase in nAb titers from baseline observed in this trial was higher than the ~1.5 to 4-fold rises observed with previous postfusion RSV-F protein-based vaccine candidates. As an example, in Novavax's Phase 1 clinical trial of an RSV-F candidate in adults aged 18-49, a 1.5 to 2.4-fold rise across non-adjuvanted or aluminum salt (Adjuphos) adjuvanted groups was observed over a similar time period, as illustrated in the figure on the left below. We believe the NIH data supported the hypothesis that stabilizing the prefusion structure has the potential to improve the functional immune response against the RSV F antigen. Neutralizing titers against the important viral subtype RSV/B were also increased 4.4 to 8.4-fold in the NIH trial, indicating comparative increases in breadth of the humoral response. The aluminum salt adjuvants showed limited effect in both the NIH and Novavax trials.





Novavax data from Glenn et al., 2013; DS-Cav1 data from Ruckwardt et al., 2021

### 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 Preclinical Results

We have completed multiple preclinical studies of IVX-121 and precursor candidates in animal models of RSV. As all adults are expected to have been exposed to RSV, we believe the most relevant animal models are those that use animals that are first infected with RSV prior to vaccination. In these models, animals' immune systems are given prior exposure to the virus (i.e., primed), similar to what would be expected in human adults.

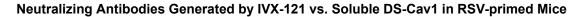
*IVX-121 Preclinical Data in RSV-Primed Models.* To evaluate the ability of IVX-121 to stimulate immune responses in animals with pre-existing immunity, BALB/c mice were infected with RSV and allowed to recover over a 3-month period. To reduce experimental variability, animals were randomized into groups based on their Day 28 RSV/A neutralizing titers. Animals were evaluated for pre-boost baseline titers on Day 91 and then immunized with either IVX-121 or soluble DS-Cav1 vaccine formulations, with or without Alhydrogel, a commonly used aluminum-based adjuvant. Ten days after the immunization blood was collected for assessment of nAb titers.

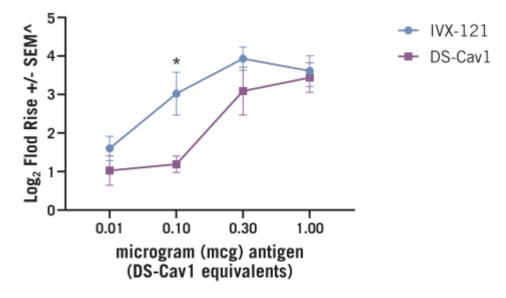
To account for variability in the immune response of individual animals to RSV infection, it is necessary to evaluate the relative rise in nAb titers over baseline in each animal. Dose levels of IVX-121 were matched with dose levels of DS-Cav1 meaning a 0.1 microgram dose of IVX-121 would have 0.1 micrograms of DS-Cav1 in the VLP preparation.

As shown in the figure below, IVX-121 induced strong nAb responses that were statistically superior to DS-Cav1 at the 0.1 microgram dose (p<0.05) using both parametric (t-test) and non-parametric tests (Wilcoxon test). The maximum increase in nAb titers (>15x) for the aqueous IVX-121 formulation was seen at the 0.3 microgram dose level, which was higher than the increase observed with the equivalent dose of DS-Cav1, although the results were not statistically



significant. At the 1 microgram dose IVX-121 and soluble DS-Cav1 induced similar increases in nAb titers. Use of Alhydrogel did not significantly increase the immune response to IVX-121 in RSV-primed mice (not shown).





 $^{SEM}$  = standard error of log<sub>2</sub> transformed fold rise in nAb titers  $^{*}p$  = 0.011 (t-test); p = 0.024 (Wilcoxon test)

A p-value is the probability that the reported result was achieved purely by chance, such that a p-value of less than or equal to 0.05 means that there is a less than or equal to 5% probability that the difference between the control group and the treatment group is purely due to chance. A p-value of 0.05 or less typically represents a statistically significant result. The FDA's evidentiary standard of efficacy when evaluating the results of a clinical trial generally relies on a p-value of less than or equal to 0.05.

In addition, to assess the cellular immune response to IVX-121 splenocytes from individual mice were collected and analyzed in an IFN-gamma ELISpot assay following stimulation with F-specific peptide. As compared to a saline control group, IVX-121 treated mice showed an increase in IFN-gamma positive CD4+ T cells, which suggests a boosted cellular immune response induced by IVX-121.

Preclinical Data in RSV-naïve Animals. Studies performed at the UW IPD on a precursor VLP-based antigen to IVX-121, DS-Cav1-I53-50, showed superiority of the multivalent, VLP presentation of DS-Cav1 over the soluble antigen. The preclinical studies with DS-Cav1-I53-50 in both naïve (non-primed) mice and naïve non-human primates, demonstrated a ~10-fold increase in neutralizing titers over the soluble DS-Cav1 antigen. In the mouse study, DS-Cav1 and DS-Cav1-I53-50 were formulated with the oil-in-water adjuvant Addavax and a 5 mcg DS-Cav1 dose equivalent was utilized for all groups. A statistically significant difference in nAbs titers induced by DS-Cav1-I53-50 and DS-Cav1 was observed (p<0.01). In the primate study, DS-Cav1 and DS-Cav1-I53-50 were formulated with the oil-in-water adjuvant SWE and a 50 mcg DS-Cav1 equivalent dose was given to both groups. A statistically significant difference in nAbs titers induced by DS-Cav1-I53-50 and DS-Cav1 was observed (p<0.05). In a subset of the primates, bone marrow was collected to assess level of induction of antigen-specific long-lived plasma cells (LLPCs), an early marker of a potential durable immune response. Primates immunized with the DS-Cav1-I53-50 VLPs showed a non-significant, but numerical increase in antigen-specific LLPC induction in bone marrow and spleen compared with animals immunized with soluble DS-Cav1. A separate non-human primate study evaluated the potential impact of Adjuphos, an aluminum salt adjuvant different from the one we plan to use in the clinic, on the IVX-121 formulation. The formulation of IVX-121 using Adjuphos induced similar levels of nAb titers to DS-Cav1 formulated with Adjuphos. The specific aluminum salt adjuvant we plan to utilize in clinical testing is Alhydrogel. Preclinical data in naïve mice suggest this adjuvant could yield improved nAb titers in naïve animals.

*IVX-121 Preclinical Safety Studies.* We have completed a Good Laboratory Practices (GLP) toxicology study to support regulatory submissions and entry into Phase 1 trials in Europe. The toxicology study evaluated both injection site and systemic reactions to the vaccine candidate. No adverse effects were seen following administration of the anticipated



maximum human dose of IVX-121 (250ug +/- Alhydrogel), with minor injection site reactivity comparable to animals receiving saline control. The only histological finding that differed from the saline control was a modest increase in the spleens of animals receiving IVX-121, consistent with the induction of a robust immune response.

### 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 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.

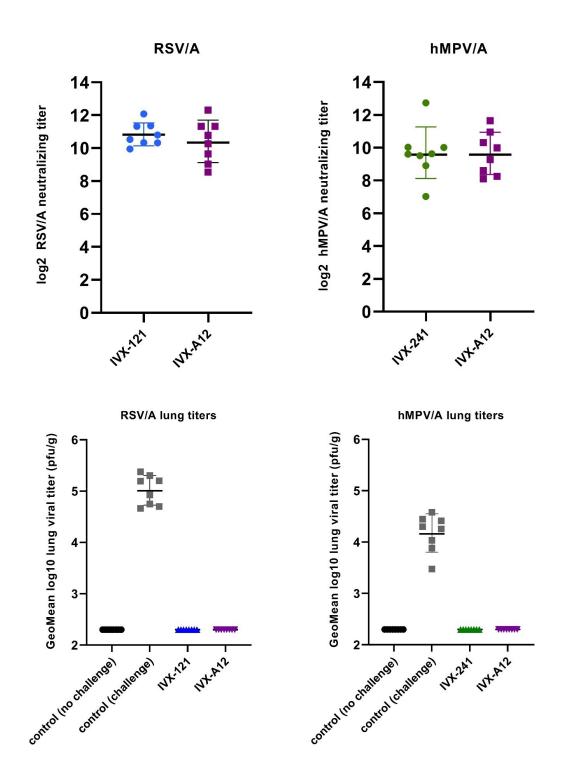
### hMPV Antigen Selection and Immunogenicity Results

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-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 105 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 are also currently evaluating IVX-A12 in a GLP toxicology study.

### 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 plan to first evaluate the immunogenicity of our vaccine candidate in a Phase 1 first-in-human (FIH) trial in healthy young and older adults by measuring the change in RSV and hMPV nAb levels compared to baseline antibody levels. We also plan to



assess different combinations of RSV and hMPV for potential immune interference caused by the addition of hMPV VLPs to the RSV VLP vaccine candidate. Contingent upon favorable safety results, demonstration of immunogenicity and determination of the optimal RSV-hMPV dose combination, we plan to assess the efficacy of our RSV-hMPV combination vaccine candidate. We expect that the efficacy will be assessed by measuring incidence of LRI caused by either RSV or hMPV in patients receiving IVX-A12 compared to those receiving placebo.

We are evaluating both unadjuvanted and Alhydrogel-adjuvanted RSV monovalent VLP candidate IVX-121 formulations in our Phase 1 FIH trial. However, based on the NIH and our own preclinical studies, we may not see a significant enhancement in the nAb titers induced by Alhydrogel adjuvant. For this reason, in parallel with the clinical assessment of IVX-121, we also are assessing alternative adjuvants in our ongoing Phase 1/2 clinical trial of IVX-411 and in preclinical studies with our combination candidate IVX-A12. Based on the IVX-121 and IVX-411 clinical data as well as preclinical data to be generated with respect to IVX-121, IVX-241 and related candidates, and different formulations of IVX-A12, we will determine whether to investigate an adjuvanted formulation, in addition to a non-adjuvanted formulation for the planned Phase 1 clinical trial of IVX-A12.

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

Our plan for the clinical development of IVX-A12 is to first assess safety and immunogenicity of the RSV monovalent VLP candidate IVX-121 in an initial Phase 1/1b trial, which was initiated in September 2021.

This FIH trial with IVX-121 is 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) and 60-75 years of age (Phase 1b). Dosing in this study has completed, with 90 adults 18-45 years of age and 130 adults 60-75 years of age dosed with IVX-121, respectively. All subjects in the trial are being evaluated for safety and persistence of antibody response for six months following a single intramuscular administration of either IVX-121 or placebo.

We expect to conduct an interim analysis of the IVX-121 Phase 1/1b trial to determine the IVX-121 dose level to be assessed in the IVX-A12 combination Phase 1 trial. We are also currently evaluating alternative adjuvant formulations in preclinical studies and will assess the need for an alternative adjuvant in the initial IVX-A12 clinical trial pending the outcome of the Phase 1/1b IVX-121 and Phase 1/2 IVX-411 clinical trials, and preclinical evaluation of different formulations of IVX-A12.

We also plan to enroll a subset of older adult subjects who completed the Phase 1b part of the trial into a Phase 1b extension trial. The Phase 1b extension trial will begin with a continuation of the follow up period of up to approximately twelve months after first dosing to monitor for safety and to evaluate persistence of antibodies. Twelve months following their first IVX-121 administration, we plan to administer a single booster dose of unadjuvanted IVX-121 to enrolled subjects and follow them for an additional six months to evaluate safety and immune responses to the booster dose. Safety assessments will include solicited adverse events (AEs), unsolicited AEs, and serious AEs throughout the 28-day treatment period following booster vaccination.

### IVX-A12 Phase 1 Trial

We completed 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 we expect to begin our Phase 1 trial for IVX-A12 in the second half of 2022. We will evaluate the combination candidate IVX-A12 in this trial, with no evaluation of IVX-241 as a monovalent candidate.

The goal of the planned Phase 1 trial of IVX-A12 will be to assess safety and immunogenicity of varying doses of IVX-A12, with and without adjuvant, in healthy young adults 18-45 years of age, and older adults 60-75 years of age. The adjuvant to be assessed will depend on preclinical data on IVX-A12 as well as clinical data from the IVX-121 and IVX-411 clinical trials. In the planned Phase 1 trial, IVX-A12 will be given with a fixed IVX-121 dose and one of three dose levels of IVX-241 VLP formulated with and without adjuvant. We expect this design will enable evaluation of the immune responses to both individual components of IVX-A12 and to see if the combination of VLPs increases the reactogenicity or leads to immune interference (i.e., imbalanced immune responses to component VLPs). All subjects in the Phase 1 trial will be evaluated for safety and antibody response for twelve months following administration of IVX-A12 or placebo. Our plan is



to proceed dosing with cohorts receiving one- and two-dose regimens and to evaluate interim data from the Phase 1 trial to determine the need for adjuvant, and to select the dose regimen for evaluation in the Phase 2 dose-confirmation trial.

### IVX-A12 Phase 2 Dose-Confirmation Trial

Following completion of the IVX-A12 Phase 1 clinical trial, we plan to initiate a Phase 2 dose-confirmation clinical trial in healthy older adults 60-75 years of age. 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 will evaluate different combinations of varying concentrations of hMPV and RSV VLPs in healthy older adults to assess safety and immunogenicity of varying concentrations of hMPV and RSV VLPs, and guide final dose selection for a subsequent PoC Phase 2b trial.

### IVX-A12 Phase 2 Extension Trial

We plan to enroll older adult subjects who complete the Phase 2 trial into a Phase 2 extension trial to assess duration of antibody persistence and long-term safety over multiple years.

### IVX-A12 Phase 2b PoC Trial

We plan to conduct a global Phase 2b randomized observer-blind placebo-controlled PoC efficacy trial to evaluate the formulation of IVX-A12 selected from the Phase 2 dose-confirmation trial. The planned PoC objectives for the Phase 2b trial will include assessment of safety, immunogenicity, and efficacy against LRI caused by either RSV or hMPV. We expect that the trial population will include adults 60 years of age or older, including nested cohorts of frail and at-risk elderly, as well as healthy subjects over 85 years of age.

### SARS-CoV-2

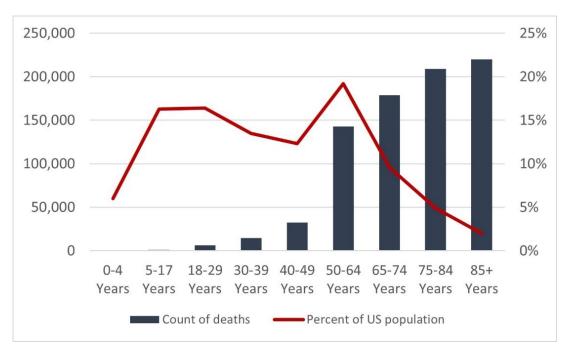
We are developing additional vaccine candidates as part of our strategy to develop combination VLP vaccines in older adults. IVX-411 is designed to present 60 copies of the RBD protein from the SARS-CoV-2 virus strain first identified in China (original viral strain). We have also initiated preclinical development of candidates incorporating RBD variants, including Omicron, for evaluation as possible back-up candidates or as components of a multivalent COVID-19 vaccine candidate. For our COVID-19 vaccine candidates, 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 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 1/2 clinical trial in South Korea, and has begun Phase 3 clinical trials, as well as rolling registration applications with the UK Medicines and Healthcare products Regulatory Agency (MHRA) and the South Korean Ministry of Food and Drug Safety (MFDS), for a product candidate similar to IVX-411, and is also pursuing variant vaccine candidates.

In October 2020, we announced a grant for \$10 million, awarded by the Bill & Melinda Gates Foundation (BMGF), a global non-profit dedicated to improving global health. We deployed this grant to evaluate IVX-411 in a Phase 1/2 clinical trial that we initiated in Australia in June 2021. In this clinical trial, we are evaluating the safety and immunogenicity of IVX-411 in naïve subjects and previously vaccinated individuals for its potential use as a booster vaccine. Topline interim data from this ongoing clinical trial were announced in March 2022. Overall, although an immune response was observed and the initial reactogenicity data were favorable, the immunogenicity response was below our expectations and inconsistent with preclinical data on our platform and other data on similar VLP technology, including SK's COVID-19 VLP vaccine. Further analysis of the data and our IVX-411 vaccine candidate is ongoing, including an investigation into the manufacture, shipment, and administration of the vaccine candidate in the Phase 1/2 clinical trial. Based on the results of these efforts, we will review our plans for the clinical development of IVX-411 and variant candidates, including a potential Omicron or multivalent back-up candidate. We remain committed to the development of pan-respiratory vaccine(s) incorporating COVID-19.

### IVX-411—Our COVID-19 Vaccine Candidate

Overview of SARS-CoV-2 and COVID-19

Copyright © 2022 <u>www.secdatabase.com</u>. All Rights Reserved. Please Consider the Environment Before Printing This Document SARS-CoV-2 is a viral pathogen responsible for the coronavirus disease 2019 (COVID-19) global pandemic. As of February 2022, there were over 430 million cumulative cases and over 5.9 million deaths from COVID-19 worldwide with over 900,000 deaths in the United States alone. Rates of serious morbidity and mortality from COVID-19 are disproportionately higher in older adults as compared to other age groups, likely due to age-induced immunosenescence. Although adults aged 65 or older constitute about 17% of the United States population, over 75% of the deaths in the United States due to COVID-19 have been in this age group, as illustrated in the graph below.



U.S. COVID-19 Deaths by Age (as of February 2022)

Source: CDC, U.S. Census Bureau

Vaccines have been developed to combat the COVID-19 pandemic at an unprecedented pace and there are several mRNA and adenoviral vector-based COVID-19 vaccines that have been licensed or approved under EUA in the United States and other countries. Data have been publicly released regarding different SARS-CoV-2 vaccine candidates, including protein-based vaccines and the VLP vaccine candidates being developed by Medicago, Bavarian Nordic, and SK, that have shown high nAb induction. We believe these data support continued development of VLP-based vaccines such as IVX-411. Further, development of the first wave of vaccines to fight the pandemic focused on speed rather than other critical attributes that are now important considerations for second wave vaccine candidates such as durability, potential to address variant strains, ease of manufacturing and distribution, stability, and reactogenicity profile.

Coronaviruses are prone to mutation but the pace at which the SARS-CoV-2 virus has mutated is faster than many were anticipating. Some of these emerging strains appear to enhance transmission and pathogenicity, with complete replacement of the original pathogen by the emerging strains in some countries. Data has shown that some vaccines against the original SARS-CoV-2 virus strain are less immunogenic against some of the emerging variants, particularly the Beta and Omicron variants. Several companies have initiated efforts to make either booster shots to supplement existing vaccines to address emerging variants or new vaccines incorporating key mutations found in variant strains. However, it remains to be seen if initial exposure to the original strain through natural infection or vaccination has resulted in a focusing of the immune system on the original strain in such a way as to interfere with the development of an immune response against the new strain, a phenomenon called "original antigenic sin".

We believe that there are still gaps in the COVID-19 vaccine landscape that need to be filled by new vaccine candidates. We believe that our technology may have the potential to address these gaps:

•Global access to effective vaccines against variant strains: We believe that highly scalable vaccines will be needed in order to address the ongoing demand for billions of doses worldwide. We aim to develop vaccines targeting the prevalent strains to induce high nAb levels, which we believe may be able to more

effectively protect against emerging variants than the first wave vaccines.

•Reduced reactogenicity: Reactogenicity of the mRNA vaccines appears to remain high with subsequent doses; we believe that in the long-term less reactogenic vaccines will be preferred, particularly if repetitive boosters are needed. We believe that a COVID-19 VLP vaccine candidate has the potential to be less reactogenic.

•Ability to overcome "original antigenic sin": We believe that new vaccines targeting specific key mutations in the variant SARS-CoV-2 virus strains may be less effective in individuals already exposed to the original SARS-CoV-2 strain through infection or vaccination. We further believe that variant vaccines developed using differentiated technologies, expressed viral proteins, or formulations with different adjuvants may be more successful in overcoming the original-strain immune-focused memory response present in these individuals, particularly if they are able to induce high nAb titers.

•Ability to confer long-lasting protection: The durability of currently marketed vaccines against COVID-19 appears to be suboptimal, with boosters proving to be necessary and developers suggesting a potential need for annual vaccinations. We believe this drives a need for vaccines with longer duration of response.

•Ability to be incorporated into pan-respiratory combinations: 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 vaccines. We believe that a SARS-CoV-2 antigen is an important part of a future combination vaccine, and that our technology may be suited to combination vaccines because of its potential combinability and low reactogenicity.

# COVID-19 Vaccine Candidates

IVX-411 is our current lead COVID-19 vaccine candidate that incorporates the ACE2 RBD from the SARS-CoV-2 spike (S) protein of the original virus. The RBD is a fragment of the S protein that contains several known nAb epitopes, including those that prevent viral entry, and is responsible for ~90% of the nAb titers induced following SARS-CoV-2 infection. The RBD protein in IVX-411 is genetically fused to Component A and manufactured in mammalian cells. Component A-RBD is then combined with the same Component B used for our other programs to make the fully assembled VLPs, each of which incorporates 60 copies of the monomeric RBD antigen. We are evaluating IVX-411 in the clinic in both aqueous (non-adjuvanted) and adjuvanted formulations. We chose to move into clinical development with an oil-in-water adjuvant based on preclinical adjuvant comparison data and clinical data on other products using similar adjuvants.

We also initiated preclinical development of candidates incorporating RBD proteins with critical mutations found in variant SARS-CoV-2 virus strains, including Omicron, for evaluation as possible back-up candidates or as components of a multivalent COVID-19 vaccine candidate. In our preclinical studies we assess whether these variant-specific candidates induce stronger immunogenicity against variant strains than seen with IVX-411. Following review of clinical data on IVX-411 and preclinical data on variant-specific backup and multivalent candidates, we may incorporate one of these candidates into our clinical evaluation plan.

Our COVID-19 vaccine candidates including IVX-411 were designed to utilize the same VLP backbone as other candidates in our pipeline and to have the following potential advantages:

•Robust immunogenicity, durability, and breadth of response: Our candidates including IVX-411 incorporate the RBD of SARS-CoV-2 on the VLP and we believe this design has the potential to improve the functional antibody response as compared to many spike soluble antibody approaches.

•Scalability and stability: Our vaccine development process leverages highly scalable recombinant protein production with well-established cell line and fermentation technologies. In addition, our VLP vaccine candidates are highly thermostable and we have designed the final drug product to be stable at two to eight degrees Celsius. We believe the potential scalability and stability of our vaccine candidates will allow for a lower cost of goods, as well as ease of scaled-up manufacturing and distribution, compared to other

vaccine approaches such as mRNA vaccines. We believe both scalability and thermostability are especially important for addressing the large-scale need for billions of doses worldwide.

•Ability to boost: In an endemic setting, we believe the ability to boost and sustain immune response against the prevalent strains will become increasingly important.

•Potential to boost multiple times with same vaccine candidate (homologous boosting): Our candidates are protein-based VLPs, and we have not observed interference after multiple doses in several species. We believe that our candidates including IVX-411 have the potential to be administered multiple times without risk of interference or anti-vector immunity that has historically been seen in other approaches, such as vector-based approaches.

•Potential to boost response from alternative vaccine technologies (heterologous boosting): We believe that protein-based vaccines, which strongly enhance nAb levels, may be ideal booster vaccines for other vaccine technologies such as adenoviral vector vaccines. In addition, we believe that to overcome original antigenic sin, the heterologous vaccine regimen used for boosting may need to be distinct from the initial vaccine regimen, particularly when attempting to boost a response to a variant virus strain. As our VLP vaccine candidates present the RBD subunit, we believe they are distinct from most of the other vaccines on market presenting the full Spike antigen and may be capable of boosting response from marketed heterologous vaccine regimens.

In March 2022 we reported interim topline results from our IVX-411 Phase 1/2 clinical trial, as further described below. Overall, the level of immunogenicity response was below our expectations given what we know about VLPs, including from SK clinical data on a similar COVID-19 vaccine candidate and from our own preclinical data. We have initiated an investigation into the potential causes of these discordant clinical results, including manufacture, shipment, and administration of the vaccine candidate, and continue to believe that a COVID-19 VLP vaccine candidate based on the technology licensed to us from UW has the potential to provide the advantages listed above.

We have a worldwide non-exclusive license to our COVID-19 vaccine candidates from the UW, with the exception of South Korea, where we have no license. This license will become exclusive in the United States, Canada, Mexico and Europe (including Switzerland and United Kingdom) starting in 2025 with maintenance of our non-exclusive rights elsewhere. SK also has a non-exclusive license to develop COVID-19 candidates based on the UW technology. We are monitoring the landscape closely, and, pending our review of the interim topline results, and of our investigation relating to IVX-411 as administered in our Phase 1/2 clinical trial, we will determine the path forward for our COVID-19 vaccine candidates.

BMGF supported work by the UW IPD to design and evaluate COVID-19 vaccine candidates. We also received a grant from BMGF to enable development of our COVID-19 vaccine candidate through Phase 1 clinical testing and in return for our grant funds, we have agreed to access and price commitments specific for low- and middle-income countries for this candidate.

# IVX-411 Preclinical Results

# Summary

To date, IVX-411 and closely related precursor molecules have been tested in mice, rats, and nonhuman primates. The immunogenicity generated in mice after vaccination with closely related precursor VLPs formulated with an oil-in-water adjuvant was durable, with nAb titers remaining as high 20-24 weeks following the boosting dose as they were two weeks post-boost. In addition, preclinical nonhuman primate data from assessment of a closely related precursor candidate with several different adjuvant formulations showed induction of robust nAb titers well in excess of titers seen in human convalescent sera, as well as protection from viral challenge.

# Preclinical data of related candidates

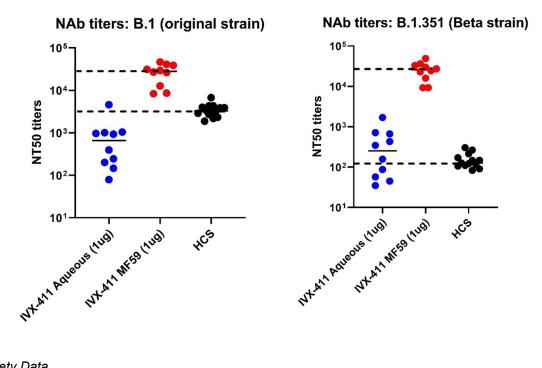
The BMGF has sponsored several preclinical studies incorporating the UW precursor candidate used in both SK Biosciences' GBP510 and our IVX-411 vaccine candidates. In these preclinical studies in rodents and non-human primates, the candidates were evaluated with several adjuvants. The most recent study in non-human primates showed

nAb titers against the wild-type strain that were maintained at a high level for at least six months after two doses. Although following a primary regimen, titers against the Omicron strain were relatively low compared with those against the wild

type virus, there was a significant impact of a booster at month 6 against the Omicron strain. Overall, we believe this data supports the potential for durability and breadth of response of our VLP platform.

### IVX-411 Preclinical Data in Naïve Mice

To evaluate the potential of IVX-411 to stimulate an immune response to the original and Beta variant SARS-CoV-2 strains, BALB/c mice were administered IVX-411 with and without MF59. All animals were administered two doses three weeks apart and blood was collected two weeks following the second dose for measurement of neutralizing titers against the original and Beta strains. As shown in the figure below, IVX-411 adjuvanted with MF59 induced robust nAb responses that were higher than those observed for IVX-411 alone, although the results were not statistically significant, and induced nAb titers (mean nAb titer of 26,979 across all animals) that were higher than those observed in human convalescent serum (mean nAb titer of 3,492 across all runs of a single HCS sample). In addition, the nAb titers induced by IVX-411 adjuvanted with MF59 against the Beta variant (mean nAb titer of 25,699 across all animals), which was in contrast to human convalescent sera, which showed a significant drop in nAb titer of 26,979 across all animals), which was in contrast to human convalescent sera, which showed a significant drop in nAb titer of 154 across all runs of a single HCS sample).



#### IVX-411 Safety Data

We have completed a GLP toxicology repeat intramuscular dose study in rats to support regulatory submissions and initiation of our ongoing and planned Phase 1/2 clinical trials in Australia, United States, and Europe. The study evaluated both injection site and systemic reactions to IVX-411, including non-adjuvanted and adjuvanted formulations. No test article-related effects were seen following administration of IVX-411 on mortality, clinical observations, ophthalmic observations, body weights, food consumption, or body temperature. No observed effects were considered adverse.

#### COVID-19 Vaccine Candidates Clinical Development Plan

We are conducting a Phase 1/2 randomized, placebo-controlled, observer-blinded, dose-escalation clinical trial evaluating safety and immunogenicity of IVX-411, and reported interim topline data in March 2022. The trial is designed to evaluate the safety and immunogenicity of IVX-411 administered as primary and booster vaccines. There are two parts to the trial. Part 1 is a Phase 1 assessment of primary vaccination with IVX-411 in adults 18-69 years of age who have not been previously exposed to SARS-CoV-2 (seronegative). Part 2 is a Phase 2 evaluation of IVX-411 booster vaccination in adults previously exposed through COVID-19 vaccination (seropositive). IVX-411, either unadjuvanted or formulated with MF59 adjuvant, was administered in either one or two-dose regimens. For groups receiving two doses, administration of doses was 28 days apart.



A schema of the Phase 1/2 trial design is given in the figure below:

PH 1/2 PART 1: PRIMARY IMMUNIZATION WITH IVX-411	PH 1/2 PART 2: BOOST PREVIOUSLY VACCINATED WITH IVX-411
Candidate: IVX-411 (VLP with original	Candidate: IVX-411
strain RBD antigen)	<ul> <li>Subjects: 84 Adults (18-69 years of age)</li> </ul>
<ul> <li>Subjects: 84 Adults (18-69 years of age); seronegative</li> </ul>	SARS-CoV-2 seropositive due to prior vaccination with licensed SARS-CoV-2
Regimen: 2 doses on Days 0 and 28	vaccines
Formulation: aqueous or MF59-	<ul> <li>Regimen: 1 dose</li> </ul>
adjuvanted; 3 dose levels assessed	<ul> <li>Formulation: aqueous or MF59-</li> </ul>
<ul> <li>Part 1 dosing complete</li> </ul>	adjuvanted; 3 dose levels assessed
	Part 2 dosing complete

In Parts 1 and 2, six formulations of IVX-411 were tested, including three dose levels each tested with and without MF59 adjuvant.

### IVX-411 Clinical Results

#### Safety

In this topline interim data, IVX-411 was generally safe and well-tolerated. Solicited local and systemic AEs were all mild or moderate, without dose-limiting reactogenicity. The most common local and systemic AEs were injection site tenderness, and headache and fatigue, respectively. There were no serious AEs deemed to be related to vaccine, AE of special interest, or AEs leading to discontinuation. In the naïve setting, across the six dosage groups for IVX-411 with or without adjuvant, the proportion of subjects experiencing any systemic AE within seven days of any dose was 33-67%, versus 50% for placebo. In the booster setting, across the six dosage groups, 17-42% of subjects experienced any systemic AE within seven days of the booster dose, versus 25% for placebo.

# Immunogenicity

In the naïve setting, a clear adjuvant effect on immunogenicity and a dose response were observed with IVX-411; however, the level of immune response in this initial data was comparable to or below the Human Convalescent Sera (HCS) control. At day 49 (or three weeks following the second dose), responses were up to 154 IU/mL across dosage groups in the live virus neutralization assay (HCS: 281 IU/mL), and up to 592 BAU/mL across groups in the spike IgG assay (HCS: 361 BAU/mL).

In previously vaccinated subjects, these initial data showed that IVX-411 boosted immunity following primary vaccination with an mRNA or adenovirus vaccine, and adjuvanted and unadjuvanted groups were generally similar. Preversus post-boost fold increases of up to 5x (599 IU/mL) for wild type virus were observed at day 28 post boost. For the Omicron variant, neutralizing antibody titers were up to 8-fold lower than observed for wild type virus in the same assay.

Overall, the level of immunogenicity response was below our expectations given what we know about VLPs, including from SK clinical data on a similar COVID-19 vaccine candidate and from our own preclinical data. We have initiated an investigation into the potential causes of these discordant clinical results, including manufacture, shipment, and administration of the product.

Based on the outcome of the investigation, as well as additional evaluation of preclinical and clinical data, our ongoing evaluation of SARS-CoV-2 variants, the state of the vaccine landscape for COVID-19, the regulatory guidelines on clinical development of COVID-19 vaccines and additional factors as appropriate, we will determine our future development efforts for IVX-411 and backup candidates.

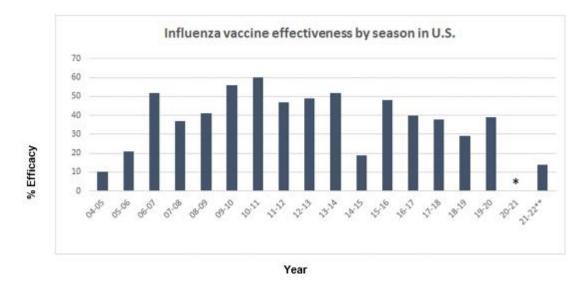
# Influenza Program

Overview of Influenza



Influenza is caused by a respiratory viral pathogen that infects the nose, throat, and lungs. There are two main types of flu 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 flu A and B viruses that routinely spread in people are responsible for seasonal flu epidemics each year. Existing vaccines have sub-par efficacy (ranging from 10% to 60% 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 flu 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

\* 2020-2021 flu vaccine effectiveness was not estimated due to low flu virus circulation during the 2020-2021 flu season \*\*Interim vaccine effectiveness estimates, as of March 2022

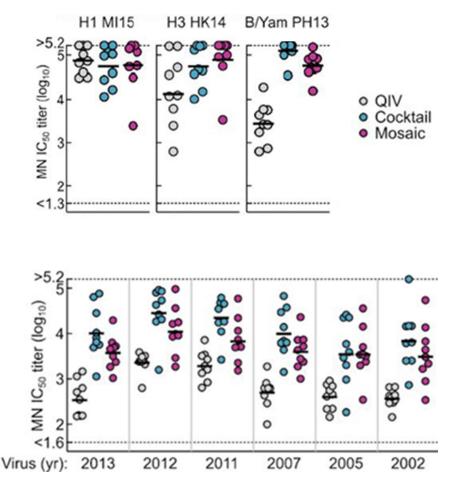
Influenza results in an estimated 500,000 hospitalizations and 35,000 deaths per year in the United States despite numerous marketed vaccines. Many of these hospitalizations and deaths are in people over the age of 65. In the 2019-2020 flu season, for example, 45% of the hospitalizations and 59% of the 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 has already established 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 2022.

#### 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. We have initiated preclinical development on a quadrivalent influenza VLP candidate. We see our emerging flu program as part of our strategy to develop combination or pan-respiratory VLP vaccines targeting the viral causes of pneumonia in older adults.

### **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. 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, manufacturing, marketing, sales and supply resources or experience than we do.

The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, reactogenicity, safety, 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 vaccine candidates. Many 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, Medicago and 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 believe that our VLP technology allows for incorporation of a broad and complex array of viral antigens and targets as well as ease of manufacturing and scale-up, which may allow us to compete with other VLP vaccine candidates in development.

#### **RSV and hMPV Vaccines for Older Adults**

There is no vaccine currently 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 and Meissa, with several currently in Phase 3 trials. As far as we are aware, no company 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; however, Moderna has an RSV and hMPV combination vaccine in clinical trials for pediatric use and Sanofi has announced that it is exploring RSV monovalent 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 nAb response than other vaccine technologies.

### **COVID-19 Vaccines**

We expect that, if approved, IVX-411 or any other COVID-19 VLP candidate we develop will compete with any currently approved vaccines against COVID-19. Moderna, Pfizer/BioNTech, AstraZeneca, Janssen, and Novavax, along with many other companies, are currently marketing COVID-19 vaccines. Medicago has obtained an approval to market their VLP COVID-19 vaccine in Canada. We are also aware of numerous COVID-19 vaccines in clinical development, including VLP approaches being developed by Bavarian Nordic, SpyBiotech and VBI Vaccines. We believe that our vaccine candidates have the potential to be differentiated or play a potential role 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 preclinically, and Novavax has a combined COVID-19/ influenza combination vaccine in Phase 1 clinical development.

# 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 product candidates. We may work in partnership with one or more pharmaceutical partners for certain vaccine candidates, for certain patient 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 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 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, as our license agreements may dictate.

Regardless of the coverage we seek under our existing patent applications, there is always a risk that an alteration to the product or process may provide sufficient basis for 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 December 31, 2021, our patent estate included three issued patents and 23 non-provisional patent applications with 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, and two pending international patent applications; more than 15 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; and a non-exclusive license from UW to patent applications directed to nanoparticle-based influenza vaccines.

More specifically, we have exclusively licensed our main VLP icosahedral platform (as well as several alternative platforms) from UW. Two issued U.S. patents that will expire in 2035 and 2036 cover our platform as compositions of matter: polypeptides and the nucleic acids encoding them, respectively.

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, having actual or expected expirations in 2038, that cover various alternative icosahedral nanoparticles. We intend to continue to work with UW on development of further nanoparticle platforms and may have the opportunity to license them as appropriate.

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. Any patents that ultimately issue from this patent family are expected to expire in 2038. UW's inter-institutional agreements (IIA) with the Institute for Research in Biomedicine in Bellinzona, Switzerland conferred on 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. The same license covers one issued U.S. patent directed to compositions of matter covering the antigenic portion of our hMPV candidate, and this patent will expire in 2035. 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. We further intend to pursue company-owned patent rights on improvements underlying our hMPV product, with such patent rights potentially extending the term of exclusivity until at least 2041.

HHS and the Institute for Research in Biomedicine in Bellinzona, Switzerland jointly own two U.S. patents on conformationally stabilized hMPV antigens, which we have non-exclusively licensed, subject to an IIA between HHS and the Institute for Research in Biomedicine. These patents expire in 2035. A continuation application and corresponding European patent application are currently pending in this patent family.

We also have a non-exclusive license from UW to a patent family with claims directed to our coronavirus product candidate (IVX-411), 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 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.

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. 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 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 12 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, 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 therapeutic 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 product 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 filed for trademark registration at the USPTO for "Icosavax" and our company logo. 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 and November 2020 (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 five 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 of March 2022, 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 three of the six pathogens (excluding RSV and two others) for humanitarian purposes. 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 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 six licensed product candidates. We are also required to pay UW commercial milestone payments of one million dollars for each of the six licensed product 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 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 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 and May 2021 (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 2022, the UW Option and License Agreement is applicable to our IVX-411 and SARS-CoV-2 variant programs.

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 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 on, for example, a combination product.

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. Specifically, with respect to IVX-411, our obligations include initiating clinical trials of specified phases by certain dates between 2022 and 2025 and obtaining regulatory approval by a specified date thereafter. 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 2022, 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 2022, 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 the University of Texas at Austin (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 2022, 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.

### Agreements with the Bill & Melinda Gates Foundation

On September 24, 2020, we entered into a grant agreement (the Grant Agreement) with BMGF relating to our development of a COVID-19 vaccine. Under the Grant Agreement, BMGF provided funding to us to (i) assemble select components into a COVID-19 vaccine for pandemic use (the COVID-19 vaccine) and perform related product fill and finish, (ii) develop regulatory submission-enabling data regarding the COVID-19 vaccine, and (iii) conduct a Phase 1 clinical trial to assess safety and immunogenicity of the COVID-19 vaccine in healthy adults and older adults, which we refer to collectively as the Funded Developments. Pursuant to the Grant Agreement, we granted BMGF a nonexclusive, perpetual, royalty-free, fully paid up, sublicensable humanitarian license to make, use, sell, offer to sell, import, distribute, or otherwise exploit the Funded Developments to provide people most in need within developing countries with access at



an affordable price to the Funded Developments and to support the U.S. educational system and public libraries. We and BMGF may agree to modify or terminate the humanitarian license if we can demonstrate to BMGF's satisfaction that global access can be best achieved with modifications or termination of the humanitarian license.

In connection with the Grant Agreement, we entered into a Global Access and Price Commitment Agreement (the GACA) with BMGF on February 17, 2021, which is incorporated into the Grant Agreement. Under the GACA, we agreed to certain global access and price commitments regarding the COVID-19 vaccine we develop with the funding under the Grant Agreement. In addition, we are required to use reasonable and diligent steps to publish results of the project in one or more peer reviewed journals or in a form available to the interested public. In the event we successfully complete any Phase 1 clinical trials, we are obligated to take reasonable steps to continue further development, manufacture, and/or distribution of such COVID-19 vaccine. If development and commercialization continue beyond the Phase 1 trials, we will be required to pursue regulatory approvals and WHO prequalification of such COVID-19 vaccine. We also committed to price such COVID-19 vaccine no higher than a certain percentage rate above the cost of goods sold when selling such COVID-19 vaccine to public sector purchasers for use in select Global Alliance for Vaccines and Immunization (GAVI)-eligible and low to low-middle income countries. For a period commencing with the first supply of such COVID-19 vaccine to these countries at a mutually agreed upon percentage of our total annual doses.

In the event we fulfill all the global access commitments and if through no fault of ours or our manufacturing or commercial partner(s) there is insufficient demand to sell an agreed upon percentage of our total doses of such COVID-19 vaccine, then the price and volume commitments will terminate beginning with the next annual period and we will be required to meet with BMGF for good faith discussions regarding the remaining annual periods. Conversely, if demand outstrips our supply capacities, then we will be required to have good faith discussions with BMGF about increased funding to meet the demand. If no agreement is reached, we will be required to provide adequate technology transfer and a non-exclusive license to BMGF to the Funded Developments and our background technology to allow for continued use of such COVID-19 vaccine in such eligible countries for charitable purposes.

If we are unable to continue development past Phase 1 trials, if requested by BMGF, we will be required to cooperate in good faith in making such Funded Developments and our background technology available to BMGF, assign an accompanying supply agreement to BMGF, and provide adequate technology transfer to continue development of such COVID-19 vaccine and enable its use in such eligible countries for charitable purposes.

The Grant Agreement will expire on March 31, 2022 unless terminated earlier by BMGF. BMGF can terminate the Grant Agreement, or suspend, discontinue, or modify the grant payments if (i) BMGF is not reasonably satisfied with our progress on the funded project, (ii) there are significant changes to our leadership or other factors that BMGF believes may threaten the funded project's success, (iii) we undergo a change of control, (vi) there is a change to our tax status, or (v) we fail to comply with the terms of the Grant Agreement.

# **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 product 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;

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 product 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. 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 product candidate may be eligible for priority review. 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 post-marketing clinical trials to verify and describe the anticipated effect on irreversible morbidity or withdrawal procedures if the sponsor fails to conduct the required post-marketing studies 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.

# Emergency Use Authorization

The Commissioner of the FDA, under delegated authority from the Secretary of HHS may, under certain circumstances in connection with a declared public health emergency, allow for the marketing of a product that does not otherwise comply with FDA regulations by issuing an EUA for such product. Before an EUA may be issued by HHS, the Secretary must declare an emergency based a determination that public health emergency exists that affects or has the significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents (CBRN), or a specified disease or condition that may be attributable to such CBRN. On February 4, 2020, the HHS Secretary determined that there was such a public health emergency that involves the virus now known as



SARS-CoV-2, the virus that causes the COVID-19 infection. Once the determination of the threat or emergency has been made, the Secretary of HHS must then declare that an emergency exists justifying the issuance of EUAs for certain types of products (referred to as EUA declarations). On March 27, 2020, the Secretary of HHS declared – on the basis of his determination of a public health emergency that had the potential to affect national security or the health and security of U.S. citizens living abroad that involves SARS-CoV-2 – that circumstances exist justifying authorization of drugs and biologics during the COVID-19 pandemic, subject to the terms of any EUA that is issued.

Once an EUA declaration has been issued, the FDA can issue EUAs for products that fall within the scope of that declaration. To issue an EUA, the FDA Commissioner must conclude that (1) the CBRN that is referred to in the EUA declaration can cause serious or life-threatening diseases or conditions; (2) based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing the disease or condition attributable to the CBRN and that the product's known and potential benefits outweigh its known and potential risks; and (3) there is no adequate, approved, and available alternative to the product. Products subject to an EUA must still comply with the conditions of the EUA, including labeling and marketing requirements. Moreover, the authorization to market products under an EUA is limited to the period of time the EUA declaration is in effect, and the FDA can revoke an EUA in certain circumstances.

#### 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. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

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 product 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 product 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 product 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 product 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 therapies. 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 products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Even if approved for reimbursement, historically, product 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 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 of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through July 1, 2022 (with a 1% payment reduction from April 1 to June 30, 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.

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. For example, the Build Back Better Act, if enacted, would introduce substantial drug pricing reforms, including the establishment of a drug price negotiation program within the United States Department of Health and Human Services that would require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, and the establishment of rebate payment requirements on manufacturers under Medicare Parts B and D. If the Build Back Better Act is not enacted, similar or other drug pricing proposals could appear in future legislation.

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.

#### 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 product 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 product candidate, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product 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 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, 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. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. For example, the General Data Protection Regulation (GDPR) imposes strict requirements for processing the personal data of individuals within the EEA. Companies that must comply with the GDPR 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. Further, from January 1, 2021, companies have had to comply with the GDPR and also the United Kingdom GDPR (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, i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate 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, 2021, we had 34 full-time employees and no part-time employees. Of these employees, 12 hold Ph.D. or M.D. degrees and 24 are engaged in research and development. Twenty-three 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 currently located at 1616 Eastlake Avenue E., Suite 208, Seattle, Washington 98102, and our telephone number is (206) 737-0085. As described below under Item 2. Properties, in December 2021 we entered into a new lease for laboratory and office space located at 1930 Boren Avenue, Seattle, Washington, which term will begin in May 2022, and which we expect will serve as our new corporate headquarters.

#### **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 and 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 have not completed clinical trials for any of our vaccine candidates, and 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 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.

•Our business is subject to risks arising from the COVID-19 pandemic and other epidemic diseases, including with respect to clinical trial and manufacturing timelines.

•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.

•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 related to and developing our VLP platform technology, identifying vaccine candidates, establishing our intellectual property portfolio, process development for manufacturing, manufacturing our product candidates to support preclinical studies and clinical trials, and preparing for and conducting our ongoing and planned 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 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 \$18.9 million and \$67.0 million for the years ended December 31, 2020 and December 31, 2021, respectively. As of December 31, 2021, we had an accumulated deficit of \$94.1 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 and restricted cash will not be sufficient to complete development of IVX-A12, IVX-411, an influenza product candidate, or any other vaccine candidate, 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 strategic considerations even if we believe we have sufficient funds for our current or future operating plans. 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 product 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 product candidates, including commercial scale manufacturing, if any product candidate is approved;
- •the costs, timing and outcome of regulatory reviews of current or future product candidates;
- •any delays and cost increases that may result from the COVID-19 pandemic;
- •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 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 product 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.

### 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, though 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, IVX-411 and IVX-121, 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 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.

In March 2022, we announced that the interim topline results from our ongoing Phase 1/2 clinical trial of IVX-411 showed a level of response that was below our expectations. While we plan to investigate the potential cause of such results, including evaluating the manufacture, shipment and administration of the product, we may not be able to resolve all ambiguity in such results and we may be unable to identify the root cause or contributing factors for the discordant results and even if we do, such cause or factors, may negatively affect the potential of IVX-411 and our other development programs which are based on our VLP technology platform. In addition, the findings from the investigation into the IVX-411 interim results could also potentially impact our ongoing trial for IVX-121, and these interim topline results for IVX-411 increase the risk that the interim topline results for IVX-121 could also be below expectations and fail to support the differentiation we hope our platform will offer as compared with existing marketed vaccine technologies.

### 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 INDs and have such INDs authorized to enable us to commence clinical trials 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. For example, the level of response observed in our Phase 1/2 clinical trial of IVX-411 may be related to our platform technology, or may be perceived to be related to our platform technology, which could negatively affect the potential and viability of our other development 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, which may reduce the immunogenicity of either or both of the combined vaccine candidates. 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 our Phase 2 clinical trials. In addition to limiting the prospects of our combined vaccine candidates, immunologically interference in VLP combination 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. Our future success will depend in part on our ability to maintain a competitive position with our VLP platform technology. 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. For example, in certain preclinical studies of IVX-121, IVX-121 induced similar increases in nAb titers as soluble DS-Cav1 at high dose levels, and a formulation of IVX-121 using Adjuphos induced similar increases in nAb titers as soluble DS-Cav1 formulated with Adjuphos. 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, adverse effects of using VLP technologies generally 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-121 and, to date, we have only evaluated IVX-241 in preclinical studies. We have not yet commenced clinical testing of IVX-241, nor have we initiated clinical trials of the combination of IVX-121 and IVX-241 in IVX-A12. Although IVX-121, IVX-241 and the combination candidate IVX-A12 have produced successful results in animal studies, 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 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 have not completed clinical trials for any of our vaccine candidates and 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, we do not know whether they or our other potential vaccine candidates will perform in current and future clinical trials as they have performed in these prior studies. Specifically, immunosenescence in older adults (our targeted population) cannot be fully replicated in preclinical studies, which increases the risk that the results at certain dose levels or formulations of our vaccine candidates tested in our preclinical models may not be predictive of results in clinical trials. In addition, formulations and adjuvants can behave differently in different species, so results of preclinical studies with specific formulations may not be replicated in clinical trials. Animals used in preclinical studies are often highly inbred, with homogenous genetic backgrounds that lead to results that are not replicable across diverse human populations. Preclinical models of infection that rely on host-pathogen interactions that do not normally occur in nature can generate misleading results as the pathogens are not well adapted to replicate and infect the animals used in the model, making it possible to protect against infection with weaker immune responses than would be required to provide protection in humans from the same pathogen. For these reasons and others, it is not uncommon to observe results in 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.

As a result, we cannot be certain that our ongoing and planned preclinical studies and clinical trials will be successful. Inadequate immunogenicity, 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, including a potential pan-respiratory vaccine, 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 authorization to proceed with clinical development. For example, our planned initiation of a clinical trial for IVX-A12 is subject to our submission of an IND and the acceptance of such IND by the FDA. We are also conducting or planning to conduct clinical trials in additional jurisdictions including Australia and Belgium, and regulatory authorities in these jurisdictions, as well as the FDA, could require us to conduct additional preclinical studies, or added clinical evaluation under any CTA, IND 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 ongoing and planned 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;

•obtaining regulatory authorizations to commence a trial or reaching 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;

•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;

•manufacturing sufficient quantities of a vaccine candidate for use in clinical trials, which could be impacted by the COVID-19 pandemic and related supply chain disruption;

•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 the evolving COVID-19 pandemic 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 continue 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 the COVID-19 pandemic 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 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, our ability to obtain and maintain informed consents, the risk that enrolled subjects will not complete a 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 therapies, including any new products that may be approved for the indications we are investigating as well as any vaccine candidates under development. Additionally, across our ongoing and anticipated clinical trials and target subjects, other vaccine companies targeting these same infections are recruiting 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 the evolving COVID-19 pandemic. 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 therapies, the effects of the COVID-19 pandemic, 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. For example, while we continue to expect to report interim topline data from our IVX-121 Phase 1/1b trial in Belgium in the second guarter of 2022, challenges associated with COVID-19 and competing trials have made it more difficult than projected to enroll subjects in the older adult arm. 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, which would result in the delay of completion of such trials beyond our expected timelines or in increased clinical development costs.

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 treatment 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 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 assessment of hMPV and RSV infections in older adults prior to commencing our planned Phase 2b clinical trial to inform our determination of the 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 Phase 2b clinical trial than we are currently planning for, which would result in increased clinical development costs.

# 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 further development of the compound. 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.

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 never completed any clinical trials, and may be unable to do so 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 is a complicated process. In general, in order to proceed with clinical trials, we must receive authorization to proceed under INDs or comparable applications submitted to foreign regulatory authorities. We have not previously completed any clinical trials, have limited experience as a company in preparing, submitting and prosecuting regulatory filings and our company has only previously submitted a Clinical Trial Notification in Australia for IVX-411, and a clinical trial application in Belgium for IVX-121 and has otherwise not previously submitted any IND, BLA or other comparable foreign regulatory submission. We also plan to conduct a number of clinical trials for multiple vaccine candidates in parallel 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 are in the early stages of consultation with the FDA. Therefore, we cannot be certain how many clinical trials of our IVX-411 or IVX-A12 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. Such adverse developments may also negatively impact the perception of our vaccine candidates in the future if approved. For example, SK is developing a vaccine candidate that is similar to IVX-411 and uses the same VLP technology that we have licensed from UW for our vaccine candidates. SK is conducting clinical trials of this vaccine candidate in South Korea, and any future adverse developments related to its vaccine candidate could negatively impact the development of IVX-411 and our other vaccine candidates.

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 EUA, 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.

Further, the COVID-19 pandemic has created a more uncertain regulatory landscape that may adversely impact our ability to receive approvals for our vaccine candidates. For example, it is unclear how the increased population of individuals receiving COVID-19 vaccines will impact the approval processes of other vaccine candidates for COVID-19. In addition, there is a less clearly defined regulatory path for booster vaccines, which may be our target development path for our COVID-19 vaccine candidates, and the rapid evolution of variants in the COVID-19 pandemic may complicate the approval of a vaccine candidate. As of March 2022, the FDA has not provided guidance on the path to regulatory approval for a second generation COVID-19 vaccine in the United States. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us or any of our potential future collaborators from commercializing our vaccine candidates.

### 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. We are also conducting and plan to conduct several clinical trials for multiple vaccine candidates in parallel over the next several years, which may make our decision as to which vaccine candidates to focus on more difficult. As a result, we may forgo or delay pursuit of opportunities with other vaccine candidates that could have had greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future 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, 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.

# If available, we may seek an EUA from the FDA or comparable emergency authorizations from foreign regulatory authorities of our COVID-19 vaccine candidate(s), and if we fail to obtain or maintain such authorizations, we may be required to pursue a more lengthy clinical development process than we expect, and our business may be harmed.

If available, we may seek an EUA from the FDA or comparable emergency authorizations with respect to our COVID-19 vaccine candidate(s). The FDA has the authority to issue an EUA under certain circumstances, such as during a public health emergency, pursuant to a declaration by the Secretary of the Department of Health and Human Services, or HHS, that an emergency exists justifying the issuance of EUAs for certain types of products (referred to as EUA declarations). On March 27, 2020, the Secretary of HHS declared that circumstances exist justifying authorization of drugs and biologics during the COVID-19 pandemic, subject to the terms of any EUA that is issued for a specific product. Once an EUA declaration has been issued, the FDA can issue EUAs for products that fall within the scope of that declaration. To issue an EUA, the FDA Commissioner must conclude that (1) the chemical, biological, radioactive or nuclear agent (CBRN) that is referred to in the EUA declaration can cause serious or life-threatening diseases or conditions; (2) based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing the disease or condition attributable to the CBRN and that the product's known and potential benefits outweigh its known and potential risks; and (3) there is no adequate, approved, and available alternative to the product.

The FDA evaluates whether to grant an EUA on a case-by-case basis in the context of a public health emergency. Even if we seek and obtain an EUA for one or more of our vaccine candidates, we cannot assure you that the FDA would approve a BLA for such vaccine candidate, if such approval is required. Accordingly, even if we obtain an EUA for one or more of our vaccine candidates, we may be required to conduct additional clinical trials before we are able to submit BLAs or comparable marketing applications for such vaccine candidates.

In addition, the authorization to market products under an EUA is limited to the period of time the EUA declaration is in effect, and the FDA can revoke an EUA in certain circumstances. The FDA's policies regarding an EUA can change unexpectedly. We cannot predict how long any authorization, if obtained, will remain in place. The FDA's policies regarding vaccines and other products used to diagnose, treat or mitigate COVID-19 remain in flux as the FDA responds to new and evolving public health information and clinical evidence. Therefore, even if we obtain an EUA or other emergency authorizations for one or more of our vaccine candidates, it is possible that such EUA or other authorizations

may be revoked and we may be required to cease any commercialization activities, which would adversely impact our business, financial condition and results of operations.

### 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 clinical trial we are conducting in Belgium of IVX-121 in adults aged 18-45 and 60-75 and the Phase 1/2 clinical trial of IVX-411 that we are conducting in Australia. 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, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-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 reguirements. 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.

Interim, topline and preliminary data from our preclinical studies and clinical trials that we announce or publish from time to time may change as more subject 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 trial. 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 or by our competitors 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.

# 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. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, in March 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, in July 2020, the FDA resumed certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA utilized this risk-based assessment system to assist in determining when and where it was safest to conduct prioritized domestic inspections. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites, among other facilities. According to the guidance, the FDA may request such remote interactive evaluations where the FDA determines that remote evaluation would be appropriate based on mission needs and travel limitations. In May 2021, the FDA outlined a detailed plan to move toward a more consistent state of inspectional operations, and in July 2021, the FDA resumed standard inspectional operations of domestic facilities and was continuing to maintain this level of operation as of September 2021. More recently, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

# We rely on third parties to conduct many of our preclinical studies and 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 has 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 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. 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 flu 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 to 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 vaccine that we 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 cGMPs 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 product 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 treatment 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 fix 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 products, vaccine candidates and processes competitive with our vaccine candidates. Any vaccine candidates that we successfully develop and commercialize will compete with existing therapies and new therapies 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 treatment of conditions for which we may attempt to develop vaccine candidates. In particular, there is intense competition in the VLP technology field and the RSV and COVID-19 vaccine fields. Our competitors include larger and better funded pharmaceutical, biopharmaceutical, biotechnological and therapeutics 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, of non-VLP vaccine candidates targeting RSV, hMPV and SARS-CoV-2. For example, GlaxoSmithKline, Pfizer, Bavarian Nordic,

Janssen Moderna, and Meissa are currently developing vaccines against RSV for use in older adults, with several currently in Phase 3 trials. 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 clinical trials for pediatric use and Sanofi has announced that it is exploring RSV monovalent and RSV and hMPV combination vaccines for older adults preclinically. Moderna, Pfizer/ BioNTech, AstraZeneca, Janssen, Novavax and Medicago 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 Novavax which has a COVID-19/influenza combination vaccine in Phase 1 clinical development. We also compete with companies that have developed VLP technologies targeting COVID-19 and may target RSV or hMPV in the future. These companies include Bavarian Nordic, SpyBiotech, VBI Vaccines, and Medicago. 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 and our commercial opportunity.

Many of our competitors have significantly greater financial, technical, 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 treatment 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 gualified individuals, generate sufficient sales leads, provide adeguate 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.

## We received a grant from the Bill & Melinda Gates Foundation, which subjects our IVX-411 vaccine candidate to pricing and other restrictions.

In September 2020, we entered into a grant agreement (Grant Agreement) with the BMGF, pursuant to which BMGF awarded us a grant (the Grant) to help fund our development of a COVID-19 vaccine for pandemic use. We used the

Grant to develop IVX-411. The Grant Agreement, along with the Global Access and Price Commitment Agreement (the GACA), which we entered into with BMGF in February 2021, subjects our COVID-19 vaccine candidate IVX-411 to certain pricing requirements in certain geographies, global access requirements and reporting and other covenants to ensure that it is made available by us worldwide and on a nondiscriminatory basis. Such covenants may limit the prices we can charge for IVX-411 in low and middle income countries, and include a license to use certain of our proprietary technology related to IVX-411 for use in low and middle income countries if we do not comply with the Grant Agreement or GACA. Such price limitations or license, if invoked, could limit the prices we charge, or in some cases, restrict our control over the manufacturing and distribution of IVX-411, which could harm our ability to initiate or continue clinical trials of IVX-411, adversely affect the development or commercialization of IVX-411, or otherwise negatively impact our market position.

#### **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

## 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.

We had 34 full-time employees as of December 31, 2021. 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 the COVID-19 pandemic and other epidemic diseases.

The current COVID-19 worldwide pandemic has presented substantial public health and economic challenges and is affecting our employees, clinical trial subjects, physicians and other healthcare providers, communities and business operations, as well as the United States and global economies and financial markets. International and U.S. governmental authorities in impacted regions have taken, and are continuing to take, actions in an effort to slow the spread of COVID-19 and variants of the virus. To the extent possible, and consistent with applicable guidance from federal, state and local authorities, we are conducting business as usual, with necessary or advisable modifications to employee travel, and with our employees generally working both remotely and onsite, consistent with safety and applicable guidance. We will

continue to actively monitor the evolving situation related to COVID-19 and may take further actions that alter our operations, including those that may be required by federal, state or local authorities, or that we determine are in the best

interests of our employees and other third parties with whom we do business. To date, we have not experienced material disruptions in our business operations. However, while it is not possible at this time to estimate the impact that COVID-19 could have on our business in the future, particularly as we advance our vaccine candidates through clinical development, the continued spread of COVID-19 and the measures taken by the governmental authorities, and any future epidemic disease outbreaks, could disrupt the supply chain and the manufacture or shipment of drug substances and finished drug products for our vaccine candidates for use in our research, preclinical studies and clinical trials, delay, limit or prevent our employees and CROs from continuing 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. For example, with respect to clinical trial recruitment and enrollment specifically, while we continue to expect to report interim topline data from our IVX-121 Phase 1/1b trial in Belgium in the second quarter of 2022, challenges associated with COVID-19 have made it more difficult than projected to enroll subjects in the older adult arm of this trial. 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.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the COVID-19 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 continued geographic spread of variants, the duration of the pandemic, the timing and effectiveness of vaccine distribution, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this section. In addition, if in the future there is an outbreak of another highly infectious or contagious disease or other health concern, we may be subject to similar risks as posed by COVID-19.

## 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, including consulting agreements with certain physicians who are paid in the form of stock or stock options as compensation for services provided to us, 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 Public Health program; increases 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; created a new Medicare Part D coverage gap discount program; 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 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 of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through July 1, 2022 (with a 1% payment reduction from April 1 to June 30, 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.

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. At the federal level, for example, the Build Back Better Act, if enacted, would introduce substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, and the establishment of rebate payment requirements on manufacturers under Medicare Parts B and D. If the Build Back Better Act is not enacted, similar or other drug pricing proposals could appear in future legislation. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

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 is expected to increase data breach litigation. Further, the California Privacy Rights Act (CPRA) recently passed in California. The CPRA significantly amends the CCPA and will impose 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 will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1. 2023, and additional compliance investment and potential business process changes may be required. Similar laws have passed in Virginia 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). The European Commission issued revised standard contractual clauses on June 4, 2021 to account for the decision of the CJEU and recommendations made by the European Data Protection Board. The revised standard contractual clauses must be used for relevant new data transfers from September 27, 2021; existing standard contractual clauses arrangements must be migrated to the revised clauses by December 27, 2022. The new SCCs apply only to the transfer of personal data outside of the EEA and not the United Kingdom; the United Kingdom's Information Commissioner's Office launched a public consultation on its draft revised data transfers mechanisms in August 2021. There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non-EEA entities subject to the GDPR. 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. The relationship between the United Kingdom and the European Union and the EEA in relation to certain aspects of data protection law remains unclear, and it is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term. The European Commission has adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from EU member states to the United Kingdom without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews or extends that decision.

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 internal computer 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 internal information technology systems and those of our third-party collaborators, service providers, vendors, contractors and consultants are vulnerable to damage or interruption from computer viruses, 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, 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. 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.

If any failure of our information technology systems were 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.

#### 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 therapeutic programs 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. For example, many of the patent applications related to discoveries in the SARS-CoV-2 and COVID-19 vaccine field have not yet published and could impact our freedom to operate using our technology in the SARS-CoV-2 and COVID-19 space. 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 therapeutic programs 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 therapeutic programs and eventual 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 therapeutic 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 including (i) 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 products for the prophylactic and/or therapeutic treatment of RSV, hMPV and four other infectious diseases, (ii) 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. This license converts to an exclusive license in 2025 for North America and the European Union (including Switzerland and the United Kingdom), with other territories remaining non-exclusive, and (iii) certain non-exclusive licenses to use certain know-how related to the foregoing. 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. With respect to our COVID-19 vaccine candidate, we granted BMGF a humanitarian license that allows BMGF to make our COVID-19 vaccine available to certain developing countries. 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, IVX-A12 and IVX-411 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 product 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 product 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 product 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



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 product 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.

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.

Certain provisions of the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS Agreement) limit the use of compulsory licenses by World Trade Organization (WTO) members. Several WTO members and various public interest advocates have proposed the WTO implement a waiver of such provision of the TRIPS Agreement so that members may improve the supply of COVID-19 vaccines without fear of trade retaliation. In May 2021, the United States Trade Representative announced that the Biden Administration "will actively participate in text-based negotiations at the World Trade Organization (WTO) needed to make that happen. Those negotiations will take time given the consensus-based nature of the institution and the complexity of the issues involved." A waiver is unlikely to impact patent protection in the jurisdictions where we anticipate having the majority of our sales. Rather, with respect to our COVID-19 vaccine candidates, BMGF has retained or been granted rights in the jurisdictions where patent protection would be impacted. Nevertheless, the outcome of these negotiations is highly uncertain, and if the WTO agrees to waive provisions of the TRIPS Agreement relevant to our COVID-19 vaccine candidates, 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. 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. The COVID-19 pandemic may impair our and our licensors' ability to comply with these procedural, document submission, fee payment, and other requirements imposed by government patent agencies, which may materially and adversely affect our ability to obtain or maintain patent protection for our products and vaccine candidates.

### 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 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 will require us to be cognizant going forward 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 therapeutic 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 affect the way patent applications will be prosecuted and also may 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. Therefore, the America Invents Act and its implementation 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, all of which could 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 therapeutic 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 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 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**

### Prior to our IPO, there was no public market for our common stock, and an active, liquid and orderly market for our common stock may not develop or be maintained.

Prior to our IPO, there was no public market for our common stock. Our common stock only recently began trading on the Nasdaq Global Market (Nasdaq), and we can provide no assurance that we will be able to develop an active trading market for our common stock. Even if an active trading market is developed, it may not be maintained. 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.

### 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 and market conditions other events or factors, many of which are beyond our control;

•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.

### 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, 2021, our executive officers, directors and greater than 5% stockholders, in the aggregate, own approximately 38% 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

### 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 \$1.07 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 increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. 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 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.

We expect the rules and regulations applicable to public companies to substantially 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, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, 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, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. The biotech sector has experienced particular volatility in the past year. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

#### 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. For example, we may face litigation following the recent significant stock price drop following the release of interim topline results from our ongoing Phase 1/2 clinical trial of IVX-411. 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, 2021, we had federal and state net operating loss (NOL) carryforwards of approximately \$57.0 million and \$11.9 million, respectively.

Federal NOL carryforwards generated in periods after December 31, 2017, 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 will be required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2022. When we lose our status as an "emerging growth company" and do not otherwise qualify as a "smaller reporting company" with less than \$100 million in annual revenue, 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 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 in Seattle, Washington, where we lease laboratory and office space pursuant to a lease agreement that commenced in February 2020, and is subject to annual renewals, and will expire in May 2022. In December 2021, we entered into a new lease for laboratory and office space located at 1930 Boren Avenue in Seattle, Washington (the Premises), which we expect will serve as our new corporate headquarters. Under the terms of the lease, we will lease 15,063 square feet at the Premises for a temporary period starting in May 2022. As of the earlier of the date on which we substantially complete our initial tenant work or October 1, 2022, we will lease 25,253 square feet at the premises. The lease has a term of 63 months and 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 has been listed on the Nasdaq Global Market under the symbol "ICVX" since our initial public offering on August 2, 2021, which was completed at a price to the public of \$15.00 per share. Prior to our initial public offering, there was no public market for our common stock.

### Holders of Common Stock

As of March 29, 2022, we had approximately 48 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**

In March 2021, before we effected a one-for-4.1557 reverse stock split of our issued and outstanding common stock and a proportional adjustment to the existing conversion ratios for each series of the our convertible preferred stock in July 2021, we issued an aggregate of 32,958,612 shares of Series B-1 convertible preferred stock to investors at a purchase price of \$2.82172 per share, for aggregate consideration of approximately \$99.5 million, which included the conversion of a convertible promissory note with a principal amount of \$6.5 million issued in August 2020, into 2,805,850 shares of Series B-2 convertible preferred stock, at a conversion price of \$2.39846 per share.

The issuance of securities described in the paragraph above was deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) (or Regulation D promulgated thereunder) in that the issuance of securities to the accredited investors did not involve a public offering. The recipients of securities in this transaction acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited investor under Rule 501 of Regulation D. No underwriters were involved in these transactions.

All other unregistered securities issued and sold during the year ended December 31, 2021 are disclosed in the Company's Quarterly Reports on Form 10-Q for the quarters ended June 30, 2021 and September 30, 2021.

# **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, 2021, 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 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 for either RSV or hMPV, which are two common causes of pneumonia in older adults. We initiated a clinical trial of IVX-121 in September 2021, with interim topline data expected in the second quarter of 2022. Contingent on favorable results from the IVX-121 clinical trial and completion of cGMP manufacturing of IVX-241, we plan to submit an investigational new drug application (IND) to the U.S. Food and Drug Administration (FDA) and, thereafter, initiate a clinical trial of our combination vaccine candidate, IVX-A12, in the second half of 2022.

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. We are conducting a Phase 1/2 clinical trial of our coronavirus disease 2019 (COVID-19) candidate IVX-411 in Australia and reported interim topline results on this clinical trial in March 2022. Overall, although an immune response was observed and the initial reactogenicity data were favorable, the level of immunogenicity response was below our expectations. We are conducting further analysis of the data and our IVX-411 vaccine candidate, including an investigation into the manufacture, shipment, and vaccine administration in the Phase 1/2 clinical trial. We will further evaluate our plans with respect to our current COVID-19 vaccine candidates based on the results of these efforts. We also have licensed the rights to develop and commercialize an influenza VLP vaccine from the University of Washington (UW) and have an emerging flu program.

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 our preclinical studies and current and planned 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 \$340.2 million. In August 2021, we completed our initial public offering (IPO) with the sale of 13,953,332 shares of common stock at an IPO price of \$15.00 per share with net proceeds of \$190.7 million, which included the exercise in full by the underwriters of their option to purchase 1,819,999 additional shares. 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, 2021, we had cash of \$279.1 million and restricted cash of \$1.6 million.

We have incurred significant operating losses since inception. Our net losses for the years ended December 31, 2021 and 2020 were \$67.0 million and \$18.9 million, respectively. As of December 31, 2021, we had an accumulated deficit of \$94.1 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 and restricted cash 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.

# COVID-19

The global COVID-19 pandemic continues to evolve, and we will continue to monitor the COVID-19 situation closely. The extent of the impact of the COVID-19 pandemic on our business, operations and clinical development timelines and plans remains uncertain, and will depend on certain developments, including its impact on our clinical trial enrollment, trial sites, manufacturers, contract research organizations (CROs) and other third parties with whom we do business, as well as its impact on regulatory authorities and our key scientific and management personnel. The ultimate impact of the COVID-19 pandemic, including the impact of new variants of the virus that causes COVID-19, or a similar health epidemic is highly uncertain and subject to change. To the extent possible, and consistent with applicable guidance from federal, state and local authorities, we are conducting business as usual, with necessary or advisable modifications to employee travel. We will continue to actively monitor the evolving situation related to COVID-19 and may take further actions that alter our operations, including those that may be required by federal, state or local authorities, or that we determine are in the best interests of our employees and other third parties with whom we do business. At this point, the extent to which the COVID-19 pandemic may affect our business, operations and development timelines and plans, including the resulting impact on our expenditures and capital needs, remains uncertain and is subject to change.

# **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, 2021 and 2020, 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 a COVID-19 vaccine. As of December 31, 2021, we have received the full \$10.0 million of funding under the Grant Agreement. Unless terminated earlier by BMGF, the Grant Agreement will continue in effect until March 31, 2022. We do not currently expect future grant revenues to be a material source of funding.

# **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 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 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 patients;
- •the number of patients 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 the ongoing COVID-19 pandemic; and
- •the efficacy and safety profile of the vaccine candidate.

#### 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 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 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, 2021 and 2020

The following table summarizes our results of operations for the years ended December 31, 2021 and 2020 (in thousands):

	Year Ended December 31,				
		2021		2020	Change
Grant revenue	\$	7,802	\$	1,616	\$ 6,186
Operating expenses:					
Research and development		38,776		17,667	21,109
General and administrative		34,887		2,659	 32,228
Total operating expenses		73,663		20,326	 53,337
Loss from operations		(65,861)		(18,710)	(47,151)
Other income (expense)					
Change in fair value of embedded derivative liability		(205)		187	(392)
Loss on extinguishment of convertible promissory note		(754)		—	(754)
Interest and other expense		(151)		(331)	 180
Total other expense		(1,110)		(144)	 (966)
Net loss and comprehensive loss	\$	(66,971)	\$	(18,854)	\$ (48,117)

#### Grant Revenue

We recognized revenue from the Grant Agreement of \$7.8 million for the year ended December 31, 2021 compared to \$1.6 million for the year ended December 31, 2020. As of December 31, 2021, we have received the full \$10.0 million of funding under the Grant Agreement.

#### Research and Development Expenses

Research and development expenses were \$38.8 million for the year ended December 31, 2021, compared to \$17.7 million for the year ended December 31, 2020. The increase of \$21.1 million was primarily due to a \$10.8 million increase in direct costs related to preclinical development and manufacturing, a \$4.0 million increase in direct costs related to clinical development and manufacturing, a \$3.2 million increase in personnel related expenses due to increased headcount to support our development activities, a \$2.6 million increase related to non-cash stock-based compensation expense, and a \$0.5 million increase in other expenses.



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 on a program-by-program basis. Research and development expenses are summarized by program in the table below (in thousands):

	Year E Decem	 -	
	2021	2020	
RSV-hMPV	\$ 12,484	\$ 12,830	
SARS-CoV-2	13,487	1,415	
Unallocated research and development expense	 12,805	 3,422	
Total research and development expense	\$ 38,776	\$ 17,667	

#### General and Administrative Expenses

General and administrative expenses were \$34.9 million for the year ended December 31, 2021, compared to \$2.7 million for the year ended December 31, 2020. The increase of \$32.2 million consisted of increased non-cash stock-based compensation expense of \$26.2 million, inclusive of \$21.0 million in expense related to the modification of options accelerated in connection with the death of our former Chairman, Dr. Yamada, increased professional services including legal fees of \$2.2 million, increased personnel-related expenses of \$2.1 million, and increased other expenses of \$1.7 million.

#### Other Income (Expense)

Other income (expense) was expense of \$1.1 million for the year ended December 31, 2021, compared to expense of \$0.1 million for the year ended December 31, 2020. The increase of \$1.0 million in expense was the result of a loss on extinguishment of convertible promissory note of \$0.8 million, an increase in expense recognized on the change in fair value of derivative liability of \$0.4 million, offset by a decrease in interest expense of \$0.2 million.

#### 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 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. Additionally, in July 2021, we received the final \$3.3 million in restricted cash awarded under the Grant Agreement. As of December 31, 2021, we had cash of \$279.1 million, restricted cash of \$1.6 million and an accumulated deficit of \$94.1 million.

# Funding Requirements

Based on our current operating plan we believe that our existing cash and restricted cash 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 the COVID-19 pandemic;

-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 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 and restricted cash will not be sufficient to complete development of IVX-A12, IVX-411, an influenza vaccine candidate, or any other 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,			
	2021	2020		
Net cash (used in) provided by				
Operating activities	\$ (38,540)	\$	(14,208)	
Investing activities	(1,006)		(11)	
Financing activities	304,772		6,638	
Net change in cash and restricted cash	\$ 265,226	\$	(7,581)	

# **Operating Activities**

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 Dr. Yamada, \$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.

Net cash used in operating activities for the year ended December 31, 2020 was \$14.2 million, consisting primarily of our net loss incurred during the period of \$18.8 million adjusted for \$0.5 million of non-cash charges, and \$4.1 million for net changes in operating assets and liabilities. Non-cash charges consisted primarily of \$0.4 million non-cash interest expense and \$0.3 million in stock-based compensation, which were partially offset by \$0.2 million of non-cash income recognized related to the change in fair value of the derivative liability. The net change in operating assets and liabilities consisted of a \$2.2 million increase in accounts payable and accrued and other current liabilities and \$2.4 million increase in deferred revenue, partially offset by a \$0.5 million increase in prepaid and other current assets in support of the growth in our operating activities.

#### **Investing Activities**

Net cash used in investing activities for the years ended December 31, 2021 and 2020 was \$1.0 million and less than \$0.1 million, respectively, for purchases of property and equipment.

#### **Financing Activities**

Net cash provided by financing activities for the year ended December 31, 2021 was \$304.8 million consisting of \$190.7 million in proceeds related to the issuance of common stock in the IPO in August 2021, \$92.6 million in proceeds related to the issuance of Series B-1 convertible preferred stock in March 2021, \$21.0 million in 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.

Net cash provided by financing activities for the year ended December 31, 2020 was \$6.6 million, consisting of \$6.4 million related to issuance of a convertible promissory note in August 2020, and \$0.2 million proceeds from early exercises of stock options.

#### **Contractual Obligations and Commitments**

We had no contractual obligations and commitments as of December 31, 2021 and 2020.

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, 2021 and 2020, 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 below and 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.

#### Fair Value of Derivative Liability and Convertible Promissory Note

We adjusted the carrying value of the derivative liability that was bifurcated from our 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. There were significant judgments and estimates inherent in the determination of the fair value of these liabilities. If we had made different assumptions including, among others, those related to the timing and probability of various financing scenarios, discount rates, volatilities and exit valuations, the carrying values of our derivative liability and convertible promissory note, and our net loss and net loss per share of common stock could have been significantly different. 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.

#### Stock-Based Compensation Expense

Stock-based compensation expense represents the cost of the grant date fair value of employee, officer, director and non-employee stock options. We estimate the fair value of stock options on the date of grant using the Black-Scholes option pricing model and recognize the expense over the requisite service period of the awards, which is generally the vesting period, on a straight-line basis. We account for forfeitures when they occur and reverse any compensation cost previously recognized for awards for which the requisite service has not been completed, in the period that the award is forfeited.

See Note 2 to our audited financial statements included elsewhere in this Annual Report for more information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options. The Black-Scholes option pricing model uses inputs which are assumptions that generally require judgment. For example, before our IPO, we estimated the fair value of the common stock underlying our stock-based awards on each grant date using valuation approaches appropriate for privately held companies that involved significant judgment. Also given our limited history of common stock price data, we derive the expected volatility of our common stock price from the average historical volatilities of comparable publicly traded companies within our peer group. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation could be materially different.

# Income Taxes

We are subject to corporate U.S. federal and state income taxation. As of December 31, 2021 and 2020, we had federal net operating loss carryforwards of \$57.0 million and \$21.0 million, respectively, and state net operating loss carryforwards of \$11.9 million, and \$2.2 million, respectively. As a result of the Tax Cuts and Jobs Act of 2017, for U.S. income tax purposes, net operating losses generated after January 1, 2018 will be carried forward indefinitely. As of December 31, 2021, we had federal research and development tax credit carryforwards of approximately \$3.0 million, which begin to expire in 2037. Additionally, as of December 31, 2021, we had state research and development credit carryforwards of approximately \$168,000, which carryforward indefinitely.

Utilization of the net operating loss carryforwards may be subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended, and similar state provisions.



This annual limitation may result in the expiration of net operating losses and credits before utilization. We have not performed an analysis to determine the limitation of our net operating loss carryforwards.

We estimate our income tax provision, including deferred tax assets and liabilities, based on management's judgment. We record a valuation allowance to reduce our deferred tax assets to the amounts that are more likely than not to be realized. We consider future taxable income, ongoing tax planning strategies and our historical financial performance in assessing the need for a valuation allowance. Due to the uncertainty surrounding the realization of deductible tax attributes in future tax returns, we have recorded a valuation allowance against our net deferred tax assets as of December 31, 2021 and 2020. If we expect to realize deferred tax assets for which we have previously recorded a valuation allowance, we will reduce the valuation allowance in the period in which such determination is first made.

We record liabilities related to uncertain tax positions in accordance with the guidance that clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements by prescribing a minimum recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return.

#### **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 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 \$1.07 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.

# **Off-Balance Sheet Arrangements**

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

#### Item 7a. Quantitative and Qualitative Disclosures about Market Risk

# Interest Rate Risk

Our cash and restricted cash consist of cash in readily available checking accounts and money market funds. As a result, the fair value of our portfolio is relatively insensitive to interest rate changes.

# 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

	Page
Report of Independent Registered Public Accounting Firm; Ernst and Young LLP, Seattle, WA, (PCAOB ID: 42)	119
Balance Sheets	120
Statements of Operations and Comprehensive Loss	121
Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)	122
Statements of Cash Flows	123
Notes to Financial Statements	124

# **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, 2021 and 2020, 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, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, 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, 2022

# **Balance Sheets**

(in thousands, except share and par value data)

	December 31,			
	2021		2020	
Assets				
Current assets:				
Cash	\$ 279,082	\$	13,114	
Restricted cash	1,642		2,384	
Prepaid expenses and other current assets	 5,829		662	
Total current assets	286,553		16,160	
Property and equipment, net	 1,076		10	
Total assets	\$ 287,629	\$	16,170	
Liabilities, convertible preferred stock, and stockholders' equity (deficit) Current liabilities:				
Accounts payable	\$ 3,899	\$	1,918	
Accrued and other current liabilities	4,757		1,532	
Deferred revenue	582		2,384	
Total current liabilities	9,238		5,834	
Long-term convertible promissory note	_		4,947	
Embedded derivative liability	—		1,604	
Other noncurrent liabilities	 171		426	
Total liabilities	9,409		12,811	
Commitments and contingencies (Note 2)				
Convertible preferred stock, \$0.0001 par value; no shares authorized at December 31, 2021 and 54,039,749 shares authorized at December 31, 2020; no shares issued and outstanding at December 31, 2021 and 32,198,879 shares issued and outstanding at December 31, 2020; \$0 and \$30,007 aggregate liquidation preference at December 31, 2021 and 2020, respectively Stockholders' equity (deficit):	_		30,062	
Preferred stock, \$0.0001 par value; 50,000,000 and no shares authorized at December 31, 2021 and 2020, respectively; no shares issued and outstanding at either December 31, 2021 or 2020	_		_	
Common stock, \$0.0001 par value; 500,000,000 and 78,000,000 shares authorized at December 31, 2021 and 2020, respectively; 39,429,103 and 3,596,936 shares issued as of December 31, 2021 and 2020, respectively; 39,175,279 and 2,639,026 shares outstanding as of December 31, 2021 and				
December 31, 2020, respectively	5		2	
Additional paid-in capital	372,284		393	
Accumulated deficit	(94,069)		(27,098)	
Total stockholders' equity (deficit)	 278,220		(26,703)	
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	\$ 287,629	\$	16,170	

See accompanying notes to financial statements

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

	Year Ended December 31,			
		2021		2020
Grant revenue	\$	7,802	\$	1,616
Operating expenses:				
Research and development		38,776		17,667
General and administrative		34,887		2,659
Total operating expenses		73,663		20,326
Loss from operations		(65,861)		(18,710)
Other income (expense):				
Change in fair value of embedded derivative liability		(205)		187
Loss on extinguishment of convertible promissory note		(754)		
Interest and other expense		(151)		(331)
Total other expense		(1,110)		(144)
Net loss and comprehensive loss	\$	(66,971)	\$	(18,854)
Net loss per share, basic and diluted	\$	(3.73)	\$	(8.40)
Weighted-average common shares outstanding, basic and diluted		17,965,894		2,245,223

See accompanying notes to financial statements

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

(in thousands, except share amounts)

	Convertible Pi Shares	referred Stock Amount	Commo Shares	n Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance at December 31, 2019	32,198,879	\$ 30,062	1,901,656	\$1	\$ —	\$ (8,244)	\$ (8,243)
Shares released from restriction upon vesting of early-exercised stock options	_	_	267,894	1	136	_	137
Vesting of shares of restricted common stock	_	—	469,476	—	—	—	—
Stock-based compensation	_	_	_	_	257	_	257
Net loss and comprehensive loss						(18,854)	(18,854)
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 Issuance of common stock for Employee Stock Purchase Plan			469,493 16,606				 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

See accompanying notes to financial statements

# **Statements of Cash Flows**

(in thousands)

	Year Ended December 31,			
		2021		2020
Operating activities:				
Net loss	\$	(66,971)	\$	(18,854)
Adjustments to reconcile net loss to cash used in operating activities:				
Stock-based compensation		29,031		257
Depreciation		82		1
Non-cash interest expense		264		417
Change in fair value of embedded derivative liability		205		(187)
Loss on extinguishment of convertible promissory note		754		_
Changes in operating assets and liabilities:				
Prepaids and other current assets		(5,167)		(453)
Accounts payable		<b>`1,839</b> ´		1,119
Accrued and other current liabilities		3,225		1,108
Deferred revenue		(1,802)		2,384
Net cash used in operating activities		(38,540)		(14,208)
Investing activities:				
Purchases of property and equipment		(1,006)		(11)
Net cash used in investing activities		(1,006)		(11)
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 convertible promissory notes, net of issuance costs		-		6,464
Proceeds from exercise of stock options, including early exercise		400		174
Net cash provided by financing activities		304,772		6,638
Net increase (decrease) in cash and restricted cash		265,226		(7,581)
Cash and restricted cash at beginning of period		15,498		23,079
Cash and restricted cash at end of period	\$	280,724	\$	15,498
Supplemental disclosure of noncash activities				
Conversion of preferred stock to common stock	\$	151,613	\$	
Purchases of property and equipment included in accounts payable	\$	142	\$	

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, and clinical efficacy of the Company's products under development. In addition, any of the technologies covering the Company's existing products under development 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 \$94.1 million, cash of \$279.1 million, and restricted cash of \$1.6 million at December 31, 2021.

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 vaccines candidates, scaling up manufacturing of vaccine candidates, and preparing for its ongoing and planned 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, 2021, 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.

The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition, including expenses, clinical trials and research and development costs, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat COVID-19, as well as the economic impact on local, regional, national and international markets. The Company has considered potential impacts arising from the COVID-19 pandemic and is not presently aware of any events or circumstances that would require the Company to update its estimates, judgments or revise the carrying value of its assets or liabilities.

#### **Concentration of Credit Risk**

Financial instruments which potentially subject the Company to significant concentration of credit risk consist of cash and restricted cash. 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 an Insured Cash Sweep account where balances are maintained in interest bearing demand accounts. The Company has not experienced any losses on its deposits of cash since inception, 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.

# **Comprehensive Loss**

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company's comprehensive loss was the same as its reported net loss for all periods presented.

#### 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 all cash, restricted cash, 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.

The carrying values of the derivative liability of \$1.6 million (level 3 fair value) and the convertible promissory note of \$4.9 million in the accompanying balance sheet at December 31, 2020 approximate fair value because they collectively converted into 2,805,850 shares of Series B convertible preferred stock in March 2021.

# Cash

Cash represents funds in the Company's operating bank account. The Company has no cash equivalents.



# **Restricted Cash**

The Company's restricted cash includes payments received under the Grant Agreement (as defined in Note 4) with the Bill & Melinda Gates Foundation ("BMGF") under which the Company was awarded a grant of up to \$10.0 million. The Company will utilize the Grant Agreement funds as it incurs expenses for services performed under the agreement. Restricted cash also includes cash collateral supporting the standby letter of credit discussed in "Leases" below.

#### 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).

#### 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, 2021.

# 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 income (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 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 right-of-use 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 right-of-use 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.



In January 2020, and amended in March 2020, the Company entered into a lab license agreement for office and lab space in Seattle, Washington. The lab license agreement is twelve months and provides for renewal options. The monthly base rent is approximately \$16,000. The lab license agreement is considered short-term and therefore, no right-of-use asset or lease liability has been recorded.

In December 2021, the Company entered into a lease agreement for corporate office and lab space in Seattle, Washington. The Company took possession of certain leased space at various dates in January 2022 and March 2022. The lease agreement is five years and 3 months 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 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 at the first anniversary, and further reduced to \$0.7 million at the second anniversary of the lease. As of December 31, 2021, the Company had not taken control of the space and the lease term had not commenced; therefore, no right-of-use asset or lease liability has been recognized.

#### Grant Revenue

The Company's revenue consists of revenue under its Grant Agreement with BMGF (see Note 4). The Company is 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 COVID-19 RBD VLP vaccine in Australia. The Company's Grant Agreement does 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. As BMGF ultimately determines if milestones under the agreement are met and if funding should continue, there may be a difference in timing between when research and development expenses are incurred and when grant revenue is recognized.

## 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 interest bearing demand accounts.

# 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 253,824 and 488,226 shares as of December 31, 2021 and 2020, respectively. As of December 31, 2021 and 2020, the Company had \$0.2 million and \$0.2 million respectively, of amounts related to shares issued with repurchase rights classified as other noncurrent liabilities in the accompanying balance sheets.

## 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 Black-Scholes option pricing model uses inputs which are assumptions that generally require judgment. These assumptions include:

•Fair Value of Common Stock. Prior to the Company's IPO, the grant date fair market value of the shares of common stock underlying stock options was historically determined by the Company's board of directors. Because there was no public market for the Company's common stock, the board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair market value. which included contemporaneous valuations performed by an independent third-party, the Company's results of operations and financial position, including its levels of available capital resources, its stage of development and material risks related to the Company's business, progress of the Company's research and development activities, the Company's business conditions and projections, the lack of marketability of the Company's common stock and preferred stock as a private company, the prices at which the Company sold shares of its convertible preferred stock to outside investors in arms-length transactions, the rights, preferences and privileges of the Company's redeemable convertible preferred stock relative to those of its common stock, the analysis of initial public offerings and the market performance of similar companies in the biopharmaceutical industry, the likelihood of achieving a liquidity event for the Company's securityholders, such as an initial public offering or a sale of the Company, given prevailing market conditions, the hiring of key personnel and the experience of management, trends and developments in the Company's industry, and external market conditions affecting the life sciences and biopharmaceutical industry sectors. Subsequent to the Company's IPO, 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 never paid dividends on its common stock and do 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 common stock at each valuation date.

### **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, 2021 or 2020.

#### 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, 2021 and 2020, 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, 2021, the Company had no accrued interest or penalties.

### **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 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,			
		2021		2020
Numerator:				
Net loss	\$	(66,971)	\$	(18,854)
Denominator:				( , , ,
Weighted-average common shares outstanding, basic and diluted		18,587,782		3,517,671
Less: Weighted-average unvested common stock		(621,888)		(1,272,448)
Weighted-average shares used to compute net loss per share, basic and		<u>, , , , , , , , , , , , , , , , , , , </u>		<u>, , , , , , , , , , , , , , , , , , , </u>
diluted		17,965,894		2,245,223
Net loss per share, basic and diluted	\$	(3.73)	\$	(8.40)

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 Ei Decemb	
	2021	2020
Series A convertible preferred stock		32,198,879
Common stock options	6,591,727	641,427
ESPP shares	16,606	_
Unvested common stock	253,824	957,711
Total	6,862,157	33,798,017

#### 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.

#### 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 following table summarizes financial liabilities that the Company measured at fair value on a recurring basis, classified in accordance with the fair value hierarchy (in thousands):

			Fair Value Measurements at Report Date Using				rt Date	
	-	Total	(Level	1)	(Leve	el 2)	(Le	evel 3)
As of December 31, 2020								
Embedded derivative liability	\$	(1,604)	\$		\$		\$	(1,604)

There were no assets or liabilities measured at fair value on a recurring basis as of December 31, 2021.

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 has 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	December 31, 2020	August 20, 2020
Probability of financing	100%	90%	90%
Probability of dissolution	—	10%	10%
Time to liquidity (years)	—	0.50 - 1.00	0.83 - 1.33
Discount rate	7.6%	8.3%	11.9%

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.

For the year ended December 31, 2020, the Company recognized \$0.2 million of other income in the statements of operations and comprehensive loss related to decreases 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 in other expense in the statements of operations and comprehensive loss for the year ended December 31, 2021, which included the write off 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):

	Derivati	ive Liability
Fair value at December 31, 2019	\$	_
Fair value of derivative liability at issuance of convertible promissory note		(1,791)
Change in fair value of derivative liability (Note 7)		187
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 a 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, including the Company's regulatory filing preparations and planned Phase 1 clinical trial. Unless terminated earlier by BMGF, the Grant Agreement will continue in effect until March 31, 2022. The Company concurrently entered into a Global Access Commitments Agreement ("GACA") with BMGF as part of the Grant Agreement. Under the terms of the GACA, among other things, the Company agreed to make a certain amount of its COVID-19 vaccine available and accessible at affordable pricing to people in certain low- and middle-income countries, if the vaccine is commercialized.

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

At December 31, 2021, the Company had \$0.6 million of restricted cash and deferred revenue, and at December 31, 2020, had \$2.3 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.

During the years ended December 31, 2021 and 2020, the Company received \$6.0 million and \$4.0 million in funding, respectively, from BMGF.

During the years ended December 31, 2021 and 2020, the Company recognized revenue from the Grant Agreement of \$7.8 million and \$1.6 million, respectively, and has recognized approximately \$9.4 million in revenue since the inception of the Grant Agreement. As of December 31, 2021, the Company has received the full \$10.0 million in funding under the Grant Agreement.

#### 5. Balance Sheet Details

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

	As of December 31,			
	 2021		2020	
Laboratory equipment	\$ 856	\$	11	
Construction in progress	303		—	
Property and equipment, cost	1,159		11	
Accumulated depreciation	(83)		(1)	
Property and equipment, net	\$ 1,076	\$	10	

Depreciation expense was \$0.1 million for the year ended December 31, 2021, and was a negligible amount for the year ended December 31, 2020.

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



	As o	As of December 31,			
	2021		2020		
Taxes payable	\$	— \$	91		
Accrued paid time off		342	137		
Accrued bonus	2	2,216	696		
Other accrued liabilities	1	,977	608		
Accrued 401k		156			
ESPP liability		66			
Total accrued and other current liabilities	\$ 4	,757 \$	1,532		

## 6. License Agreements

## License Agreement with the National Institutes of Health

On June 28, 2018, the Company entered into a non-exclusive patent license agreement (the "NIH Agreement") with a U.S. government entity, the National Institutes of Health, represented by National Institute of Allergy and Infectious Disease ("NIAID"). The NIH Agreement was amended in September 2018 and September 2020. 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 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. There are milestone payments due upon the completion of certain development, regulatory, and commercial milestones for the licensed products in the future. The Company is obligated to pay aggregate potential milestone payments of up to \$2.1 million with respect to future development and regulatory based milestones, and up to \$6.5 million with respect to future sales milestones following commercialization. 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.

During the years ended December 31, 2021 and 2020, the Company paid \$0.2 million and \$0.1 million, respectively, in fees associated with the license, which were recorded as research and development expenses.

### License Agreements with University of Washington

### License Agreement with respect to RSV and Other Pathogens

On June 29, 2018, the Company entered into an exclusive license agreement with an academic entity, University of Washington (the "UW 2018 Agreement"), for an exclusive license to covered intellectual property, a non-exclusive, worldwide license to use licensed know-how, and rights to sublicense for computationally designed nanoparticles and vaccines. The UW 2018 Agreement was amended in June 2019 and again in November 2020. 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 University of Washington ("UW").

The Company issued 192,276 shares of common stock on August 1, 2018 in exchange for the UW 2018 Agreement's exclusive license. The shares issued were recorded at their estimated fair value, which is de minimis, with the related expense classified as research and development in 2018.

Under the UW 2018 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 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 \$1.4 million per indication, up to a maximum of \$6.8 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 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.

The UW 2018 Agreement will terminate when all licensed rights have been terminated and all obligations due to UW have been fulfilled, or the Company may terminate the entirety of the agreement upon written notice thereof to UW.

On July 2, 2020, the Company entered into a non-exclusive license agreement with respect to specified intellectual property with options for exclusivity in North America and Europe subject to the performance of certain development milestones, with UW (the "UW 2020 Agreement"). Under the UW 2020 Agreement, the Company also received a non-exclusive, worldwide license to use specific know-how and rights to sublicense for computationally designed nanoparticles and vaccines. The UW 2020 Agreement was amended in August 2020 and subsequently in May 2021. The Company's rights and obligations under the UW 2020 Agreement as amended 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 as amended, 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. 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 as amended 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.

The UW 2020 Agreement as amended will terminate when all licensed rights have been terminated and all obligations due to UW have been fulfilled, or the Company may terminate the entirety of the agreement upon written notice thereof to UW.

During the years ended December 31, 2021 and 2020, the Company paid \$0.2 million and \$0.3 million respectively, in fees associated with the 2018 and 2020 Agreements.

#### License Agreement with Respect to Influenza

In September 2021, the Company entered into a license agreement with UW ("UW Flu License Agreement"). 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 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".

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 do 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 \$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. The Company is 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 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 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 the Company breaches or fails to perform one of the 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. The Company can terminate the UW Flu License Agreement at will with prior written notice to UW. The Company can also terminate certain of its licensed rights through an amendment to the UW Flu License Agreement.

During year ended December 31, 2021, the Company paid \$0.1 million in fees associated with the UW Flu License Agreement.

### License Agreement with the University of Texas

In June 2021, the Company entered into an exclusive patent license agreement with an academic entity, the University of Texas at Austin (the "UT Agreement"). Under the UT Agreement, the Company obtained 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 metapneumovirus infection in all vaccine fields, excluding mRNA-based vaccines.

The Company is obligated to pay aggregate potential milestone payments of up to \$0.8 million with respect to future development and regulatory based milestones, and up to \$3.8 million with respect to future sales milestones following commercialization for each licensed product for so long as licensed patent rights exist and have not expired, been revoked, lapsed, or held unenforceable.

The UT Agreement will terminate upon the last expiration of the patent rights or the Company may terminate the entirety of the agreement upon written notice thereof to the University of Texas at Austin.

During year ended December 31, 2021, the Company paid 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 is 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 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 approximately \$36,000 of issuance costs related to the Convertible Promissory Note, which were also recorded as a reduction to the Convertible Promissory Note.

The debt discount comprised of the initial fair value of the derivative liability and the issuance costs is 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%.

Total Convertible Promissory Note consisted of the following (in thousands):

	December	31, 2020
Principal amount	\$	6,500
Discount related to the derivative liability and issuance costs		(1,553)
Net carrying amount of Convertible Promissory Note	\$	4,947

Interest expense incurred in connection with the Convertible Promissory Note consisted of the following year ended December 31 (in thousands):

	December 31,			
	2021		2020	
Coupon interest at 6%	\$ 86	\$	143	
Accretion of discount and amortization of issuance costs	177		274	
Total interest expense on Convertible Promissory Note	\$ 263	\$	417	

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 in 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. Convertible Preferred Stock and Stockholders' Equity (Deficit)

### **Convertible Preferred Stock**

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. Convertible preferred stock authorized and issued and its principal terms as of December 31, 2020 consisted of the following (\$ amounts in thousands):

	Share Authorized and Outstanding	Shares Issued and Outstanding	Shares of Common Stock Issuable upon Conversion	Liq	gregate uidation eference	(	Carrying Value
Series A-1	49,089,955	27,249,085	6,557,031	\$	26,200	\$	25,912
Series A-2	4,949,794	4,949,794	1,191,082		3,807		4,150
Total	54,039,749	32,198,879	7,748,113	\$	30,007	\$	30,062

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.

In connection with the Company's IPO in August 2021, 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.

In addition, 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, 2021.

### **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, restricted stock units 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 is 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 our board of directors. The reserve for the 2021 Plan increased by 5%, or 1,971,455 shares, effective January 1, 2022. 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 existing grants are subject to a time-based vesting period which will generally be four years. Certain option and share 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.

137

A summary of the status of the options issued under the Company's equity incentive plans as of December 31, 2021, and information with respect to the changes in options outstanding is as follows:

	Option Pool Available for Grant	Options Outstanding	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at December 31, 2020	541,411	641,427	\$ 0.84	9.02	\$ —
Authorized increase in plan shares	22,634,965	—	—	—	—
Granted	(6,177,633)	6,177,633	8.52	—	
Exercised (including early)	_	(227,333)	0.84	—	\$ 1,012,104
Balance at December 31, 2021	16,998,743	6,591,727	\$ 8.04	9.26	\$ 101,725,631
Vested and expected to vest as of December 31, 2021		6,591,727	\$ 8.04	9.26	\$ 101,725,631
Vested and exercisable at December 31, 2021		826,952	<u>\$ 5.71</u>	9.05	<u>\$ 14,199,668</u>

Exercisable options in the table above reflect the number of options vested as of the date reported. The 2021 Plan permits early exercises of options. Cash received for early exercise of unvested options is recognized as an other noncurrent liability in the accompanying balance sheet and totaled \$0.2 million at December 31, 2021.

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, 2021.

During the year ended December 31, 2021, the Company granted 6,177,633 options, with a grant date fair value of \$48.3 million. During the year ended December 31, 2020, the Company granted 271,405 options, with a grant date fair value of \$0.3 million. The weighted-average grant date fair value of employee option grants during the years ended December 31, 2020 were \$8.52 and \$1.06 per share, respectively.

During the year ended December 31, 2021, the Company granted 388,500 restricted stock unit ("RSU") awards, with a grant date fair value of \$10.1 million. The weighted-average grant date fair value of RSU awards during the year ended December 31, 2021 was \$25.96. All RSU awards granted during the year ended December 31, 2021 were nonvested as of December 31, 2021. There were no RSU awards granted during the year ended December 31, 2020.

## Common Stock

As of December 31, 2021 and 2020, of the 500,000,000 and 78,000,000 authorized shares of common stock, respectively, 39,429,103 and 3,596,936 shares were issued, respectively, and 39,175,279 and 2,639,026 shares were outstanding, respectively.

As of December 31, 2021 and 2020, the Company had 2,347,629 shares of restricted common stock that had been issued to members of management at a price of \$0.004 per share, and 269,694 shares of common stock that had been issued to a university in connection with obtaining a licensing agreement.

At December 31, 2021 and 2020, 2,347,629 and 1,995,314 shares of the restricted common stock have vested, respectively. At December 31, 2021, no shares were subject to vesting conditions.

Common stock reserved for future issuance consisted of the following:

	As of December 31, 2021
Common stock options and restricted stock units granted and outstanding	6,980,227
Shares available for issuance under the equity incentive plans	8,187,715
Shares available for issuance under the 2021 Employee Stock Purchase Plan	1,183,394
Total common stock reserved for issuance	16,351,336

## Stock-Based Compensation Expense

Stock-based compensation expense for all equity awards and the 2021 Employee Stock Purchase Plan, has been reported in the statements of operations and comprehensive loss as follows (in thousands):

	Year E Decem	
	 2021	2020
Research and development	\$ 2,710	\$ 137
General and administrative	26,321	120
Total	\$ 29,031	\$ 257

The Company recognizes compensation expense for options and RSU awards granted to employees and the board of directors based on their grant date fair value. The compensation expense is recognized over the vesting period of 4 years on a straight-line basis.

The fair value of each stock option granted was determined using the Black-Scholes option pricing model. The assumptions used in the Black-Scholes option pricing model to determine the fair value of the employee and nonemployee stock option grants issued during years ended were as follows:

		Year Ended December 31,		
	2021	2020		
Risk-free rate of interest	0.63%-1.34%	0.31%-1.40%		
Expected term (years)	5.77 - 6.08 years	5.90 - 6.08 years		
Expected stock price volatility	84.2% - 90.9%	80.2% - 86.4%		
Dividend yield	0%	0%		

As of December 31, 2021, the unrecognized compensation cost related to outstanding stock options and RSU awards was \$39.4 million and \$9.0 million, respectively and is expected to be recognized as expense over a weighted-average period of approximately 3.41 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.

## 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 is 400,000 shares. The number of shares of common stock reserved for issuance under the ESPP increases on January 1, 2022 and 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 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 1% or 394,291 shares, on January 1, 2022. As of December 31, 2021, 16,606 shares have been purchased by employees under the ESPP. Stock-based compensation expense related to the ESPP for the year ended December 31, 2021 was \$0.1 million.

## 9. 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,	
	2021	2020
U.S. federal statutory income tax rate	21.0%	21.0%
Adjustments for the tax effects of:		
State income taxes, net of federal tax	1.0	0.6
Other permanent differences	(0.4)	(0.3) 3.8
Research and development tax credits	3.1	3.8
Research and development credit permanent adjustment	(0.6)	(1.3)
Stock-based compensation	(1.6)	(0.3)
Uncertain tax positions	(0.8)	(1.0)
Change in valuation allowance	(21.7)	(22.5)
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,		
		2021	2020
Deferred tax assets			
Net operating loss carryforwards	\$	12,623	\$ 4,549
Research and development credits		2,349	790
Deferred revenue		126	515
Stock-based compensation		5,192	
Other		533	226
Total deferred tax assets		20,823	 6,080
Less: deferred tax liabilities		(280)	(3)
Less: valuation allowance		(20,543)	 (6,077)
Net deferred tax assets	<u>\$</u>		\$ 

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, 2021 and 2020. 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 \$20.5 million as of December 31, 2021, an increase of \$14.4 million during the year ended December 31, 2021. The Company has total net operating loss carryforwards for U.S. federal income tax and state purposes of approximately \$57.0 million and \$11.9 million, respectively, as of December 31, 2021 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 \$3.0 million as of December 31, 2021, which begin to expire in 2037. Additionally, the Company has state research and development credit carryforwards of approximately \$168,000 as of December 31, 2021, which carryforward indefinitely. 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, 2021, 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,		
		2021	2020
Unrecognized tax benefits, beginning of year	\$	263	\$ 84
Additions based on tax positions relating to current year		495	242
Additions based on tax positions relating to prior year		—	—
Reductions for positions of prior years		_	(63)
Unrecognized tax benefits, end of year	\$	758	\$ 263

The Company does not believe it is reasonably possible that its unrecognized tax benefits will change materially in the next twelve months.

## 10. 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 did not make any contributions to the plan during 2021 or 2020.

141

#### 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

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the company's registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

### 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, 2021 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, 2021 (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 F-1.

## 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	Incor	porated by	Reference	Filed Herewith
		Form	Date	Number	
3.1 3.2 4.1	Amended and Restated Certificate of Incorporation Amended and Restated Bylaws Specimen stock certificate evidencing the shares of common stock	8-K 8-K S-1/A	8/2/2021 8/2/2021 7/22/21	3.1 3.2 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	7/22/21	4.2	
4.3 10.1#	Description of Registered Securities lcosavax, Inc. 2021 Incentive Award Plan, form of stock option agreement thereunder, and form of restricted stock unit agreement	S-1/A	7/22/21	10.2	Х
10.2# 10.3# 10.4#	Icosavax, Inc. 2021 Employee Stock Purchase Plan Non-Employee Director Compensation Program Amended and Restated Employment Letter Agreement, dated July 22, 2021, by and between Adam Simpson and the	S-1/A S-1/A S-1/A	7/22/21 7/22/21 7/22/21	10.3 10.4 10.12	
10.5#	Registrant Amended and Restated Employment Letter Agreement, dated July 22, 2021, by and between Douglas Holtzman, Ph.D. and the Registrant	S-1/A	7/22/21	10.13	
10.6#	Amended and Restated Employment Letter Agreement, dated July 22, 2021, by and between Niranjan Kanesa-Thasan, M.D.	S-1/A	7/22/21	10.14	
10.7#	and the Registrant Amended and Restated Employment Letter Agreement, dated July 22, 2021, by and between Cassia Cearley and the	S-1/A	7/22/21	10.15	
10.8#	Registrant Amended and Restated Employment Letter Agreement, dated July 22, 2021, by and between Charles Richardson, Ph.D. and	S-1/A	7/22/21	10.16	
10.9#	the Registrant Amended and Restated Employment Letter Agreement, dated July 22, 2021, by and between Thomas J. Russo and the	S-1/A	7/22/21	10.17	
10.10#	Registrant Employment Letter Agreement, dated August 9, 2021, by and between Elizabeth Bekiroglu and the Registrant	10-Q	11/15/21	10.10	
10.11#	Form of Indemnification Agreement for Directors and Officers	S-1	7/7/2021	10.18	

10.12†	Exclusive License Agreement, dated June 29, 2018, between	S-1	7/7/2021	10.19	
10.13†	the Registrant and University of Washington, as amended License and Exclusive Option Agreement, dated July 2, 2020,	S-1	7/7/2021	10.20	
10.10	between the Registrant and University of Washington, as	01	111/2021	10.20	
	amended				
10.14†	Non-Exclusive Patent License Agreement, dated June 28,	S-1	7/7/2021	10.21	
	2018, between the Registrant and National Institute of Allergy and Infectious Diseases, as amended				
10.15†	Grant Agreement, dated September 24, 2020, between the	S-1	7/7/2021	10.22	
I	Registrant and the Bill & Melinda Gates Foundation, as				
10.10	amended	0.4	7/7/0004	40.00	
10.16†	Global Access and Price Commitment Agreement, dated February 17, 2021, between the Registrant and the Bill &	S-1	7/7/2021	10.23	
	Melinda Gates Foundation				
10.17†	Patent License Agreement, dated June 2, 2021, between the	S-1	7/7/2021	10.24	
	Registrant and the University of Texas at Austin				
10.18†^	Lease Agreement, dated December 15, 2021, by and between				Х
10.19†	Boren Lofts Owner (DE) LLC Non-Exclusive License Agreement, dated September 16, 2021,				Х
10.19	by and between the University of Washington and the				^
	Registrant				
23.1	Consent of Independent Registered Public Accounting Firm				Х
31.1	Certification of Chief Executive Officer required by Rule				Х
	<u>13a-14(a) or Rule 15d-14(a), as adopted pursuant to Section</u>				
31.2	<u>302 of the Sarbanes-Oxley Act of 2002</u> Certification of Chief Financial Officer required by Rule				Х
31.Z	<u>13a-14(a) or Rule 15d-14(a), as adopted pursuant to Section</u>				^
	302 of the Sarbanes-Oxley Act of 2002				
32.1*	Certification of Chief Executive Officer pursuant to Section 906				Х
	of the Sarbanes-Oxley Act of 2002				
32.2*	Certification of Chief Financial Officer pursuant to Section 906				Х
101.INS	of the Sarbanes-Oxley Act of 2002 Inline XBRL Instance Document – the instance document does				Х
101.1113	not appear in the Interactive Data File because XBRL tags are				~
	embedded within the Inline XBRL document				
101.SCH	Inline XBRL Taxonomy Extension Schema Document				Х
101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document				Х
101.LAB	Inline XBRL Taxonomy Label Linkbase Document				Х
101.PRE 101.DEF	Inline XBRL Presentation Linkbase Document Inline XBRL Taxonomy Extension Definition Linkbase				X X
IUI.DEF	Document				^
104	Cover Page Interactive Data File (embedded within the Inline				Х
	XBRL document)				
	s management contract or compensatory plan.				
Portions	of this exhibit have been omitted for confidentiality nurnoses				

+ 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.

145

## 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, 2022

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, 2022
/s/ Thomas Russo, CFA Thomas Russo, CFA	Chief Financial Officer principal financial and accounting officer)	March 30, 2022
/s/ Mark McDade Mark McDade	Chairman	March 30, 2022
/s/ Elisha P. Gould III Elisha P. Gould III	Director	March 30, 2022
/s/ Peter Kolchinsky, Ph.D. Peter Kolchinsky, Ph.D.	Director	March 30, 2022
/s/ Heidi Kunz Heidi Kunz	Director	March 30, 2022
/s/ John Shiver, Ph.D. John Shiver, Ph.D.	Director	March 30, 2022
/s/ Ann Veneman Ann Veneman	Director	March 30, 2022

146

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

As of December 31, 2021, Icosavax, Inc. ("we," "us" and "our") had one class of securities registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): our common stock.

## **Description of Common Stock**

## General

The following description summarizes some of the terms of our common stock. Because it is only a summary, it does not contain all the information that may be important to you and is subject to and qualified in its entirety by reference to our amended and restated certificate of incorporation and amended and restated bylaws, copies of which are filed as exhibits to our most recent Annual Report on Form 10-K and are incorporated by reference herein. We encourage you to read our amended and restated certificate of incorporation and our amended and restated bylaws for additional information.

As of December 31, 2021, our authorized capital stock consisted of 500,000,000 shares of common stock, \$0.0001 par value per share, and 50,000,000 shares of preferred stock, \$0.0001 par value per share.

# Voting Rights

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders, including the election of directors, and do not have cumulative voting rights. Accordingly, the holders of a majority of the outstanding shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they so choose, other than any directors that holders of any preferred stock we may issue may be entitled to elect. Subject to supermajority votes for some matters, other matters shall be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter. Our amended and restated certificate of incorporation and amended and restated bylaws also provide that our directors may be removed only for cause and only by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon. In addition, the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon is required to amend or repeal, or to adopt any provision inconsistent with, several of the provisions of our amended and restated certificate of incorporation.

## Dividend Rights

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared by the board of directors out of legally available funds.

## Liquidation Rights

In the event of our liquidation, dissolution or winding up, the holders of common stock will be entitled to share ratably in the assets legally available for distribution to stockholders after the payment of or provision for all of our debts and other liabilities, subject to the prior rights of any preferred stock then outstanding.

## **Rights and Preferences**

Holders of common stock have no preemptive or conversion rights or other subscription rights and there are no redemption or sinking funds provisions applicable to the common stock.

## Fully Paid and Nonassessable

The outstanding shares of common stock are duly authorized, validly issued, fully paid and nonassessable.

## Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

## The Nasdaq Global Select Market Listing

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

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

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

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

## Undesignated Preferred Stock

The ability of our board of directors, without action by the stockholders, to issue up to 50,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

## Stockholder Meetings

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

## Requirements for Advance Notification of Stockholder Nominations and Proposals

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

## Elimination of Stockholder Action by Written Consent

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

## Staggered Board of Directors

Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, with one class being elected each year by our stockholders. This system of electing directors may tend to discourage a third party from attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

## Removal of Directors

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

## Stockholders Not Entitled to Cumulative Voting

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

## Delaware Anti-Takeover Statute

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

## Choice of Forum

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative form, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of

breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders, creditors or other constituents; (iii) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our amended and restated certificate of incorporation or amended and restated bylaws; (iv) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (v) any action asserting a claim governed by the internal affairs doctrine. The 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 will also provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause or causes of action arising under the Securities Act of 1933, as amended, including all causes of action asserted against any defendant to such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. In any case, stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. 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.

Our amended and restated certificate of incorporation also provides that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision.

## Amendment of Charter Provisions

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock, would require approval by holders of at least two thirds of the total voting power of all of our outstanding voting stock.

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

Exhibit 10.18

# BOREN LABS 1930 BOREN AVENUE SEATTLE, WASHINGTON

## LEASE AGREEMENT

# BETWEEN

# BOREN LOFTS OWNER (DE) LLC, a Delaware limited liability company, AS LANDLORD

## AND

ICOSAVAX, INC., a Delaware corporation, AS TENANT

# TABLE OF CONTENTS

# Page

1.	Basic Lease Information	1
2.	Lease Grant	4
3.	Term and Commencement Date	6
4.	Rent	8
5.	Permitted Use; Compliance with Laws	8
6.	Letter of Credit	11
7.	Building Services	12
8.	Alterations	15
9.	Repairs and Maintenance	17
10.	Entry by Landlord	19
11.	Assignment and Subletting	19
12.	Notices	21
13.	Indemnity and Insurance	22
14.	Casualty Damage	24
15.	Condemnation	26
16.	Events of Default	26
17.	Limitation of Liability	29
18.	Intentionally Omitted	30
19.	Holding Over	30
20.	Surrender of Premises	30
21.	Subordination to Mortgages; Estoppel Certificate	32
22.	Environmental Provisions.	33
23.	Parking	36
24.	Miscellaneous	37

|US-DOCS\129492181.2||

(i)

# LEASE AGREEMENT

This Lease Agreement (this "Lease") is made and entered into as of December <u>15</u>, 2021 (the "Effective **Date**"), by and between BOREN LOFTS OWNER (DE) LLC, a Delaware limited liability company ("Landlord"), and ICOSAVAX, INC., a Delaware corporation ("Tenant").

# **1.** Basic Lease Information.

- 1.01 "**Building**" shall mean the building located at 1930 Boren Avenue, Seattle, Washington and commonly known as Boren Labs. The "**Rentable Floor Area of the Building**" is deemed to be 134,778 square feet.
- 1.02 "**Premises**" shall mean demised space on the entirety of the ninth (9<sup>th</sup>) and tenth (10<sup>th</sup>) floors of the Building and commonly known as Suites 900 and 1000, as generally depicted in <u>Exhibit A</u> to this Lease.
- 1.03 "Rentable Floor Area of the Premises": 25,253 square feet.
- 1.04 *Intentionally Omitted.*
- 1.05 "Term Commencement Date": See <u>Section 3.01</u>.
- 1.06 **"Term Expiration Date**": The last day of the sixty-third (63<sup>rd</sup>) full calendar month following the Term Commencement Date.

Period	Annual Base Rent Rate Per Square Foot of Rentable Floor Area	Monthly Base Rent
Lease Year 1	\$84.00	\$176,771.00
Lease Year 2	\$86.52	\$182,074.13
Lease Year 3	\$89.12	\$187,536.35
Lease Year 4	\$91.79	\$193,162.45
Lease Year 5	\$94.54	\$198,957.32
Lease Year 6 (months 61 – 63)	\$97.38	\$204,926.03

1.07 **"Base Rent**":

As used above, the first "Lease Year" shall commence on the Term Commencement Date and end on the day immediately preceding the first anniversary thereof (provided that if the Term Commencement Date does not occur on the first day of a calendar month, the first Lease Year shall further include the balance of the calendar month such first anniversary occurs), and each subsequent Lease Year shall mean each successive period of twelve (12) calendar months following the first Lease Year during the initial Term, provided that the last Lease Year of the initial Term shall end on the Term Expiration Date set forth above for the initial Term.

Provided Tenant is not in Default of the terms of this Lease, after expiration of any applicable notice and cure period, Tenant shall be entitled to receive a Base Rent abatement for the first three (3) full calendar months of the Term in an aggregate amount not to exceed Five Hundred Thirty Thousand Three Hundred Thirteen Dollars (\$530,313.00); the expiration of such three (3) month abatement period to be referred to herein as the "**Rent Commencement Date**.". Tenant shall be obligated to pay Tenant's Share of Expenses and Taxes attributable to such period. In the event of a Default by Tenant under the terms of this Lease that results in early termination pursuant to the provisions of <u>Article 16</u> of this Lease, then as a part of the recovery set forth in <u>Article 16</u> of this Lease, Landlord shall be entitled to the recovery of the Base Rent that was abated under the provisions of this <u>Section 1.07</u>.

- 1.08 **"Tenant's Share**": 18.74%, based on the ratio that the Rentable Floor Area of the Premises bears to the Rentable Floor Area of the Building.
- 1.09 "**Net Lease**" Tenant shall pay Tenant's Share of all Expenses and Taxes as more particularly described in Exhibit B.
- 1.10 **"Tenant Work Allowance"**: [\*\*\*] Dollars (\$[\*\*\*]) per square foot of Rentable Floor Area of the Premises, as further described in the Work Letter attached hereto as <u>Exhibit C</u>. Tenant shall construct improvements in the Premises in accordance with the terms of <u>Exhibit C</u>.
- 1.11 **Extension Option**: See Exhibit F.
- 1.12 "Letter of Credit" shall mean the letter of credit in the amount of \$1,060,626.00, as provided in <u>Article 6</u>, which amount is subject to adjustment pursuant to <u>Article 6</u>.
- 1.13 Intentionally Omitted
- 1.14 "**Broker(s)**": Jones Lang LaSalle Brokerage, Inc. ("**Broker**") represents Landlord and Tenant in connection with this Lease.
- 1.15 "**Permitted Use**": General office, research and development, laboratory and, incidental and accessory thereto, storage uses and other lawful accessory uses reasonably related to and incidental to such specified uses, all (i) consistent with comparable life sciences projects in the Seattle, Washington area, and (ii) in compliance with, and subject to, applicable laws and the terms of this Lease.

US-DOCS\129492181.2||

## -2-

## 1.16 "Notice Address(es)"

For Landlord:

BOREN LOFTS OWNER (DE) LLC c/o Oxford Properties Group 125 Summer Street Boston, Massachusetts 02110 Attention: Leasing Email: amondani@oxfordproperties.com

BOREN LOFTS OWNER (DE) LLC c/o Oxford Properties Group 125 Summer Street Boston, Massachusetts 02110 Attention: Legal Email: kbinck@oxfordproperties.com For Tenant:

Prior to the Term Commencement Date: Icosavax, Inc. 1616 Eastlake Ave. E. Suite 208 Seattle, WA, 98102 Attention: Cassia Cearley, Ph.D., Chief Business Officer Email: cassia.cearley@icosavax.com

From Temporary Space occupancy to Term Commencement Date: Icosavax, Inc. 1930 Boren Avenue 4<sup>th</sup> floor Seattle, WA, 98101 Attention: Cassia Cearley, Ph.D., Chief Business Officer Email: cassia.cearley@icosavax.com

From and after the Term Commencement Date: Icosavax, Inc. 1930 Boren Avenue 10<sup>th</sup> floor Seattle, WA, 98101 Attention: Cassia Cearley, Ph.D., Chief Business Officer Email:\_cassia.cearley@icosavax.com

- 1.17 Parking: Tenant shall have the right to lease up to nineteen (19) unreserved parking passes in the subterranean parking serving the Building at the initial rate of \$[\*\*\*] per month per pass. Subject to availability (as determined by Landlord in Landlord's sole discretion), Tenant shall have the right to lease additional parking passes on a month-to-month basis at Landlord's then-prevailing rate. Landlord shall have the right to, from time-to-time throughout the Term (i) determine in Landlord's reasonable discretion the location of Tenant's parking spaces in the Building in any combination and (ii) increase the then current rate per parking pass to the then prevailing market rate (as determined in Landlord's commercially reasonable discretion).
- 1.18 **"Business Day(s)**" are Monday through Friday of each week, exclusive of New Year's Day, Presidents Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day and Christmas Day (**"Holidays**"). Landlord may designate

-3-

additional Holidays that are commonly recognized by other research and development buildings in the area where the Building is located. "**Building Service Hours**" are 8:00 a.m. to 6:00 p.m. on Business Days (excluding Holidays).

- 1.19 **"Property**" means the Building and the parcel(s) of land on which it is located and, at Landlord's discretion, the parking facilities and other improvements, if any, serving the Building and the parcel(s) of land on which they are located.
- 1.20 <u>Other Defined Terms</u>: Other capitalized terms shall have the meanings set forth in this Lease and its Exhibits below. References in this Lease to numbered Articles and Sections shall be deemed to refer to the numbered Articles and Sections of this Lease unless otherwise specified.
- 1.21 <u>Exhibits</u>: The following exhibits and attachments are incorporated into and made a part of this Lease:

<u>Exhibit A</u>	(Outline and Location of Premises)
<u>Exhibit A-1</u>	(Legal Description of the Property)
<u>Exhibit B</u>	(Expenses and Taxes)
<u>Exhibit C</u>	(Work Letter)
<u>Exhibit D</u>	(Commencement Letter)
<u>Exhibit E</u>	(Building Rules and Regulations)
<u>Exhibit F</u>	(Additional Provisions)
<u>Exhibit G</u>	(Temporary Space)

# 2. Lease Grant.

2.01 <u>Premises</u>. Landlord hereby leases the Premises to Tenant and Tenant hereby leases the Premises from Landlord. The Premises exclude the exterior faces of exterior walls, the common stairways and stairwells, elevators and elevator wells, fan rooms, electric and telephone closets (unless such rooms and closets are located within the Premises and solely contains Tenant's personal property), janitor closets, freight elevator vestibules, and pipes, ducts, conduits, wires and appurtenant fixtures serving other parts of the Building (exclusively or in common), and other Common Areas (as defined below) of the Building. If the Premises include the entire rentable area of any floor, the common corridors, elevator lobby, and restroom facilities located on such full floor(s) shall be considered part of the Premises.

2.02 <u>Appurtenant Rights</u>. During the Term, Tenant shall have, as appurtenant to the Premises, the non-exclusive rights to use in common (subject to reasonable rules of general applicability to tenants and other users of the Building from time to time made by Landlord of which Tenant is given notice) the common areas of the Building and the common areas of the Property, as follows: for the Building, (a) the common entrances, lobbies, elevators, stairways and accessways, if any, loading docks, ramps, drives and platforms and any passageways and serviceways thereto to the extent not exclusively serving another tenant or contained within another tenant's premises, and the pipes, ducts, conduits, wires and appurtenant meters and equipment serving the Premises in common with others; (b) common driveways and walkways necessary for access to the Building; (c) if the Premises include less than the entire rentable floor

area of any floor, the common corridors, elevator lobby, and restroom facilities located on such floor; and (d) all other areas or facilities in or about the Building from time to time designated for general use in common by Tenant, other Building tenants, and Landlord (collectively, the "**Building Common Areas**"), and for the Property, the parking structure and parking areas, loading and unloading areas, trash area, roadway, sidewalks, walkways, parkways, driveways, landscaped areas appurtenant to the Building, fixtures, systems, décor facilities and landscaping contained, maintained or used in connection with those areas and shall be deemed to include any city sidewalks adjacent to the Property, any pedestrian walkways system, park or other facilities located on the Property and open to the general public (collectively, the "**Property Common Areas**"). The Building Common Areas and Property Common Areas may be referred herein collectively as the "**Common Areas**."

2.03 <u>Temporary Space</u>. Subject to Force Majeure events, the original Tenant executing this Lease ("**Original Tenant**") shall have the right, commencing as of May 12, 2022 and continuing until that date which is thirty (30) days after the Substantial Completion Date ("**Temporary Space Term**"), to lease from Landlord temporary space consisting of the entirety of the fourth (4<sup>th</sup>) floor of the Building and containing approximately 15,063 square feet ("**Temporary Space**"), which Temporary Space is depicted on <u>Exhibit G</u> attached hereto; provided, however (i) in no event shall the Temporary Space Term extend beyond December 15, 2022, and (ii) Tenant shall not be obligated to pay Base Rent for the Temporary Space upon the occurrence of the Term Commencement Date. Tenant's lease of the Temporary Space shall be subject to all of the terms, conditions and limitations set forth in this Lease regarding the Premises except as follows:

2.03.1 All obligations of Tenant contained in this Lease with respect to the Premises (including, without limitation, Tenant's indemnification obligations and Tenant's obligation to obtain and maintain insurance) shall be applicable with respect to the Temporary Space throughout the Temporary Space Term except that Base Rent for the Temporary Space shall be based on Fifty Dollars (\$50.00) per rentable square foot of the Temporary Space per year (i.e., an amount equal to Sixty-Two Thousand Seven Hundred Sixty-Two and 50/100 Dollars (\$62,762.50) per month based on 15,063 rentable square feet in the Temporary Space. Tenant shall pay for the costs of utilities and Additional Rent for the Temporary Space; provided, however, that Tenant's Share shall be deemed to be 11.18%;

2.03.2 Tenant agrees that Tenant shall accept the Temporary Space in its then "as-is" condition, and that Landlord shall not be required to construct any improvements in, or contribute any improvement allowance for, the Temporary Space. Tenant further acknowledges that neither Landlord nor any agent of Landlord has made any representation or warranty with respect the Temporary Space or its suitability for the conduct of Tenant's business therein;

2.03.3 Throughout the Temporary Space Term, Tenant shall be entitled to utilize nine (9) unreserved parking passes, subject to all other terms and conditions of this Lease;

2.03.4 Tenant shall not be entitled to construct any Alterations in the Temporary Space.

-5-

2.03.5 Tenant shall use Tenant's commercially reasonable efforts to cooperate with Landlord in connection with any work performed by Landlord in the Temporary Space; in no event shall Landlord's performance of such work constitute a constructive eviction nor entitle Tenant to any abatement of Rent, provided that Landlord shall use commercially reasonable efforts to minimize interference with Tenant's quiet use and enjoyment of the Temporary Space during the Temporary Space Term and provided that Landlord shall be responsible for and indemnify Tenant from any claims for personal injury and any damage to Tenant's Property to the extent caused by Landlord's gross negligence or willful misconduct while performing such work in the Temporary Space and not covered by insurance required to be maintained by Tenant under this Lease; and

2.03.6 Tenant shall vacate and surrender the Temporary Space in the same condition as received, reasonable wear and tear excepted, on or before that date which is thirty (30) days after the Substantial Completion Date (and in any event on or before December 15, 2022) and Tenant's failure to do so shall constitute a holdover pursuant to <u>Article 19</u> of this Lease. Tenant acknowledges and agrees that such Temporary Space is subject to an expansion right provided by Landlord to an existing tenant of the Building and that Tenant's failure to surrender the Temporary Space on or before the date that is thirty (30) days after the Substantial Completion Date (or December 15, 2022, whichever is sooner) shall cause Landlord to suffer damages (including consequential damages and loss of profits) and that Tenant shall be liable to Landlord for all such damages to the extent caused by Tenant's holdover in the Temporary Space later than thirty (30) days after the Substantial Completion Date (or after such December 15, 2022 outside date).

# **3.** Term and Commencement Date.

3.01 <u>Term</u>. The "**Term**" of this Lease shall begin at 12:01 a.m. on the earlier to occur of the following dates under clauses .1 or .2, which date shall be the "**Term Commencement Date**":

3.01.1 the date on which Tenant substantially completes the Initial Tenant Work ("**Substantial Completion Date**"); or

3.01.2 October 1, 2022, which date is subject to adjustment pursuant to <u>Section 3.03</u> below.

The Term of this Lease shall end at 11:59 p.m. on the Term Expiration Date set forth in <u>Article 1</u>, unless sooner terminated or extended in accordance with the provisions of this Lease. Promptly after the determination of the Term Commencement Date, Landlord and Tenant shall execute and deliver a commencement letter in the form attached as <u>Exhibit D</u> (the "**Commencement Letter**"). Tenant's failure to execute and return the Commencement Letter, or to provide written objection to the statements contained in the Commencement Letter, within thirty (30) days after its delivery to Tenant shall be deemed an approval by Tenant of the statements contained therein.

3.02 <u>Initial Tenant Work</u>. As used herein, the "**Initial Tenant Work**" shall mean the initial work performed by Tenant in accordance with, and subject to, the provisions of <u>Exhibit C</u> attached hereto. Subject to Landlord's obligations as expressly provided in <u>Exhibit C</u>, the Premises

-6-

shall be leased by Tenant in their current "as is" condition and configuration without any representations or warranties by Landlord.

3.03 Delivery. Subject to Force Majeure events and delays caused by Tenant, (i) Landlord shall make possession of the ninth (9<sup>th</sup>) floor portion of the Premises available to Tenant on or before November 1, 2021 ("Anticipated Ninth (9th) Floor Delivery Date") with Landlord's Delivery Work substantially completed and (ii) Landlord shall make possession of the tenth (10<sup>th</sup>) floor portion of the Premises available to Tenant on March 20, 2022 (or as soon thereafter as reasonably possible) ("Anticipated Tenth (10th) Floor Delivery Date"), with Landlord's Delivery Work pertaining to the lab upgrades described in Exhibit C-1 substantially completed; provided, however, that Tenant acknowledges and agrees that Landlord's remaining Delivery Work on the tenth (10<sup>th</sup>) floor will not be completed until April 15, 2022 and Tenant will use commercially reasonable efforts to not interfere with Landlord's remaining work on the tenth (10<sup>th</sup>) floor during the period between Tenant's Early Access (as defined below) and until Tenant's possession of the tenth (10th) floor portion of the Premises. Landlord will use commercially reasonable efforts to not unreasonably interfere with Tenant's work on the tenth (10th) floor Premises during Landlord's performance of Landlord's Delivery Work. By taking possession of the Premises, Tenant agrees that the Premises are in good order and satisfactory condition and that Landlord's Delivery Work is substantially completed. Landlord shall not be liable for any delay or failure to deliver possession of the Premises in accordance with the dates set forth above. Any delay in the delivery of the applicable portion of the Premises shall not give rise to any liability or default by Landlord or affect any of the terms of this Lease or Tenant's obligation to accept the Premises when delivered. Tenant's possession of the Premises before the Term Commencement Date shall be subject to all of the terms and conditions of this Lease; provided, however, except for the cost of services used or requested by Tenant (e.g., after-hours HVAC service), Tenant shall not be required to pay Rent for any such possession or entry before the Term Commencement Date during which Tenant, with Landlord's approval, has entered, or is in possession of, the Premises for the sole purpose of performing improvements or installing furniture, fixtures, equipment or other personal property including without limitation the Initial Tenant Work in accordance with Exhibit C. Notwithstanding anything to the contrary contained herein, Tenant and its vendors and contractors shall have access to the tenth (10<sup>th</sup>) floor portion of the Premises on or before March 1, 2022, ("Early Access") for purposes of planning and measurement, and preliminary construction of the Initial Tenant Work, and other activities reasonably necessary to prepare the tenth (10<sup>th</sup>) floor portion of the Premises for occupancy provided that during such Early Access Tenant shall use commercially reasonable efforts to cooperate with Landlord in connection with any work performed by Tenant in the tenth (10<sup>th</sup>) floor and Tenant shall use commercially reasonable efforts to minimize interference with Landlord's work and provided that Tenant shall be responsible for and indemnify Landlord from any claims for personal injury and any damage to Landlord's property to the extent caused by Tenant's gross negligence or willful misconduct while performing such work during Early Access in the tenth (10<sup>th</sup>) floor portion of the Premises and not covered by insurance required to be maintained by Landlord. Notwithstanding anything to the contrary contained herein and provided Tenant is not in Default of the terms of this Lease, after expiration of any applicable notice and cure period, the October 1, 2022 date set forth in Section 3.01.2 above shall be extended by one (1) day for each day after March 20, 2022 (subject to extension due to Force Majeure events and delays caused by Tenant) that the Anticipated Tenth (10th) Floor Delivery Date (pertaining to substantial completion of the lab upgrades only) does not

-7-

occur; provided further, however, that in the event of such extension, the Term Expiration Date shall be extended for each day of any such extension of such October 1, 2022 date.

# 4. Rent.

4.01 <u>Base Rent and Additional Rent</u>. Subject to the abatement as provided in <u>Section 1.07</u>, Tenant hereby covenants and agrees to pay to Landlord, without any setoff or deduction, beginning on the Term Commencement Date, (a) all Base Rent (as provided in <u>Article 1</u>), (b) Tenant's Share of Expenses and Taxes (as provided in <u>Exhibit B</u> attached hereto), and (c) all other Additional Rent due for the Term (collectively referred to as "**Rent**"). "Additional Rent" means all sums (exclusive of Base Rent) that Tenant is required to pay to Landlord from time to time under this Lease.

4.02 Manner and Timing of Payments. Base Rent and other recurring monthly charges of Additional Rent shall be due and payable in advance on the first day of each calendar month without notice or demand, but Tenant shall pay to Landlord the Base Rent for the fourth full month of the Term at the time of Tenant's execution and delivery of this Lease. Base Rent and Additional Rent shall together be deemed "Rent." All other items of Rent shall be due and payable by Tenant within thirty (30) days after billing by Landlord. Rent shall be made payable to the entity, and sent to the address, that Landlord from time to time designates for such purposes and shall be paid by Tenant by good and sufficient check payable in United States of America currency or by electronic or wire transfer to an account from time to time designated by Landlord. Landlord's acceptance of less than the entire amount of Rent shall be considered, unless otherwise specified by Landlord, a payment on account of the oldest obligation due from Tenant hereunder, notwithstanding any statement to the contrary contained on or accompanying any such payment from Tenant. Rent for any partial month during the Term shall be prorated on a per diem basis. Except as expressly set forth in this Lease. Tenant's obligation to pay Rent shall be absolute, unconditional and independent of any Landlord covenants. Tenant shall pay and be liable for all rental, sales and use taxes (but excluding income taxes), if any, imposed upon or measured by Rent. No endorsement or statement on a check or letter accompanying payment shall be considered an accord and satisfaction.

4.03 <u>Net Lease</u>. It is the purpose and intent of Landlord and Tenant that this Lease is a net lease and that all rent shall be absolutely net to Landlord so that this Lease shall yield net to Landlord the Rent to be paid each month during the Term of this Lease. Accordingly, and except as otherwise provided in this Lease, all costs, expenses and obligations of every kind or nature whatsoever relating to the Premises which may arise or become due during the Term of this Lease, including, without limitation, all costs and expenses of maintenance and repair, insurance and taxes shall be paid by Tenant, subject to the express limitations contained in this Lease. Tenant agrees that Tenant shall pay all costs, charges and expenses of every kind and nature whatsoever against or in connection with the construction and development of the Initial Tenant Work, and use and operation of the Premises that may arise or become due during the Term, including all of those that, except for the execution and delivery hereof, would or could have been payable by Landlord.

-8-

#### 5. Permitted Use; Compliance with Laws.

US-DOCS\129492181.2||

5.01 Permitted Use. Tenant shall have access to the Building and Premises 24 hours per day, 7 days per week, 365 days per year, and shall use the Premises only for the Permitted Use and shall not use or permit the use of the Premises for any other purpose. Tenant shall comply with all statutes, codes, ordinances, orders, rules and regulations of any municipal or governmental entity whether in effect now or later, including without limitation, the Americans with Disabilities Act, ("ADA"), and all environmental Laws (collectively, "Law(s)"), regarding the operation of Tenant's business and the use, condition, configuration, and occupancy of the Premises and the Building systems located in or exclusively serving the Premises; provided that Tenant shall only be responsible for ADA requirements that are specific to Tenant's use of the Premises or that are required as a result of the Initial Tenant Work or any Alterations. In addition, Tenant shall, at its sole cost and expense, promptly comply with any Laws that relate to the Base Building (defined below), but only to the extent such obligations are triggered by Tenant's use of the Premises or Alterations (as defined in Section 8.01) in or about the Premises performed or requested by Tenant. "Base Building" shall include the structural portions of the Building, the common restrooms, and the Building mechanical, electrical, and plumbing systems and equipment located in the internal core of the Building on the floor or floors on which the Premises are located. Tenant shall promptly provide Landlord with copies of any notices it receives regarding an alleged violation of Law. Except as otherwise provided in this Lease, Tenant shall be solely responsible, at Tenant's sole cost and expenses, for obtaining all operational permits, licenses and approvals required in order for Tenant to use the Premises for the Permitted Use. As part of the Landlord's performance of the Landlord's Delivery Work, Landlord shall tie the Premises into the existing Base Building pH neutralization system (the "**pH Neutralization System**"), in accordance with any discharge permits required by applicable Laws (the "pH Permits"), which pH Permits shall be held in Landlord's name, provided that, to the extent required by the State of Washington for Tenant's specific use, Tenant shall obtain a wastewater treatment operator license from the State of Washington. The monitoring, repair and maintenance costs of the pH Neutralization System shall be passed through to Tenant on a pro-rata basis, based upon the proportion that the Rentable Floor Area of the Premises bears to the total rentable floor area of all tenant-occupied space tied into the pH Neutralization System; provided that any capital repairs and capital replacements shall be passed through only to the extent the same are Permitted Capital Expenses, in which event the amortized cost thereof shall be passed through to Tenant in the same manner as provided in Exhibit B. If any governmental license or permit required to be obtained by Tenant shall be required for the proper and lawful conduct of Tenant's business at the Premises (including, without limitation, all permits and approvals required for the use and operation of the vivarium and any required wastewater treatment operator license), Tenant, at Tenant's expense, shall duly procure and thereafter maintain such license and, on Landlord's request, submit the same to inspection by Landlord. Tenant, at Tenant's expense, shall at all times comply in all material respects with the terms and conditions of each such license or permit. Tenant shall, on Landlord's request, provide Landlord with copies of all such licenses, permits and approvals required for Tenant's use, including any permits, licenses and registrations required pursuant to environmental Laws that are obtained or renewed during the Term.

5.02 <u>Rules and Regulations</u>. Tenant shall not exceed the standard density limit for the Building (one (1) person per 125 usable square feet). Tenant shall not use or permit the use of any portion of the Premises in a manner that results in objectionable noise, odors, or vibrations

-9-

emanating from the Premises or any equipment installed by Tenant or any party acting under or through Tenant, or which violates or conflicts with Landlord's sustainability standards (set forth in Section 24.21 below) or certification for the Building. Without limiting the generality of the foregoing sentence, Tenant shall not use any portion of the Premises for a personal fitness or exercise area or install or use any exercise equipment therein. Tenant shall comply with the rules and regulations of the Building attached as Exhibit E and such other reasonable rules and regulations adopted by Landlord from time to time, including rules and regulations for the performance of Alterations. If the Premises or any portion thereof are located on a multi-tenant floor, Tenant shall cause all portions of such Premises that are visible from the Common Areas on such floors to be arranged, furnished, and lighted in a manner in which such Premises appears at all times to be occupied for the Permitted Use. Upon Landlord's written notice to Tenant that any Negative Condition (as defined on Exhibit E) exists, Tenant shall thereafter promptly undertake actions to remedy such Negative Condition (which actions may include the installation, operation, maintenance and inspection of odor, noise, vibration, water and/or smoke control devices, and the establishment of effective control procedures to eliminate such odors, noise, vibration, smoke, or water or other objectionable emissions) within five (5) business days following receipt of such notice, or such longer period of time as is reasonably necessary to remedy such Negative Condition so long as Tenant promptly undertakes to remedy any such condition and diligently and continuously pursues such remedy to completion within forty-five (45) days of receipt of such notice from Landlord. Tenant shall cease the activity causing the Negative Condition upon receipt of Landlord's notice until the Negative Condition has been remedied. The means Tenant uses to prevent such migration may include but not be limited to: (i) operating the HVAC systems, including any special exhaust systems, under negative pressure, (ii) sealing all openings in the demising walls, (iii) providing continuous waterproof base (per Landlord's criteria) along the demising walls in the showers (if any), kitchen and laboratory areas in the Premises, and (iv) placing machines or equipment in settings of cork, rubber or spring type noise and vibration eliminators. If any such Negative Condition is not so remedied, Landlord may, at its discretion either: (i) cure such Negative Condition and charge Tenant for any cost and expense incurred by Landlord therefor, and Tenant shall then pay such amount as within thirty (30) days after its receipt of an invoice thereof, or (ii) treat Tenant's failure to remedy such Negative Condition as a Default, entitling Landlord to any of its remedies pursuant to the terms of this Lease.

5.03 Tenant shall be allowed the exclusive use (including reasonable confidentiality and security measures) of up to its pro rata share of any control area or zone (located within the Premises), as designated by the applicable building code, for Hazardous Material and chemical use or storage. As used in the preceding sentence, Tenant's pro rata share of any control areas or zones located within the Premises shall be determined based on the Rentable Floor Area of the Premises that Tenant leases within the applicable control area or zone. For purposes of example only, if a control area or zone contains 10,000 rentable square feet and 2,000 rentable square feet of a tenant's premises are located within such control area or zone (while such premises as a whole contains 5,000 rentable square feet), the applicable tenant's pro rata share of such control area would be 20%.

5.04 <u>Recorded Covenants</u>. This Lease may, after the date hereof, be subject to any commercially reasonable and recorded covenants, conditions or restrictions on the Property, as the same may be amended, amended and restated, supplemented or otherwise modified from time to time (the "CC&Rs"); provided that any such CC&Rs (a) do not materially impact Tenant's use

-10-

and enjoyment of the Premises and Common Areas (b) do not modify Tenant's rights or obligations hereunder and (c) are commercially reasonably and generally applicable to all occupants of the Building. Subject to the foregoing, Tenant shall comply with the CC&Rs. As of the date hereof, there are no CC&Rs encumbering the Property.

## 6. Letter of Credit.

6.01 Letter of Credit. Concurrently with Tenant's execution and delivery of this Lease, Tenant shall deliver to Landlord a clean, irrevocable letter of credit in the amount set forth in <u>Article 1</u>, which shall comply with, and may be drawn by Landlord in accordance with, the provisions of this <u>Section 6.01</u> (such letter of credit, together with any renewal or replacement thereof in accordance herewith, being referred to herein as the "Letter of Credit").

6.01.1 The Letter of Credit shall be for the amount set forth in Article 1 of this Lease, subject to the terms of Article 6 of this Lease. The Letter of Credit (i) shall be irrevocable and shall be issued by a commercial bank that has a financial condition reasonably acceptable to Landlord and has an office in San Francisco, California; Boston, Massachusetts; or New York City that accepts requests for draws on the Letter of Credit, (ii) shall require only the presentation to the issuer of a certificate of the holder of the Letter of Credit stating that Landlord is entitled to draw on the Letter of Credit pursuant to the terms of this Lease, (iii) shall be payable to Landlord or its successors in interest as the Landlord and shall be freely transferable without cost to any such successor or any lender holding a collateral assignment of Landlord's interest in this Lease, (iv) shall be for an initial term of not less than one year and contain a provision that such term shall be automatically renewed for successive one-year periods unless the issuer shall, at least forty five (45) days prior to the scheduled expiration date, give Landlord notice of such nonrenewal, (v) shall permit drawings to be made via facsimile transmission and (vi) shall otherwise be in form and substance reasonably acceptable to Landlord. Notwithstanding the foregoing, the term of the Letter of Credit for the final period shall be for a term ending not earlier than the date forty five (45) days after the last day of the Term. In the event that the issuer ceases to be reasonably acceptable to Landlord, due to a deterioration in its financial condition or change in status that threatens to compromise Landlord's ability to draw on the Letter of Credit as determined in good faith by Landlord, then Tenant shall provide a replacement Letter of Credit from an issuer satisfying the terms of this Section within thirty (30) days after Landlord's notice of such event.

6.01.2 Landlord shall be entitled to draw upon the Letter of Credit for its full amount or any portion thereof if (a) Tenant shall fail to perform any of its obligations under this Lease after the expiration of any applicable notice and cure period, or fail to perform any of its obligations under this Lease and transmittal of a default notice or the running of any cure period is barred or tolled by applicable law, or fail to perform any of its obligations under this Lease and transmittal of a default notice or the running of any cure period is barred or tolled by applicable law, or fail to perform any of its obligations under this Lease and any applicable notice and cure period would expire after the expiration of the Letter of Credit, or (b) not less than thirty (30) days before the scheduled expiration of the Letter of Credit, Tenant has not delivered to Landlord a new Letter of Credit in accordance with this Section. Without limiting the generality of the foregoing, Landlord may, but shall not be obligated to, draw on the Letter of Credit from time to time in the event of a bankruptcy filing by or against Tenant and/or to compensate Landlord, in such order as Landlord may determine, for all or any part of any unpaid rent, any damages arising from any termination of this Lease in a bankruptcy proceeding

-11-

commenced by or against Tenant and/or any damages that Landlord reasonably estimates it will suffer as a result of any breach or default by Tenant under this Lease. Landlord may, but shall not be obligated to, apply the amount so drawn to the extent necessary to cure Tenant's failure.

After any application by Landlord of the Letter of Credit, Tenant shall reinstate the 6.01.3 Letter of Credit to the amount originally required to be maintained under this Lease, upon demand. Provided that Tenant is not then in default under this Lease, and no condition exists or event has occurred which after the expiration of any applicable notice or cure period would constitute such a default, within forty five (45) days after the later to occur of (i) the payment of the final Rent due from Tenant or (ii) the later to occur of the Term Expiration Date or the date on which Tenant surrenders the Premises to Landlord in compliance with Article 20 of this Lease, the Letter of Credit shall be returned to the Tenant. Tenant acknowledges that the Letter of Credit is not a security deposit; instead, it is a credit enhancement in order to induce Landlord to lease the Premises to Tenant. Tenant hereby waives any and all provisions of law, now or hereafter in effect, which (i) establish the time frame by which a landlord must refund a security deposit under a lease, and/or (ii) provide that a landlord may claim from a security deposit only those sums reasonably necessary to remedy defaults in the payment of rent, to repair damage caused by a tenant or to clean the premises, it being agreed that Landlord may, in addition, claim those sums specified in this Section above and/or those sums reasonably necessary to compensate Landlord for any loss or damage caused by Tenant's default of the Lease. Tenant agrees not to interfere in any way with any payment to Landlord of the proceeds of the Letter of Credit, either prior to or following a "draw" by Landlord of all or any portion of the Letter of Credit, regardless of whether any dispute exists between Tenant and Landlord as to Landlord's right to draw down all or any portion of the Letter of Credit. No condition or term of this Lease shall be deemed to render the Letter of Credit conditional and thereby afford the Letter of Credit bank a justification for failing to honor a drawing upon such Letter of Credit in a timely manner. Tenant shall not request or instruct the Bank of any Letter of Credit to refrain from paying sight draft(s) drawn under such Letter of Credit.

6.01.4 In the event of a sale of the Building or lease, conveyance or transfer of the Building, Landlord shall transfer the Letter of Credit to the transferee. Upon such transfer, Landlord shall be released by Tenant from all liability for the return of such Letter of Credit, and Tenant agrees to look to the transferee solely for the return of said Letter of Credit. The provisions hereof shall apply to every transfer or assignment made of the Letter of Credit to such a transferee. Tenant further covenants that it will not assign or encumber or attempt to assign or encumber the Letter of Credit and that neither Landlord nor its successors or assigns shall be bound by any assignment, encumbrance, attempted assignment or attempted encumbrance.

6.01.5 Notwithstanding anything to the contrary contained herein and provided Tenant is not in Default of the terms of this Lease, after expiration of any applicable notice and cure period, the Letter of Credit amount shall be automatically reduced as follows: (i) on the first annual anniversary of the Rent Commencement Date, the Letter of Credit amount shall be reduced to Eight Hundred Eighty-Three Thousand Eight Hundred Fifty-Five Dollars (\$883,855.00); and (ii) on the expiration of the second (2<sup>nd</sup>) Lease Year, the Letter of Credit amount shall be reduced to Seven Hundred Seven Thousand Eighty-Four Dollars (\$707,084.00).

-12-

# 7. Building Services.

Building Utilities and Services. Subject to the terms and conditions of this Lease, and the 7.01 obligations of Tenant as set forth herein, Landlord shall furnish or cause to be furnished to the Premises (where specified) and otherwise to the Building the following utilities and services at all times, all of which shall be included in Expenses except to the extent such utilities or services are separately metered to the Premises: (a) electricity in accordance with the terms and conditions in Section 7.02; (b) customary heating, air conditioning and ventilation in the Premises for normal lab and office use on a 24/7 basis; (c) standard janitorial service for the Common Area on Business Days, including trash removal in all parking areas (it being acknowledged and agreed that Tenant shall be solely responsible for all cleaning and janitorial services for the Premises); (d) water for drinking and lavatory purposes and sewer services to the Premises, all as reasonably required for the Permitted Use on a 24/7 basis, (e) elevator service within the Building for Tenant's non-exclusive use on a 24/7 basis, (f); (g) access to the Building for Tenant and its employees on a 24/7 basis, subject to the terms of this Lease; and (h) such security or protective services in the Building and parking areas or other monitoring systems, if any, as Landlord may from time to time impose, including, without limitation, sign-in procedures and/or presentation of identification cards (provided however, Landlord shall not be liable for losses due to theft, vandalism or similar causes except to the extent caused by Landlord's gross negligence or willful misconduct); and (i) such other services as Landlord reasonably determines are necessary or appropriate for the Property. Tenant shall, subject to all of the terms and conditions of Article 8 hereof, have the right, at Tenant's sole expense to install and maintain a security system within the Premises ("Tenant's Security"), and if installed, Tenant shall be solely responsible for the monitoring and operation of Tenant's Security system. If, at Tenant's request, Landlord, or an affiliated or third party service provider, provides any services that are not Landlord's express obligation under this Lease, including, without limitation, any repairs which are Tenant's responsibility pursuant to Article 9 below, Tenant shall pay to the applicable service provider the cost of such services plus a reasonable administrative charge.

7.02 Tenant Electricity. Tenant shall pay to Landlord, as Additional Rent, the costs of electricity used in or for the Premises (including, without limitation, air handling units or other HVAC equipment serving the Premises) and, if applicable, for any special equipment installed by or for Tenant elsewhere in the Building, by a separate charge payable by Tenant to Landlord based on check-meters installed for the Premises (or for any applicable portion thereof or equipment serving the Premises) or, for any portion of the Premises or equipment that from time to time does not have operational check-meters, based on reasonable allocations prepared by Landlord's building engineer for the space and period in question. Tenant shall make estimated monthly payments for the electricity charges hereunder, in advance on the first day of each month or partial month of the Term, based on amounts estimated by Landlord from time to time for such electricity charges, subject to periodic reconciliations based on actual check-meter readings and utility rates for the space and period in question. Notwithstanding anything above to the contrary, Landlord shall have the right, in Landlord's sole discretion, to include the costs to provide electricity as part of Expenses and, in such event, Tenant shall pay Tenant's Share of the same. Without the consent of Landlord, Tenant's use of electrical service shall not exceed 300 Amps of 480/ 277 kW. Landlord shall have the right to measure electrical usage by commonly accepted methods, including the installation of measuring devices such as submeters and check-meters, which to the extent not in place prior to the Effective Date shall be installed at Landlord's sole cost and expense.

-13-

If it is determined, for any electrical service that is not separately check-metered to Tenant, that Tenant is using electricity in such quantities or during such periods as to cause the total cost of Tenant's electrical usage, on a monthly, per-rentable-square-foot basis, to materially exceed that which Landlord reasonably deems to be standard for the Building, Tenant shall pay Landlord Additional Rent for the cost of such excess electrical usage. Notwithstanding the foregoing, to the extent any electricity service is from time to time metered directly by the utility company to the Premises, Tenant shall timely pay the separate charges for such electricity service directly to the applicable utility company and, if requested by Landlord from time to time, provide copies of such utility company invoices and evidence of such payments.

7.03 Interruption of Services. Landlord's failure to furnish, or any interruption, diminishment or termination of services due to the application of Laws, the failure of any equipment, the performance of maintenance, repairs, improvements or alterations, utility interruptions or the occurrence of an event of Force Majeure (defined in Section 24.06) or any other causes (collectively a "Service Failure") shall not render Landlord liable to Tenant, constitute a constructive eviction of Tenant, give rise to an abatement of Rent, nor relieve Tenant from the obligation to fulfill any covenant or agreement except as provided in the next sentence. If the Premises, or a material portion of the Premises, are made untenantable for a period in excess of five (5) consecutive Business Days as a result of a Service Failure that is reasonably within the control of Landlord to correct and was not caused by Tenant or any Tenant Related Parties (as defined in Section 13.01) or any of Tenant's transferees, contractors or licensees, then Tenant, as its sole remedy, shall be entitled to receive an abatement of Rent payable hereunder during the period commencing on the first day following such five (5)-Business-Day period and ending on the day the service has been restored. If the entire Premises has not been rendered untenantable by the Service Failure, the amount of abatement shall be equitably prorated. This Section shall not apply to any Service Failure arising from a casualty event governed by <u>Article 14</u> below.

Reservations. Landlord reserves the right from time to time to do any of the following: (a) 7.04 expand the Building and construct or alter other buildings or improvements on the Property as long as Tenant's parking ratio (i.e., .75 spaces per 1,000 rentable square feet of the Premises) is not materially and adversely affected; (b) make any changes, additions, improvements, maintenance, repairs or replacements in or to the Building, Common Areas of the Property (including the Premises if required to do so by any applicable laws to the extent reasonably necessary in connection with any improvements to the Building, Common Areas and/or the Property, provided that Tenant's use of the Premises is not materially and adversely affected), and the fixtures and equipment thereof, including, without limitation: (i) maintenance, replacement and relocation of pipes, ducts, conduits, wires and meters and equipment above the ceiling surfaces, below the floor surfaces and within the walls of the Building and Premises, and (ii) changes in the location, size, shape and number of driveways, entrances, stairways, elevators loading and unloading areas, ingress, egress, direction of traffic, landscaped areas and walkways, easements, parking spaces and parking areas as long as Tenant's use of the Premises is not materially and adversely affected and Tenant's parking ratio is not materially and adversely impacted (c) close temporarily any of the Property while engaged in making repairs, improvements or alterations to the Property; and (d) perform such other acts and make such other changes with respect to the Property, as Landlord, may, in its good faith business judgment, determine is appropriate provided that Tenant's use of the Premises is not materially and adversely affected by such acts or other changes. Landlord will provide Tenant with at least fifteen (15) days' prior

-14-

notice of any of the actions set forth in this Section 7.04, to be taken by Landlord if such action will interfere with (i) Tenant's ability to conduct business within the Premises, (ii) gain access to and from the Premises, or (iii) use or have access to and egress from the parking area serving the Building. Landlord shall use commercially reasonable efforts to ensure that the performance of any such work of repairs or alterations shall not interfere with Tenant's use of the Premises and such efforts may include limiting the performance of any such work which might be disruptive to weekends or the evening. Without limiting the generality of the foregoing, Landlord reserves the right from time to time to modify components of the access procedures for the Building or other portions of the Property, to change the number of lobby attendants, or to institute, modify, supplement, or discontinue any particular access control procedures or equipment for the Building, whether during or after business hours. Landlord does not warrant or guarantee the effectiveness of any such system or procedures. Tenant expressly disclaims any such warranty, guarantee, or undertaking by Landlord with respect thereto and acknowledges that access control procedures from time to time in effect are solely for the convenience of tenants generally and are not intended to secure the Premises or to guarantee the physical safety of any persons in or about the Premises or the Property. Tenant shall be responsible for securing the Premises, including without limitation by Tenant's installation of access card readers or other security equipment for the Premises in accordance with Exhibit C and Article 8 and by restricting or monitoring access into and from the Premises by its employees or other invitees. At the time that any Tenant employee (or other person acting under or through Tenant) who has been issued a Building access card is terminated or otherwise ceases to work at the Premises, Tenant shall retrieve and destroy the Building access card for such person and, in accordance with the Building's standard procedures, notify the Building's property manager that such person should be removed from the active list for Building access cards.

7.05 <u>Energy Statements</u>. For any utilities serving the Premises for which Tenant is billed directly by such utility provider, Tenant agrees to furnish to Landlord (a) any invoices or statements for such utilities within thirty (30) days after Tenant's receipt thereof, (b) within thirty (30) days after Landlord's request. Tenant acknowledges that any utility information for the Premises may be shared with third parties, including Landlord's consultants and governmental authorities provided that prior to providing such utility information, Landlord shall use good faith efforts to redact any reference to Tenant to the extent such redaction is allowed under applicable Laws.

#### 8. Alterations.

8.01 <u>Alterations</u>. Tenant shall not make alterations, repairs, additions or improvements or install any Cable (collectively referred to as "Alterations") in the Premises, without first obtaining the written consent of Landlord in each instance, "**Cable**" shall mean and refer to any electronic, fiber, phone and data cabling and related equipment that is installed by or for Tenant or any party acting under or through Tenant. Prior to starting work on any Alterations, Tenant shall furnish Landlord with plans and specifications (which shall be in CAD format if requested by Landlord); names of contractors acceptable to Landlord (provided that Landlord may designate specific contractors with respect to Base Building and vertical Cable, as may be described more fully below, and provided further that Landlord may require any contractor or subcontractor performing work on or about the Premises or Building be harmonious with union labor); required permits and approvals; evidence of contractor's and subcontractor's insurance in amounts

-15-

reasonably required by Landlord and naming as additional insureds the Landlord, the managing agent for the Building, and such other Additional Insured Parties (as defined in Article 13) as Landlord may designate for such purposes; and any security for performance in amounts reasonably required by Landlord. Landlord may designate specific contractors with respect to oversight, installation, repair, connection to, and removal of vertical Cable. All Cable shall be clearly marked with adhesive plastic labels (or plastic tags attached to such Cable with wire) to show Tenant's name, suite number, and the purpose of such Cable (i) every 6 feet outside the Premises (specifically including, but not limited to, the electrical room risers and any Common Areas), and (ii) at the termination point(s) of such Cable. Changes to the plans and specifications must also be submitted to Landlord for its approval. Alterations shall be constructed in a good and workmanlike manner. Tenant shall ensure that no Alteration adversely affects any Building system or Landlord's ability to perform its obligations hereunder. Tenant shall reimburse Landlord for any third-party expenses incurred by Landlord in connection with the review, inspection, and coordination of Tenant's plans for Alterations and Tenant's performance thereof in an amount not to exceed 2% of the hard costs of the Alterations provided, however, this reimbursement obligation shall not apply to the Initial Tenant Work. Upon completion, Tenant shall furnish "as-built" plans (in CAD format, if requested by Landlord) for non-Cosmetic Alterations, customary AIA completion affidavits, full and final waivers of lien (and, to the extent applicable, cause a timely Notice of Completion to be recorded in the office of the Recorder of King County in accordance with the terms of Washington Law), any applicable certificate of occupancy for the space affected by such Alterations and other applicable municipal or local sign-offs and inspection reports, and any other items reasonably required by Landlord for closing out the particular work in question. Landlord's approval of an Alteration shall not be deemed to be a representation by Landlord that the Alteration complies with Law or will not adversely affect any Building system. If any Alteration requires any change to the Base Building, any Building system or any Common Area, then such changes shall be made at Tenant's sole cost and expense and performed, at Landlord's election, either by Tenant's contractor or a contractor engaged by Landlord. Notwithstanding the foregoing, Landlord's consent shall not be required for any Alteration that satisfies all of the following criteria (a "Cosmetic Alteration") and of which Landlord is given prior notice: (a) is of a cosmetic nature such as painting, wallpapering, hanging pictures and installing carpeting; (b) is not visible from the exterior of the tenth  $(10^{\text{th}})$  floor portion of the Premises; (c) will not affect the Base Building (defined in Article 5); (d) does not require work to be performed inside the exterior walls or above the ceiling of the Premises; (e) cost less than \$[\*\*\*] for a particular job; and (f) does not require a building permit. Cosmetic Alterations shall be subject to all the other provisions of this Article  $\underline{8}$ , to the extent applicable thereto.

8.02 Liens. Tenant shall not cause or permit any mechanics' or other liens or encumbrances to be placed upon the Property, the Premises, or Tenant's leasehold interest hereunder, whether in connection with any work or service done or purportedly done by or for the benefit of Tenant, its subtenants, or any other party acting under or through Tenant, or otherwise. Tenant shall give Landlord notice at least thirty (30) days prior to the commencement of any work in the Premises to afford Landlord the opportunity to post and record notices of non-responsibility. Tenant, within twenty (20) days after notice from Landlord, shall fully discharge any such lien by settlement, by bonding or by insuring over the lien in the manner prescribed by the applicable lien Law. If Tenant fails to timely discharge such lien within such period, Tenant shall be deemed in Default under this Lease and, in addition to any other remedies available to Landlord as a result of such Default by Tenant, Landlord, at its option, may bond, insure over or otherwise discharge the

-16-

lien. Tenant shall reimburse Landlord for any amount paid by Landlord to discharge such lien, including, without limitation, reasonable attorneys' fees. Landlord shall have the right to require Tenant to post a performance or payment bond in connection with any work or service done or purportedly done by or for the benefit of Tenant. Tenant acknowledges and agrees that all such work or service is being performed for the sole benefit of Tenant and not for the benefit of Landlord.

8.03 Leasehold Improvements. All Leasehold Improvements shall, except as expressly provided in this Lease, remain upon the Premises at the end of the Term without compensation to Tenant. "Leasehold Improvements" shall mean and include all Initial Tenant Work and other leasehold improvements from time to time existing in or to the Premises, including without limitation any such leasehold improvements (if any) that exist as of the applicable delivery date or Term Commencement Date under this Lease or that are made by or for the benefit of Tenant (or any party acting under or through Tenant) before the Term Commencement Date or thereafter from time to time during the Term. Leasehold Improvements shall expressly exclude Tenant's Property which shall remain the property of Tenant unless otherwise expressly agreed to by Landlord and Tenant in writing. Landlord, by written notice to Tenant at least thirty (30) days prior to the Term Expiration Date, may require Tenant, at Tenant's expense, to remove any Initial Tenant Work or other Leasehold Improvements or other affixed installations that, in Landlord's reasonable judgment, are of a nature that would require removal and repair costs that are materially in excess of the removal and repair costs associated with standard improvements for the Permitted Use ("Required Removables"). Required Removables shall include, without limitation, internal stairways, raised floors, private baths and showers, vaults, rolling file systems, structural alterations and modifications and any Cable installed by or on behalf of Tenant. Tenant, at the time it requests approval for a proposed Alteration, including any Initial Tenant Work, as such terms may be defined in the Work Letter attached as Exhibit C, may request in writing that Landlord advise Tenant whether the Alteration, including any Initial Tenant Work, or any portion thereof, is a Required Removable. Within ten (10) Business Days after receipt of Tenant's request, Landlord shall advise Tenant in writing as to which portions of the Alteration or other Leasehold Improvements are Required Removables. The Required Removables shall be removed by Tenant before the expiration or earlier termination of this Lease in accordance with Article 20.

8.04 <u>Signage</u>. No sign, advertisement or notice shall be exhibited, painted or affixed by Tenant at the Premises in a manner visible from the exterior of the Premises except as required to identify Tenant as the tenant of the Premises and in compliance with applicable Laws. The design and installation of any such signage shall be subject to Landlord's reasonable approval. For any signage, Tenant shall, at Tenant's own cost and expense, (a) acquire all permits for such signage in compliance with applicable Laws and (b) design, fabricate, install and maintain such signage in a first-class condition. Tenant shall remove all signage identifying Tenant or anyone claiming by, through, or under Tenant prior to the expiration of the Term.

#### 9. Repairs and Maintenance.

9.01 <u>Tenant Obligations</u>. Tenant shall periodically inspect the Premises to identify any conditions that are dangerous or in need of maintenance or repair. Tenant shall promptly provide Landlord with notice of any such conditions. Tenant, at its sole cost and expense, shall perform all maintenance and repairs to the Premises that are not Landlord's express responsibility under this

-17-

Lease, and keep the Premises in good condition and repair, reasonable wear and tear excepted. Tenant's repair and maintenance obligations include, without limitation, repairs to: (a) floor covering; (b) interior partitions; (c) doors; (d) the interior side of demising walls; (e) Leasehold Improvements and Alterations; (f) any and all elements of the heating, ventilation and air conditioning system and equipment (including any supplemental HVAC units) that exclusively serves the Premises ("Tenant's HVAC"), (g) kitchens, including hot water heaters, plumbing, and similar facilities exclusively serving the Premises or any portion thereof, whether such items are installed by Tenant or are currently existing in the Premises; and (h) any Cable. Tenant shall maintain in effect throughout the Term maintenance/service contracts for Tenant's HVAC or other specialty equipment exclusively serving the Premises and, from time to time upon Landlord's request, provide Landlord with a copy of such maintenance contract and reasonable evidence of its service record. All maintenance/service contracts for Tenant's HVAC shall include all services recommended by the equipment manufacturer within the operation and maintenance manual and shall become effective within thirty (30) days after the date Tenant takes possession of the Premises. If Tenant fails to maintain any such maintenance/service contracts, Landlord shall have the right but not the obligation, upon notice to Tenant, to procure and maintain any such maintenance/service contracts, and Tenant shall reimburse Landlord, as Additional Rent, within twenty (20) days after written demand, for the costs therefor. All material and non-routine repairs and related work performed by Tenant or its contractors, including that involving Cable, shall be subject to the terms of Section 8.01 above. If Tenant fails to make any repairs to the Premises for more than fifteen (15) days after notice from Landlord (although notice shall not be required in an emergency), Landlord may (but shall not be required to do so) make the repairs, and, within thirty (30) days after demand, Tenant shall pay to Landlord the reasonable cost of the repairs, together with an administrative charge in an amount equal to five percent (5%) of the hard cost of the repairs. Tenant shall be responsible, at its sole cost and expense, for providing cleaning and janitorial services to the Premises in a neat and first-class manner consistent with the cleaning standards generally prevailing in comparable buildings in the Seattle area for laboratory and office space or as otherwise reasonably established by Landlord in writing from time to time, using an insured contractor or contractors selected by Tenant and reasonably approved in writing by Landlord and such provider shall not interfere with the use and operation of the Building or Property by Landlord or any other tenant or occupant thereof. Tenant shall also be responsible to arrange for, at Tenant's sole cost and expense, any waste (including biomedical, hazardous and laboratory waste) and refuse removal services for Tenant's operations at the Premises. All waste (including biomedical, hazardous and laboratory waste) and refuse removal shall be performed in compliance with applicable environmental Laws using licensed laboratory waste disposal companies. All biomedical, hazardous and laboratory waste and refuse shall be stored in the Premises and shall be removed in compliance with applicable environmental Laws. Tenant shall also cause all extermination of vermin in the Premises or resulting from Tenant's use of the Premises to be performed by companies reasonably approved by Landlord in writing and shall contract and use pest extermination services as reasonably necessary or as reasonably requested by Landlord. Tenant hereby waives and releases its right to make repairs at Landlord's expense under any law, statute, or ordinance now or hereafter in effect.

9.02 <u>Landlord Obligations</u>. Landlord shall keep and maintain in good repair and working order and perform maintenance upon (a) the structural elements of the Building; (b) the mechanical (including HVAC), electrical, plumbing and fire/life safety systems serving the Building in general; (c) the Common Areas; (d) the roof of the Building; (e) the exterior windows

-18-

of the Building; and (f) the elevators serving the Building. Subject to reasonable wear and tear, and damage by Casualty, or taking by eminent domain (which shall instead be governed by <u>Articles 14</u> and <u>15</u> below), Landlord shall from time to time make repairs for which Landlord is responsible hereunder.

#### **10.** Entry by Landlord.

Landlord may enter the Premises to inspect, show or clean the Premises or to perform or facilitate the performance of repairs, alterations or additions to the Premises or any portion of the Building. Except in emergencies or to provide Building services, Landlord shall provide Tenant with reasonable prior notice of entry of not less than twenty-four (24) hours (which such notice may be verbal or by email). In connection with any such entry for non-emergency work performed during Building Service Hours, Landlord shall use reasonable efforts, consistent with the operation of a first-class life sciences building, not to unreasonably interfere with Tenant's use of the Premises. If reasonably necessary, Landlord may temporarily close all or a portion of the Premises to perform repairs, alterations and additions. Landlord shall not close the Premises during Building Service Hours if the work can reasonably be performed on weekends and/or after Building Service Hours. Tenant shall at all times, except in the case of emergencies, have the right to escort Landlord or its agents, representatives, contractors or guests while the same are in the Premises, provided such escort does not materially and adversely affect Landlord's access rights hereunder. Landlord agrees to comply with any commercially reasonable confidentiality, security, and safety measures that Tenant may elect to prescribe during Landlord's entry to the Premises. Any such entry by Landlord shall not constitute a constructive eviction or entitle Tenant to an abatement or reduction of Rent.

#### 11. Assignment and Subletting.

Transfers. Except in connection with a Permitted Transfer (defined in Section 11.04), Tenant 11.01 shall not assign, sublease, transfer or encumber any interest in this Lease or allow any third party to use all or any portion of the Premises (in each such case, collectively or individually, a "Transfer" to a "Transferee") without the prior written consent of Landlord, which consent shall not be unreasonably withheld, conditioned or delayed if Landlord does not exercise its recapture rights under Section 11.02. Without limitation, it is agreed that Landlord's consent shall not be considered unreasonably withheld if the proposed Transferee (a) is a governmental entity, (b) is an occupant of the Building, (c) whether or not an occupant of the Building, has been in discussions with Landlord regarding the leasing of space within the Building within the preceding six (6) months, (d) is incompatible with the character of occupancy of the Building, (e) is an entity with which the payment for the sublease or assignment is determined in whole or in part based upon its net income or profits, or (f) would subject the Premises to a use which would: (i) involve increased personnel or wear upon the Building; (ii) violate any exclusive right granted to another tenant of the Building; (iii) require any addition to or modification of the Premises or the Building in order to comply with building code or other governmental requirements; or (iv) involve a violation of the Permitted Use clauses of this Lease. Subject to Section 11.04 below, if the entity(ies) that directly or indirectly controls the voting shares/rights of Tenant (other than through the ownership of voting securities listed on a recognized securities exchange) changes at any time, such change of ownership or control shall constitute a Transfer. Any Transfer in violation of this Section shall, at Landlord's option, be deemed a Default by

-19-

Tenant as described in <u>Section 16.01</u>, and shall be voidable by Landlord. In no event shall any Transfer, including a Permitted Transfer, release or relieve Tenant from any obligation under this Lease, and the Tenant originally named in this Lease shall remain primarily liable for the performance of the tenant's obligations under this Lease, as amended from time to time.

Process. Tenant shall provide Landlord with financial statements for the proposed Transferee 11.02 (or, in the case of a change of ownership or control, for the proposed new controlling entity(ies)), a copy of the final form of the proposed assignment, sublease, or other Transfer documentation, and such other information as Landlord may reasonably request. Within fifteen (15) Business Days after receipt of the required information and documentation, Landlord shall either: (a) consent to the Transfer by execution of a consent agreement in a form reasonably designated by Landlord; (b) reasonably refuse to consent to the Transfer in writing; or (c) in the event of a proposed assignment of this Lease or subletting for space in the Premises that is between twenty-five percent (25%) and forty-five percent (45%) of the Premises (in each case to anyone other than Affiliate), recapture the Premises or, in the case of a subletting, recapture the portion of the Premises that Tenant is proposing to Transfer for the term of such sublease. If Landlord exercises its right to recapture by written notice to Tenant (the "Recapture Notice"), this Lease shall automatically be amended (or terminated if the entire Premises is being assigned or more than forty-five percent (45%) of the Premises is sublet) to delete the applicable portion of the Premises effective on the proposed effective date of the Transfer, although Landlord may require Tenant to execute a reasonable amendment or other document reflecting such reduction or termination; provided, however, that Tenant may, within ten (10) days of receiving the Recapture Notice, rescind its request for Transfer and Landlord's recapture right shall also be automatically rescinded. Tenant shall pay to Landlord the reasonable costs and attorneys' fees incurred by Landlord in connection with such requested Transfer provided, in no event, shall such costs exceed [\*\*\*] Dollars (\$[\*\*\*]).

11.03 Excess Payments. In the event, if any, that (i) all rent and other consideration which Tenant receives as a result of a Transfer exceeds (ii) the Rent payable to Landlord for the portion of the Premises and Term covered by the Transfer, then Tenant shall, at Landlord's election, pay to Landlord an amount equal to fifty percent (50%) of such excess, from time to time on a monthly basis upon Tenant's receipt of such excess; provided that in determining any such excess, Tenant may deduct from the excess all reasonable and customary expenses directly incurred by Tenant in connection with such Transfer, except that any construction costs incurred by Tenant in connection with such Transfer, except the term of the applicable Transfer. If Tenant is in Default, Landlord may require that all sublease payments be made directly to Landlord, in which case Tenant shall receive a credit against Rent in the amount of Tenant's share of payments received by Landlord. Notwithstanding anything to the contrary contained herein, Sections 11.02 and 11.03 shall not apply to a Permitted Transfer.

11.04 <u>Permitted Transfers</u>. Tenant may assign this Lease to a successor to Tenant by merger, consolidation, or the purchase of all or substantially all of Tenant's assets, or assign this Lease or sublet all or a portion of the Premises to an Affiliate (defined below), without the consent of Landlord, provided that all of the following conditions are satisfied (a "**Permitted Transfer**"): (a) Tenant must not be in Default; (b) Tenant must give Landlord written notice at least fifteen (15) days before such Transfer; and (c) except in the case of a sublease to an Affiliate, the Credit

Requirement (defined below) must be satisfied. Tenant's notice to Landlord shall include information and documentation evidencing that any Transfer qualifies as a Permitted Transfer hereunder and that each of the above conditions has been satisfied. If requested by Landlord, Tenant's successor shall sign and deliver to Landlord a commercially reasonable form of assumption agreement. "Affiliate" shall mean an entity controlled by, controlling or under common control with Tenant. The original Tenant executing this Lease may be referred to herein as the "Original Tenant." An Affiliate that is an assignee of Original Tenant's entire interest in this Lease may be referred to herein as an "Affiliate Assignee." The "Credit Requirement" shall be deemed satisfied if, as of the date immediately preceding the date of the Permitted Transfer, the financial strength of either (i) the entity with which Tenant is to merge or consolidate or to which the Lease is otherwise to be assigned or (ii) the purchaser of all or substantially all of the assets of Tenant, as applicable, is not less than that of Tenant, as determined (x) based on credit ratings of such entity and Tenant by both Moody's and Standard & Poor's (or by either such agency alone, if applicable ratings by the other agency do not exist), or (y) if such credit ratings do not exist, then in accordance with certified financial statements for such entity and Tenant covering their last two fiscal years ending before the Transfer. If, at any time after a Permitted Transfer, the Affiliate to which the Permitted Transfer is made ceases to qualify as an Affiliate of the original Tenant, such event shall be deemed a Transfer that is subject to the provisions of Sections 11.01, 11.02, and 11.03 above.

11.05 <u>Prohibited Matters</u>. Without limiting Landlord's right to withhold its consent to any Transfer by Tenant, unless Landlord shall have consented to any Transfer, neither Tenant nor any other person having an interest in the possession, use or occupancy of the Premises or any part thereof shall enter into any lease, sublease, license, concession, assignment or other transfer or agreement for possession, use or occupancy of all or any portion of the Premises which provides for rent or other payment for such use, occupancy or utilization based, in whole or in part, on the net income or profits derived by any person or entity from the space so leased, used or occupied, and any such purported lease, sublease, license, concession, assignment or other transfer or agreement shall be absolutely void and ineffective as a conveyance of any right or interest in the possession, use or occupancy of all or any part of the Premises.

#### 12. Notices.

All demands, approvals, consents or notices (collectively referred to as a "**notice**") shall be in writing and delivered by hand, sent by registered, express, or certified mail, with return receipt requested or with delivery confirmation requested from the U.S. postal service, sent by overnight or same day courier service, or by email provided that notices sent by email must also be sent pursuant to any one of the other methods in this sentence, in all cases at the party's respective Notice Address(es) set forth in <u>Section 1.16</u>; provided, however, notices sent by Landlord regarding general Building operational matters may be posted in the Building mailroom or the general Building newsletter or sent via e-mail to the e-mail address provided by Tenant to Landlord for such purpose. In addition, if the Building is closed (whether due to emergency, governmental order or any other reason), then any notice address at the Building shall not be deemed a required notice address during such closure, any notices sent during such closure may be sent via e-mail or in any other practical manner reasonably designed to ensure receipt by the intended recipient. Each notice shall be deemed to have been received on the earlier to occur of actual

-21-

delivery or the date on which delivery is refused (in the case of email, when confirmed sent with read receipt requested), or, if Tenant has vacated the Premises or any other Notice Address of Tenant without providing a new Notice Address, three (3) Business Days after notice is deposited in the U.S. mail or with a courier service in the manner described above. Either party may, at any time, change its Notice Address (other than to a post office box address) by giving the other party written notice of the new address.

## **13.** Indemnity and Insurance.

13.01 Indemnification. Except to the extent caused by the negligence or willful misconduct of Landlord or any Landlord Related Parties (defined below), and to the maximum extent permitted under applicable law, Tenant shall indemnify, defend and hold Landlord and Landlord Related Parties harmless against and from all liabilities, obligations, damages, penalties, claims, actions, costs, charges and expenses, including, without limitation, reasonable attorneys' fees and other professional fees (collectively referred to as "Losses"), which may be imposed upon, incurred by or asserted against Landlord or any of the Landlord Related Parties arising out of or in connection with any damage or injury occurring in the Premises or any acts or omissions (including violations of Law) of Tenant, its trustees, managers, members, principals, beneficiaries, partners, officers, directors, employees and agents (the "Tenant Related Parties") or any of Tenant's transferees, contractors or licensees, or Tenant's or any Tenant Related Parties' failure to perform its obligations under this Lease, or otherwise arising out of the use or occupancy of the Premises by Tenant or any Tenant Related Parties. To the maximum extent permitted under applicable law, Tenant hereby waives all claims against and releases Landlord and its trustees, managers, members, principals, beneficiaries, partners, officers, directors, employees, Mortgagees (defined in Article 21) and agents (the "Landlord Related Parties") from all claims for any loss of business, loss of income or injury to or death of persons, damage to property, scientific research, intellectual property or business loss in any manner related to (a) Force Majeure, (b) acts of third parties, (c) the bursting or leaking of any tank, lab system, water closet, drain or other pipe, or (d) the inadequacy or failure of any security or protective services, personnel or equipment. Tenant hereby agrees that it shall not assert any industrial insurance immunity rights pursuant to Title 51 RCW (as the same may be amended, substituted or replaced) if such assertion would be inconsistent with or otherwise impair Landlord's right to indemnification under this Section 13.01, and, accordingly, hereby waives all such industrial insurance immunity rights. The foregoing waiver of industrial insurance immunity rights was specifically negotiated by Landlord and Tenant and is solely for the benefit of the Landlord and Tenant, and their successors and assigns, under the Lease, and is not intended as a waiver of Tenant's rights of immunity under such industrial insurance for any other purposes.

13.02 <u>Tenant's Insurance</u>. Tenant shall maintain the following coverages in the following amounts throughout the Term (and during any other periods before or after the Term during which Tenant or any Tenant Related Party enters into or occupies all or any portion of the Premises):

13.02.1 Commercial general liability insurance covering claims of bodily injury, personal injury and property damage arising out of Tenant's operations and contractual liabilities, including coverage formerly known as broad form, on an occurrence basis, with minimum primary limits of \$[\*\*\*] per occurrence and \$[\*\*\*] annual aggregate and a minimum excess/umbrella limit of \$[\*\*\*] per occurrence.

-22-

13.02.2 Property insurance covering (i) Tenant's Property (as defined below), and (ii) any Leasehold Improvements in the Premises, whether installed by or for the benefit of Tenant under this Lease or any prior lease or other agreement to which Tenant was a party or otherwise ("**Tenant-Insured Improvements**"). Such insurance shall be written on a special cause of loss form for physical loss or damage, for the full replacement cost value (subject to reasonable deductible amounts) without deduction for depreciation of the covered items and in amounts that meet any co-insurance clauses of the policies of insurance, and shall include coverage for damage or other loss caused by fire or other peril, including vandalism and malicious mischief, theft, water damage of any type, including sprinkler leakage, bursting or stoppage of pipes, and explosion, and providing business interruption coverage for a period of one year.

13.02.3 Worker's Compensation and Employer's Liability or other similar insurance to the extent required by Law.

13.02.4 Pollution Legal Liability insuring Tenant for defense expenses and damages including cleanup costs for pollution events caused or allegedly caused by Tenant, or those for whom Tenant may be liable, in the course of its operations at a minimum limit of \$[\*\*\*], such coverage shall specifically include this Lease as an insured contract.

The minimum limits of insurance required to be carried by Tenant shall not limit Tenant's liability. Such insurance shall (i) be issued by an insurance company that has an A.M. Best rating of not less than A-VIII and licensed to do business in the State of Washington; (ii) be in form and content reasonably acceptable to Landlord; and (iii) provide that it shall not be canceled or materially changed without thirty (30) days' prior notice to Landlord, except that ten (10) days' prior notice may be given in the case of nonpayment of premiums. Tenant's commercial general liability insurance shall (a) name Landlord, Landlord's managing agent, and any other party designated by Landlord ("Additional Insured Parties") as additional insureds; and (b) be primary insurance as to all claims thereunder and provide that any insurance carried by Landlord is excess and non-contributing with Tenant's insurance. Tenant shall deliver to Landlord, on or before the earlier to occur of the date Landlord delivers possession of the Premises to Tenant or the Term Commencement Date and at least fifteen (15) days before the expiration dates thereof, certificates from Tenant's insurance company on the forms currently designated "ACORD 28" (Evidence of Commercial Property Insurance) and "ACORD 25-S" (Certificate of Liability Insurance) or the equivalent. Attached to the ACORD 25-S (or equivalent) there shall be an endorsement naming the Additional Insured Parties as additional insureds which shall be binding on Tenant's insurance company and shall expressly require the insurance company to notify each Additional Insured Party in writing at least thirty (30) days before any termination or material change to the policies, except that ten (10) days' prior notice may be given in the case of nonpayment of premiums. Notwithstanding the foregoing, if the foregoing requirement that the insurance company provide prior notice to Landlord of cancellation or material change of the applicable policy cannot reasonably be obtained based on then-prevailing insurance industry practices, Tenant shall so advise Landlord of such unavailability and shall instead provide Landlord with notice of any such cancellation or material change as provided above. Upon Landlord's request, Tenant shall deliver to Landlord, in lieu of such certificates, copies of the policies of insurance required to be carried under Section 13.02 showing that the Additional Insured Parties are named as additional insureds.

-23-

Tenant shall maintain such increased amounts of the insurance required to be carried by Tenant under this <u>Section 13.02</u>, and such other types and amounts of insurance covering the Premises and Tenant's operations therein, as may be reasonably requested by Landlord, but not in excess of the amounts and types of insurance then being required by institutional landlords of buildings comparable to and in the general vicinity of the Building.

13.03 <u>Tenant's Property</u>. All furnishings, fixtures, equipment, and other personal property and effects of Tenant and of all persons claiming through Tenant which from time to time may be on the Premises or elsewhere in the Building or in transit thereto or therefrom (collectively, "**Tenant's Property**") shall be at the sole risk of Tenant to the maximum extent permitted by law and shall be kept insured by Tenant throughout the Term (and during any other periods before or after the Term during which Tenant or any Tenant Related Party enters into or occupies all or any portion of the Premises) at Tenant's expense in accordance with <u>Section 13.02</u>. Tenant's Property expressly includes all business fixtures and equipment, including without limitation any security or access control systems installed for the Premises, filing cabinets and racks, removable cubicles and partitions, kitchen equipment, computers and related equipment, raised flooring, supplemental cooling equipment installations, in each case including related conduits, cabling, and brackets or mounting components therefor and any connectors to base building systems and in each case whether installed or affixed in or about the Premises, in building core areas, or elsewhere in the Building.

13.04 <u>Waiver of Subrogation</u>. Subject to <u>Article 14</u>, each party waives, and shall cause its insurance carrier to waive, any right of recovery against the other for any loss of or damage to property which loss or damage is (or, if the insurance required hereunder had been carried, would have been) covered by property insurance. For purposes of this <u>Section 13.04</u>, any deductible or self-insured retention with respect to a party's insurance shall be deemed covered by, and recoverable by such party under, valid and collectable policies of insurance.

#### 14. Casualty Damage.

14.01 <u>Casualty</u>. If all or any portion of the Premises becomes untenantable or inaccessible by fire or other casualty to the Premises or the Common Areas (collectively a "**Casualty**"), Landlord, with reasonable promptness, shall cause a general contractor selected by Landlord to provide Landlord with a written estimate of the amount of time required, using standard working methods, to substantially complete the repair and restoration of the Premises and any Common Areas necessary to provide access to the Premises ("**Completion Estimate**"). Landlord shall promptly forward a copy of the Completion Estimate to Tenant. If the Completion Estimate indicates that the Premises or any Common Areas necessary to provide access to the Premises cannot be made tenantable within three hundred sixty-five (365) days from the date the repair is started, then either party shall have the right to terminate this Lease upon written notice to the other within ten (10) days after Tenant's receipt of the Completion Estimate. Tenant, however, shall not have the right to terminate this Lease if the Casualty was caused by the negligence or intentional misconduct of Tenant or any Tenant Related Parties. In addition, Landlord, by notice to Tenant within ninety (90) days after the date of the Casualty, shall have the right to terminate this Lease if: (1) the Premises have been materially damaged and less than one (1) year of the Term remains after the date of the Casualty; (2) any Mortgagee requires that the insurance proceeds be applied

to the payment of the mortgage debt; or (3) a material uninsured loss to the Building or Premises occurs.

14.02 Restoration. If this Lease is not terminated, Landlord shall promptly and diligently, subject to reasonable delays for insurance adjustment or other matters beyond Landlord's reasonable control, restore the Premises and Common Areas, subject to the following provisions. Such restoration shall be to substantially the same condition that existed prior to the Casualty, except for modifications required by Law or any other modifications to the Common Areas deemed desirable by Landlord. Notwithstanding Section 13.04, upon notice from Landlord, Tenant shall assign or endorse over to Landlord (or to any party designated by Landlord) all property insurance proceeds payable to Tenant under Tenant's insurance with respect to any Leasehold Improvements; provided if the estimated cost to repair such Leasehold Improvements exceeds the amount of insurance proceeds received by Landlord from Tenant's insurance carrier, the excess cost of such repairs shall be paid by Tenant to Landlord prior to Landlord's commencement of repairs. Within fifteen (15) days after demand, Tenant shall also pay Landlord for any additional excess costs that are determined during the performance of the repairs to such Leasehold Improvements. In no event shall Landlord be required to spend more for the restoration of the Premises, Building and Common Areas than the proceeds received by Landlord, whether from Landlord's insurance proceeds or proceeds from Tenant. Landlord shall not be liable for any inconvenience to Tenant, or injury to Tenant's business resulting in any way from the Casualty or the repair thereof. Provided that Tenant is not in Default, during any period of time that all or a material portion of the Premises is rendered untenantable as a result of a Casualty, the Rent shall abate for the portion of the Premises that is untenantable and not used by Tenant. Notwithstanding the foregoing, Landlord may, at its election, require Tenant to perform the restoration work for the Leasehold Improvements, in which event Tenant shall be responsible for performing the restoration work (including any revisions thereto that Tenant may wish to make, pursuant to plans approved by Landlord under Article 8) and the rent abatement period under the preceding sentence shall not exceed the period of time required to diligently perform the restoration of the existing Leasehold Improvements.

14.03 <u>Insurance Proceeds</u>. If this Lease is terminated by either party on account of any Casualty as provided in this <u>Article 14</u>, then Tenant shall pay to Landlord (by assignment or otherwise) the insurance proceeds paid or payable to Tenant under the policy(ies) referred to in <u>Section 13.02(b)</u> on account of the damage to or loss of the Leasehold Improvements in the Premises; however, from any such proceeds actually received by Tenant, Tenant shall be entitled to retain an amount equal to the unamortized portion (amortized over the initial Term on a straight-line basis) of the hard costs paid by Tenant to perform such Leasehold Improvements (after deduction of the Tenant Work Allowance and any other work allowance or contribution paid by Landlord for such Leasehold Improvements).

14.04 <u>Express Agreement</u>. The provisions of this Lease, including this <u>Article 14</u>, constitute an express agreement between Landlord and Tenant with respect to any and all damage to, or destruction of, all or any part of the Premises, the Building or any other portion of the Property, and any statute or regulation of the State of Washington, with respect to any rights or obligations concerning damage or destruction in the absence of an express agreement between the parties, and any other statute or regulation, now or hereafter in effect, shall have no application to

-25-

this Lease or any damage or destruction to all or any part of the Premises, the Building or any other portion of the Property.

#### 15. Condemnation.

Either party may terminate this Lease if any material part of the Premises is taken or condemned for any public or quasi-public use under Law, by eminent domain or private purchase in lieu thereof (a "**Taking**"). Landlord shall also have the right to terminate this Lease if there is a Taking of any portion of the Building or Property which would have a material adverse effect on Landlord's ability to profitably operate the remainder of the Building. The terminating party shall provide written notice of termination to the other party within forty five (45) days after it first receives notice of the Taking. The termination shall be effective as of the effective date of any order granting possession to, or vesting legal title in, the condemning authority. If this Lease is not terminated, Base Rent and Tenant's Share shall be appropriately adjusted to account for any reduction in the square footage of the Building or Premises. All compensation awarded for a Taking shall be the property of Landlord. The right to receive compensation or proceeds are expressly waived by Tenant, provided, however, Tenant may file a separate claim for Tenant's Property and Tenant's reasonable relocation expenses, provided the filing of the claim does not diminish the amount of Landlord's award. If only a part of the Premises is subject to a Taking and this Lease is not terminated, Landlord, with reasonable diligence, will restore the remaining portion of the Premises as nearly as practicable to the condition immediately prior to the Taking.

#### 16. Events of Default.

Default. In addition to any other Default specifically described in this Lease, each of the 16.01 following occurrences shall be a "Default": (a) Tenant's failure to pay any portion of Rent when due, if the failure continues for five (5) Business Days after written notice to Tenant ("Monetary Default"); (b) Tenant's failure to comply with any term, provision, condition or covenant of this Lease (other than a Monetary Default and other than as set forth in clauses (c) through (h) of this Section), if the failure is not cured within thirty (30) days after written notice to Tenant provided, however, if Tenant's failure to comply cannot reasonably be cured within such thirty-(30)-day period, Tenant shall be allowed additional time (not to exceed an additional ninety (90) days) as is reasonably necessary to cure the failure so long as Tenant begins the cure within such thirty-(30)-day period and diligently pursues the cure to completion; (c) Tenant effects or permits a Transfer without Landlord's required approval or otherwise in violation of Article 11 of this Lease; (d) Tenant becomes insolvent, makes a transfer in fraud of creditors, makes an assignment for the benefit of creditors, admits in writing its inability to pay its debts when due or forfeits or loses its right to conduct business; (e) the leasehold estate is taken by process or operation of Law; (f) if a receiver, guardian, conservator, trustee in bankruptcy or similar officer shall be appointed by a court of competent jurisdiction to take charge of all or any part of Tenant's property and such appointment is not discharged within ninety (90) days thereafter, or if a petition including, without limitation, a petition for reorganization or arrangement is filed by Tenant under any bankruptcy law or is filed against Tenant and, in the case of a filing against Tenant only, the same shall not be dismissed within ninety (90) days from the date upon which it is filed, or (g) Tenant is in default beyond any notice and cure period under any other lease or agreement with Landlord at the Building or Property. In addition, if Landlord provides Tenant with notice of Tenant's failure to comply with any specific provision of this Lease on two (2) separate occasions

-26-

during any twelve-(12)-month period, any subsequent violation of such provision within such twelve-(12)-month period shall, at Landlord's option, constitute a Default by Tenant without the requirement of any further notice or cure period as provided above. All notices sent under this Section shall be in satisfaction of, and not in addition to, any notice required by Law.

16.02 <u>Remedies</u>. Upon the occurrence of any Default, Landlord shall have, in addition to any other remedies available to Landlord at law or in equity, the option to pursue any one or more of the following remedies, each and all of which shall be cumulative and nonexclusive, without any notice or demand whatsoever.

Terminate this Lease, in which event Tenant shall immediately surrender the 16.02.1 Premises to Landlord, and if Tenant fails to do so, Landlord may, without prejudice to any other remedy which it may have for possession or arrearages in rent, enter upon and take possession of the Premises and expel or remove Tenant and any other person who may be occupying the Premises or any part thereof, without being liable for prosecution or any claim for damages therefor; and Landlord may recover from Tenant the following: (1) the worth at the time of award of any unpaid rent which has been earned at the time of such termination; plus, (2) the worth at the time of award of the amount by which the unpaid rent which would have been earned after termination until the time of award exceeds the amount of such rental loss that Tenant proves could have been reasonably avoided; plus, (3) the worth at the time of award of the amount by which the unpaid rent for the balance of the Lease Term after the time of award exceeds the amount of such rental loss that Tenant proves could have been reasonably avoided; plus, (4) any other amount necessary to compensate Landlord for all the detriment proximately caused by Tenant's failure to perform its obligations under this Lease or which in the ordinary course of things would be likely to result therefrom, specifically including, but not limited to, brokerage commissions and advertising expenses incurred, and expenses of restoring the Premises or any portion thereof for a new tenant to the condition in which Landlord delivered the Premises to Tenant, whether for the same or a different use; and (5) at Landlord's election, such other amounts in addition to or in lieu of the foregoing as may be permitted from time to time by applicable law. The term "rent" as used in this Section 16.02 shall be deemed to be and to mean all sums of every nature required to be paid by Tenant pursuant to the terms of this Lease, whether to Landlord or to others. As used clauses (1) and (2) above, the "worth at the time of award" shall be computed by allowing interest at the rate set forth in Section 5.1(A) of this Lease, but in no case greater than the maximum amount of such interest permitted by law. As used in clause (3) above, the "worth at the time of award" shall be computed by discounting such amount at the discount rate of the Federal Reserve Bank of San Francisco at the time of award plus one percent (1%).

16.02.2 If Landlord does not elect to terminate this Lease on account of any default by Tenant, Landlord may, from time to time, without terminating this Lease, enforce all of its rights and remedies under this Lease, including the right to recover all rent as it becomes due.

16.03 <u>Termination of Subleases</u>. Whether or not Landlord elects to terminate this Lease on account of any Default by Tenant, as set forth in this <u>Article 16</u>, Landlord shall have the right to terminate any and all subleases, licenses, concessions or other consensual arrangements for possession entered into by Tenant and affecting the Premises or may, in Landlord's sole discretion, succeed to Tenant's interest in such subleases, licenses, concessions or arrangements. In the event of Landlord's election to succeed to Tenant's interest in any such subleases, licenses, concessions

or arrangements, Tenant shall, as of the date of notice by Landlord of such election, have no further right to or interest in the rent or other consideration receivable thereunder.

16.04 <u>Specific Enforcement</u>. Landlord shall at all times have the rights and remedies (which shall be cumulative with each other and cumulative and in addition to those rights and remedies available under this <u>Article 16</u>, or any law or other provision of this Lease), without prior demand or notice except as required by Applicable Law, to seek any declaratory, injunctive or other equitable relief, and specifically enforce this Lease, or restrain or enjoin a violation or breach of any provision hereof. The provisions of this <u>Section 16.04</u> are not dependent upon the occurrence of a default.

16.05 <u>Efforts to Relet</u>. No re-entry or repossession, repairs, maintenance, changes, alterations and additions, reletting, appointment of a receiver to protect Landlord's interests hereunder, or any other action or omission by Landlord shall be construed as an election by Landlord to terminate this Lease or Tenant's right to possession, or to accept a surrender of the Premises, nor shall same operate to release Tenant in whole or in part from any of Tenant's obligations hereunder, unless express written notice of such intention is sent by Landlord to Tenant. Tenant hereby irrevocably waives any right otherwise available under any law to redeem or reinstate this Lease.

16.06 <u>Curative Action</u>. If Tenant is in Default of any of its non-monetary obligations under this Lease, Landlord shall have the right, but not the obligation, to perform any such obligation. Tenant shall reimburse Landlord for the cost of such performance upon demand, together with an administrative charge equal to five percent (5%) of the cost of the work performed by Landlord.

16.07 <u>Late Charges and Fees</u>. If Tenant does not pay any Rent when due hereunder, then without notice and in addition to all other remedies hereunder, Tenant shall pay to Landlord an administration fee in the amount of four percent (4%) of the unpaid Rent, plus interest on such unpaid amount at the rate of one and one half percent (1.5%) per month from the date such amount was due until the date paid (which interest, as accrued to date, shall be payable from time to time upon Landlord's demand); provided, however, in no event shall such interest exceed the maximum amount permitted to be charged by applicable law. Notwithstanding the foregoing, Tenant shall be entitled to a grace period of five (5) days for the first late payment of Rent in any twelve-(12)-month period prior to the imposition of the foregoing amounts. In addition, Tenant shall pay to Landlord a reasonable fee for any checks returned by Tenant's bank for any reason.

16.08 <u>Enforcement Costs</u>. Tenant shall pay to Landlord, as Additional Rent, the costs and expenses, including reasonable attorneys' fees, incurred in enforcing any obligations of Tenant under this Lease with which Tenant has failed to comply.

16.09 <u>General</u>. The repossession or re-entering of all or any part of the Premises shall not relieve Tenant of its liabilities and obligations under this Lease. No right or remedy of Landlord shall be exclusive of any other right or remedy, and each right and remedy shall be cumulative and in addition to any other right and remedy now or subsequently available to Landlord at law or in equity.

-28-

## **17.** Limitation of Liability.

17.01 Landlord's Liability. Tenant agrees from time to time to look only to Landlord's interest in the Building for satisfaction of any claim against Landlord hereunder or under any other instrument related to the Lease (including any separate agreements among the parties and any notices or certificates delivered by Landlord) and not to any other property or assets of Landlord. The obligations of Landlord shall not be binding on any direct or indirect partners (or members, trustees or beneficiaries) of Landlord or of any successor, individually, but only upon Landlord's or such successor's interest described above. If Landlord shall refuse or fail to provide any consent or approval for any matter for which Landlord's consent or approval is required under this Lease or is otherwise requested by Tenant, Landlord shall not be liable for damages as a result thereof, and Tenant's sole remedy to enforce any alleged obligation of Landlord to provide such consent or approval shall be an action for specific performance, injunction, or declaratory relief.

# 17.02 Assignment of Rents.

17.02.1 With reference to any assignment by Landlord of Landlord's interest in this Lease, or the rents payable hereunder, conditional in nature or otherwise, which assignment is made to the holder of a mortgage on property which includes the Premises, Tenant agrees that the execution thereof by Landlord, and the acceptance thereof by the holder of such mortgage shall never be treated as an assumption by such holder of any of the obligations of Landlord hereunder unless such holder shall, by notice sent to Tenant, specifically otherwise elect and, except as aforesaid, such holder shall be treated as having assumed Landlord's obligations hereunder only upon foreclosure of such holder's mortgage and the taking of possession of the Premises.

17.02.2 In no event shall the acquisition of Landlord's interest in the Property by a purchaser which, simultaneously therewith, leases Landlord's entire interest in the Property back to the seller thereof be treated as an assumption by operation of law or otherwise, of Landlord's obligations hereunder, but Tenant shall look solely to such seller-lessee, and its successors from time to time in title, for performance of Landlord's obligations hereunder. In any such event, this Lease shall be subject and subordinate to the lease to such purchaser. For all purposes, such seller-lessee, and its successors in title, shall be the Landlord hereunder unless and until Landlord's position shall have been assumed by such purchaser-lessor.

17.02.3 Except as provided in paragraph (b) of this <u>Section 17.02</u>, in the event of any transfer of title to the Property by Landlord, Landlord shall thereafter be entirely freed and relieved from the performance and observance of all covenants and obligations hereunder. Tenant hereby agrees to enter into such agreements or instruments as may, from time to time, be requested in confirmation of the foregoing.

17.03 <u>Landlord Default</u>. In the event Tenant alleges that Landlord is in default under any of Landlord's obligations under this Lease, Tenant agrees to give any Mortgagee (as defined in <u>Article 21</u>, by registered mail, a copy of any notice of default which is served upon the Landlord, provided that prior to such notice, Tenant has been notified, in writing (whether by way of notice of an assignment of lease, request to execute an estoppel letter, or otherwise), of the identity and address of any such Mortgagee. Tenant further agrees that if Landlord shall have failed to cure such default within the time provided by law or such additional time as may be provided in this

Lease or such notice to Landlord, such Mortgagee shall have a period of thirty (30) days after the last date on which Landlord could have cured such default within which such Mortgagee will be permitted, but not be obligated, to cure such default. If such default cannot be cured within such thirty-(30)-day period, then such Mortgagee shall have such additional time as may be necessary to cure such default, if prior to the end of such thirty-(30)-day period such Mortgagee has commenced and is diligently pursuing such cure or the remedies under the Mortgage necessary for Mortgagee to be able to effect such cure, in which event Tenant shall have no right with respect to such default while such cure and remedies are being diligently pursued by such Mortgagee. Except as may be expressly provided in this Lease, in no event shall Tenant have the right to terminate the Lease nor shall Tenant's obligations under the Lease. In no event shall Landlord or any Landlord Related Party ever be liable to Tenant for loss of profits, loss of business, or indirect or consequential damages suffered by Tenant from whatever cause.

#### **18.** Intentionally Omitted.

#### **19.** Holding Over.

If Tenant fails to surrender all or any part of the Premises at the expiration or earlier termination of this Lease, any such occupancy of all or any part of the Premises after such expiration or termination shall be that of a tenancy at sufferance only. Any such occupancy after such expiration or termination shall be subject to all the terms and provisions of this Lease, except that Tenant shall pay an amount for such occupancy (on a per month basis without reduction for partial months during the holdover) equal to one hundred fifty percent (150%) of the Base Rent (plus the actual amount of any Additional Rent) due for the month immediately preceding the holdover for the first thirty (30) days of such holdover and two hundred percent (200%) of such amounts thereafter. No holdover by Tenant or payment by Tenant after the expiration or earlier termination of this Lease shall be construed to extend the Term or prevent Landlord from immediate recovery of possession of the Premises by summary proceedings or otherwise. In addition, if as a result of such holdover, Landlord is unable to deliver possession of space to a new tenant or to perform improvements therein for a new tenant due to Tenant's failure to timely vacate all or part of the Premises, Tenant shall be liable to Landlord for all damages and losses that Landlord suffers from the holdover.

#### 20. Surrender of Premises.

20.01 <u>Condition</u>. At the expiration or earlier termination of this Lease or Tenant's right of possession hereunder, Tenant shall remove all Tenant's Property from the Premises, remove all Required Removables (if any) under <u>Section 8.03</u> (except to the extent otherwise directed in writing by Landlord), and quit and surrender the Premises to Landlord, broom clean, and in good order, condition and repair, ordinary wear and tear and damage which Landlord is obligated to repair hereunder excepted. Tenant shall repair any damage caused by the installation or removal of Tenant's Property or Required Removables and restore the affected portion of the Premises so that it is useable by a succeeding tenant in a manner consistent with first class standards. If Tenant fails to remove any of Tenant's Property or to restore or repair the Premises to the required condition as provided herein upon the expiration of the Term of this Lease (or, as applicable, within five (5) Business Days after any earlier termination of this Lease or Tenant's right to possession

hereunder), then Landlord, at Tenant's sole cost and expense, shall be entitled, but not obligated, to remove and store Tenant's Property and/or perform such restoration or repair of the Premises. Landlord shall not be responsible for the value, preservation, or safekeeping of Tenant's Property, and Tenant shall pay to Landlord, upon demand, the expenses and storage charges so incurred. If Tenant fails to remove Tenant's Property from the Premises or storage, within thirty (30) days after notice, Landlord may deem all or any part of Tenant's Property to be abandoned and, at Landlord's option, title to Tenant's Property shall vest in Landlord or Landlord may dispose of Tenant's Property in any manner Landlord deems appropriate.

20.02 Surrender Plan. Furthermore, upon the expiration of the Term or earlier termination of Tenant's right of possession, Tenant shall surrender the Premises to Landlord free of Hazardous Materials brought upon, kept, used, stored, handled, treated, generated in, or released or disposed of from, the Premises by any person other than Landlord (collectively, "HazMat Operations") and released of any license, clearance or other authorization of any kind required to enter into and restore the Premises issued by any Governmental Authority having jurisdiction over the use, storage, handling, treatment, generation, release, disposal, removal or remediation of Hazardous Materials in, on or about the Premises. At least three (3) months prior to the surrender of the Premises, Tenant shall deliver to Landlord a narrative description of the actions proposed (or required by any Governmental Authority) to be taken by Tenant in order to surrender the Premises (including any Alterations permitted by Landlord to remain in the Premises) at the expiration or earlier termination of the Term, fully decommissioned (including, without limitation, removal of all Hazardous Materials in accordance with applicable laws) and free from any residual impact from the HazMat Operations and otherwise released for unrestricted use and occupancy (the "Surrender Plan"). Such Surrender Plan shall be accompanied by a current listing of (i) all Hazardous Materials licenses and permits held by or on behalf of any Tenant Party with respect to the Premises, and (ii) all Hazardous Materials used, stored, handled, treated, generated, released or disposed of from the Premises, and shall be subject to the review and approval of Landlord's environmental consultant (such approval not to be unreasonably withheld or conditioned). In connection with the review and approval of the Surrender Plan, upon the request of Landlord, Tenant shall deliver to Landlord or its consultant such additional non-proprietary information concerning Tenant HazMat Operations as Landlord shall request. On or before such surrender, Tenant shall deliver to Landlord evidence that the approved Surrender Plan shall have been satisfactorily completed and Landlord shall have the right, subject to reimbursement at Tenant's expense as set forth below, to cause Landlord's environmental consultant to inspect the Premises and perform such additional procedures as may be deemed reasonably necessary to confirm that the Premises (including, without limitation, all floors, walls, ceiling and counters piping, supply lines, waste lines and plumbing and all exhaust and other ductwork in the Premises) are, as of the effective date of such surrender or early termination of the Lease, free from any residual impact from HazMat Operations. Tenant shall reimburse Landlord, as Additional Rent, for the actual out-of-pocket expense incurred by Landlord for Landlord's environmental consultant to review and approve the Surrender Plan and to visit the Premises and verify satisfactory completion of the same (not to exceed \$[\*\*\*] in then-current dollars). Tenants acknowledges and agrees that it shall surrender the Premises in a condition of environmental hygiene that it may be reused by a subsequent tenant for office, research and development, or laboratory use without incurring special costs or undertaking special procedures for demolition, disposal, investigation, assessment, cleaning or removal of any Hazardous Materials without giving notice in connection with such Hazardous Materials. Landlord shall have the unrestricted right to deliver such Surrender Plan and

-31-

any report by Landlord's environmental consultant with respect to the surrender of the Premises to third parties. If Tenant shall fail to prepare or submit a Surrender Plan approved by Landlord, or if Tenant shall fail to complete the approved Surrender Plan, or if such Surrender Plan, whether or not approved by Landlord, shall fail to adequately address any residual effect of HazMat Operations in, on or about the Premises, Landlord shall have the right to take such actions as Landlord may deem reasonable or appropriate to assure that the Premises are surrendered free from any residual impact from HazMat Operations, the cost of which actions shall be reimbursed by Tenant as Additional Rent.

# 21. Subordination to Mortgages; Estoppel Certificate.

21.01 Subordination. This Lease is and shall be subject and subordinate to any mortgage(s), deed(s) of trust, deeds to secure debt, ground lease(s) or other lien(s) now or subsequently arising upon the Premises, the Building or the Property, and to all renewals, modifications, refinancings, and extensions thereof (collectively referred to as a "Mortgage"). The party having the benefit of a Mortgage shall be referred to as a "Mortgagee". This clause shall be self-operative, but upon request from Landlord or a Mortgagee, Tenant shall execute a subordination agreement in favor of the Mortgagee in such Mortgagee's standard form, with such commercially reasonable changes as Tenant may request that are acceptable to Mortgagee. As an alternative, any Mortgagee shall have the right at any time to subordinate its Mortgage to this Lease. Upon request, Tenant, without charge, shall attorn to any successor to Landlord's interest in this Lease. In the event Mortgagee enforces it rights under the Mortgage, Tenant, at Mortgagee's option, will attorn to Mortgagee or its successor; provided, however, that Mortgagee or its successor shall not be liable for or bound by (i) any payment of any Rent installment which may have been made more than thirty (30) days before the due date of such installment, (ii) except for acts, omissions, or defaults that are continuing in nature, any act or omission of or default by Landlord under this Lease (but Mortgagee, or such successor, shall be subject to the continuing obligations of landlord under the Lease arising from and after such succession, but only to the extent of Mortgagee's, or such successor's, interest in the Property as provided in Article 17), (iii) any credits, claims, setoffs or defenses which Tenant may have against Landlord, or (iv) any obligation under this Lease to maintain a fitness facility at the Building, if any. Tenant, upon the reasonable request by Mortgagee or such successor in interest, shall execute and deliver an instrument or instruments confirming such attornment.

21.02 <u>Modification of Lease</u>. If any Mortgagee requires a modification of this Lease, which modification will not cause an increased cost or expense to Tenant or in any other way materially and adversely change the rights and obligations of Tenant hereunder, Tenant agrees that this Lease may be so modified and agrees to execute whatever documents are reasonably required therefor and to deliver the same to Landlord within ten (10) Business Days following a request therefor.

21.03 <u>Estoppel Certificate</u>. Tenant shall, within ten (10) Business Days after receipt of a written request, execute and deliver a commercially reasonable estoppel certificate addressed to Landlord and any parties reasonably requested by Landlord, such as a current or prospective Mortgagee or purchaser of the Building. Without limitation, such estoppel certificate may include a certification as to the status of this Lease and any particular obligations thereunder, the existence of any defaults, and the amount of Rent that is then due and payable.

-32-

Tenant Information. Upon Landlord's request from time to time during the Term only, and 21.04 only to the extent Tenant is not a public company, Tenant shall provide to Landlord the financial statements for Tenant for its most recent fiscal year and fiscal quarter. Financial statements for each fiscal year shall be prepared and certified by a certified public accountant; financial statements for each quarter shall be prepared and certified by Tenant's chief financial officer. If requested by Tenant, such financial statements shall be furnished pursuant to a confidentiality agreement in a form reasonably provided by Landlord for such purpose. Provided Tenant is not a public company, Landlord agrees, for so long as this Lease is in effect, to maintain in confidence the Tenant's financial information delivered to Landlord in connection with this Section 21.04, which Landlord shall not disclose to any third party other than (a) to its affiliates, employees, agents, advisors, attorneys, lenders, purchasers, investors, partners and representatives; (b) to the extent required by any applicable statute, law, regulation or governmental authority; and (c) in connection with any litigation that may arise between the parties in connection with the transactions contemplated by this Agreement. Landlord's agreement to maintain confidential information hereunder shall not include information which (x) was or becomes generally available to the public other than as a result of a disclosure by Landlord in violation of the foregoing provision, or (y) was available to Landlord on a non-confidential basis prior to its disclosure by the Tenant or their respective representatives or agents, or (z) becomes available to Landlord on a non-confidential basis from a source other than the Tenant, provided that such source is not bound by a confidentiality agreement with Landlord or otherwise prohibited from transmitting the information to Landlord by a contractual, legal or fiduciary obligation.

#### 22. Environmental Provisions.

22.01 Prohibition/Compliance/Indemnity. Tenant shall not cause or permit any Hazardous Materials (as hereinafter defined) to be brought upon, kept, used, stored, handled, treated, generated in or about, or released or disposed of from, the Premises or anywhere on the Property in violation of applicable Environmental Requirements (as hereinafter defined) by Tenant or any Tenant Related Parties or any of Tenant's transferees, contractors or licensees (or any of Tenant's assignees, sublessees and/or licensees respective agents, servants, employees, invitees and contractors) (collectively, "Tenant Parties"; any of them, a "Tenant Party"). If Tenant breaches the obligation stated in the preceding sentence, or if the presence of Hazardous Materials in the Premises or anywhere on the Property during the Term or any holding over results in contamination of the Premises, the Property and/or any adjacent property or if contamination of the Premises, the Property and/or any adjacent property by Hazardous Materials brought into, kept, used, stored, handled, treated, generated in or about, or released or disposed of from, the Premises by anyone other than Landlord and Landlord's employees, agents and contractors otherwise occurs during the Term or any holding over, Tenant hereby indemnifies and shall defend and hold Landlord, its officers, directors, employees, managers, agents, sub-agents, affiliates and contractors harmless from any and all actions (including, without limitation, remedial or enforcement actions of any kind, administrative or judicial proceedings, and orders or judgments arising out of or resulting therefrom), costs, claims, damages (including, without limitation, punitive damages and damages based upon diminution in value of the Premises, or the loss of, or restriction on, use of the Premises), expenses (including, without limitation, attorneys', consultants' and experts' fees, court costs and amounts paid in settlement of any claims or actions), fines, forfeitures or other civil, administrative or criminal penalties, injunctive or other relief (whether or not based upon personal injury, property damage, or contamination of, or adverse

-33-

effects upon, the environment, water tables or natural resources), liabilities or losses (collectively, "**Environmental Claims**") that arise during or after the Term as a result of such contamination. This indemnification of Landlord by Tenant includes, without limitation, costs incurred in connection with any investigation of site conditions or any cleanup, treatment, remedial, removal, or restoration work required by any federal, state or local Governmental Authority because of Hazardous Materials present in the air, soil or ground water above, on, or under the Premises, the Property, or any other adjacent property. Without limiting the foregoing, if the presence of any Hazardous Materials in, on or under the Premises, the Property, or any adjacent property caused or permitted by Tenant or any Tenant Party results in any contamination, Tenant shall promptly take all actions at its sole expense and in accordance with applicable Environmental Requirements as are necessary to return the Premises, the Property, and/or any adjacent property to the condition existing prior to the time of such contamination, provided that Landlord's approval of such action shall first be obtained.

Business. Landlord acknowledges that it is not the intent of this Article 22 to prohibit Tenant 22.02 from using the Premises for the Permitted Use. Tenant may operate its business according to prudent industry practices so long as the use or presence of Hazardous Materials is strictly and properly monitored according to all then applicable Environmental Requirements; provided, however, in no event shall Tenant or anyone claiming by through or under Tenant perform work above the risk category Biosafety Level 2 as established by the Department of Health and Human Services ("DHHS") and as further described in the DHHS publication Biosafety in Microbiological and Biomedical Laboratories (5th Edition) (as it may be or may have been further revised, the "BMBL") or such nationally recognized new or replacement standards as Landlord may reasonable designate. Tenant shall comply with all applicable provisions of the standards of the BMBL to the extent applicable to Tenant's operations in the Premises. All Hazardous Materials at the Premises must be used solely in the operation of Tenant's business (including any repairs, maintenance, and cleaning that Tenant is required to perform under this Lease), and such use shall be consistent with similar first-class facilities engaged in the Permitted Use in the Seattle market. As a material inducement to Landlord to allow Tenant to use Hazardous Materials in connection with its business, Tenant agrees to deliver to Landlord prior to the Term Commencement Date a list identifying each type of Hazardous Materials to be brought upon, kept, used, stored, handled, treated, generated on, or released or disposed of from, the Premises and setting forth any and all governmental approvals or permits required in connection with the presence, use, storage, handling, treatment, generation, release or disposal of such Hazardous Materials on or from the Premises ("Hazardous Materials List"). Upon Landlord's request, or any time that Tenant is required to deliver a Hazardous Materials List to any federal, provincial, or municipal governmental authority (e.g., the fire department) (a "Governmental Authority") in connection with Tenant's use or occupancy of the Premises, Tenant shall deliver to Landlord a copy of such Hazardous Materials List. Tenant shall deliver to Landlord prior to the Term Commencement Date true and correct copies of the following documents (the "Haz Mat Documents") relating to the use, storage, handling, treatment, generation, release or disposal of Hazardous Materials at the Premises, or if unavailable at that time, concurrent with the receipt from or submission to a Governmental Authority: permits; approvals; reports and substantive correspondence with Governmental Authorities; storage and management plans, notice of violations of any Laws; and a Surrender Plan (to the extent surrender in accordance with Article 20 cannot be accomplished in three (3) months). Tenant is not required, however, to provide Landlord with any portion(s) of the

-34-

Haz Mat Documents containing information of a proprietary nature that, in and of themselves, do not contain a reference to any Hazardous Materials or hazardous activities.

22.03 <u>Tenant Representation and Warranty</u>. Tenant hereby represents and warrants to Landlord that (i) neither Tenant nor any of its legal predecessors has been required by any prior landlord, lender or Governmental Authority at any time to take remedial action in connection with Hazardous Materials contaminating a property, which contamination was permitted by Tenant or such predecessor or resulted from Tenant's or such predecessor's action or use of the property in question, and (ii) Tenant is not subject to any enforcement order issued by any Governmental Authority in connection with the use, storage, handling, treatment, generation, release or disposal of Hazardous Materials (including, without limitation, any order related to the failure to make a required reporting to any Governmental Authority).

22.04 Testing. Landlord shall have the right but not the obligation to conduct annual tests of the Premises in accordance with a scope of work coordinated with Tenant to determine whether any contamination of the Premises has occurred as a result of Tenant's use. Landlord shall pay the cost of such annual test of the Premises without reimbursement from Tenant as an Expense or otherwise; provided, however, that if Tenant conducts its own tests of the Premises using third party contractors and test procedures acceptable to Landlord, and which tests are certified to Landlord, Landlord shall accept such tests in lieu of the annual tests to be paid for by Tenant. In addition, at any time, and from time to time, prior to the expiration or earlier termination of the Term, Landlord shall have the right to conduct additional appropriate tests of the Premises to determine if contamination has occurred as a result of Tenant's use of the Premises; provided that Landlord in such case shall demonstrate a reasonable basis for performing such tests beyond the annual tests contemplated above. In connection with such testing, upon the request of Landlord, Tenant shall deliver to Landlord or its consultant such non-proprietary information concerning the use of Hazardous Materials in or about the Premises by Tenant or any Tenant Party. Landlord shall provide Tenant with a copy of all third party, non-confidential reports and tests of the Premises made by or on behalf of Landlord during the Term without representation or warranty and subject to a confidentiality agreement. Tenant shall, at its sole cost and expense, promptly remediate any environmental conditions identified by such testing in accordance with all Environmental Requirements. Landlord's receipt of or satisfaction with any environmental assessment in no way waives any rights that Landlord may have against Tenant.

22.05 <u>Tenant's Obligations</u>. Tenant's obligations under this <u>Article 22</u> shall survive the expiration or earlier termination of the Lease. During any period of time after the expiration or earlier termination of this Lease required by Tenant or Landlord to complete the removal from the Premises of any Hazardous Materials (including, without limitation, the release and termination of any licenses or permits restricting the use of the Premises and the completion of the approved Surrender Plan), Tenant shall continue to pay the full Rent in accordance with this Lease for any portion of the Premises not relet by Landlord in Landlord's sole discretion, which Rent shall be prorated daily.

22.06 <u>Definitions</u>. As used herein, the term "**Environmental Requirements**" means all applicable present and future statutes, regulations, ordinances, rules, codes, judgments, orders or other similar enactments of any Governmental Authority regulating or relating to health, safety, or environmental conditions on, under, or about the Property, or the environment, including without

-35-

limitation, the following: all requirements pertaining to reporting, licensing, permitting, investigation and/or remediation of emissions, discharges, Releases, or threatened Releases of Hazardous Materials, whether solid, liquid, or gaseous in nature, into the air, surface water, groundwater, or land, or relating to the manufacture, processing, distribution, use, treatment, storage, disposal, transport, or handling of Hazardous Materials; and (ii) all requirements pertaining to the health and safety of employees or the public. Environmental Laws include, but are not limited to, the Comprehensive Environmental Response, Compensation and Liability Act of 1980, 42 USC § 9601, et seq., the Hazardous Materials Transportation Authorization Act of 1994, 49 USC § 5101, et seq., the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, and Hazardous and Solid Waste Amendments of 1984, 42 USC§ 6901, et seq., the Federal Water Pollution Control Act, as amended by the Clean Water Act of 1977, 33 USC § 1251, et seq., the Clean Air Act of 1966, 42 USC § 7401, et seq., the Toxic Substances Control Act of 1976, 15 USC§ 2601, et seq., the Safe Drinking Water Act of 1974, 42 USC § 300f through 300j, the Occupational Safety and Health Act of 1970, as amended, 29 USC § 651 et seq., the Oil Pollution Act of 1990, 33 USC§ 2701 et seq., the Emergency Planning and Community Right-To-Know Act of 1986, 42 USC § 11001 et seq., the National Environmental Policy Act of 1969, 42 USC § 4321 et seq., the Federal Insecticide, Fungicide and Rodenticide Act of 1947, 7 USC \$136 et seq., and any other state or local law counterparts, as amended, as such Laws, are in effect as of the Term Commencement Date, or thereafter adopted, published or promulgated. As used herein, the term "Hazardous Materials" means and includes any substance, material, waste, pollutant, or contaminant listed or defined as hazardous or toxic, or regulated by reason of its impact or potential impact on humans, animals and/or the environment under any Environmental Requirements, asbestos and petroleum, including crude oil or any fraction thereof, natural gas liquids, liquefied natural gas, or synthetic gas usable for fuel (or mixtures of natural gas and such synthetic gas) and any "hazardous material". As defined in Environmental Requirements, Tenant is and shall be deemed to be the "operator" of Tenant's "facility" and the "owner" of all Hazardous Materials brought on the Property by Tenant or any Tenant Party, and the wastes, by-products, or residues generated, resulting, or produced therefrom. "Release" or "Released" or "Releases" shall mean any release, deposit, discharge, emission, leaking, spilling, seeping, migrating, injecting, pumping, pouring, emptying, escaping, dumping, disposing, or other movement of Hazardous Materials into the environment.

#### 23. Parking.

During the Term, Landlord shall lease to Tenant, or cause the operator (the "**Operator**") of subterranean parking serving the Building to lease to Tenant parking passes, for use by standard size automobiles and small utility vehicles in an amount equal to the number of parking passes set forth in <u>Section 1.17</u>, and Tenant shall pay monthly, as Additional Rent, the current amount set forth in <u>Section 1.17</u>, per parking pass (and subject to increase as provided therein). Tenant's leasing of such parking passes shall be subject to the following:

23.01 No deductions or allowances shall be made for days when Tenant or any of its employees does not utilize the parking facilities or for Tenant utilizing less than all of the passes. Tenant shall not have the right to lease or otherwise use more than the number of unreserved passes set forth above;

-36-

23.02 Except for particular passes and areas (if any) designated by Landlord or the Operator for reserved parking, all parking in the parking facility shall be on an unreserved, first-come, first-served basis;

23.03 Neither Landlord nor the Operator shall be responsible for money, jewelry, automobiles or other personal property lost in or stolen from the parking facility regardless of whether such loss or theft occurs when the parking facility or other areas therein are locked or otherwise secured. Without limiting the terms of the preceding sentence, Landlord shall not be liable for any loss, injury or damage to persons using the parking facility or automobiles or other property therein, it being agreed that, to the fullest extent permitted by law, the use of the passes shall be at the sole risk of Tenant and its employees;

23.04 Landlord or its Operator shall have the right from time to time to designate the location of the passes and to promulgate reasonable rules and regulations regarding the parking facility, the passes and the use thereof, including, but not limited to, rules and regulations controlling the flow of traffic to and from various parking areas, the angle and direction of parking and the like. Tenant shall comply with and cause its employees to comply with all such rules and regulations and all reasonable additions and amendments thereto;

23.05 Tenant shall not store or permit its employees to store any automobiles in the parking facility without the prior written consent of Landlord. Except for emergency repairs, Tenant and its employees shall not perform any work on any automobiles while located in the parking facility or on the Property. If it is necessary for Tenant or its employees to leave an automobile in the parking facility overnight, Tenant shall provide Landlord with prior notice thereof designating the license plate number and model of such automobile;

23.06 Landlord or the Operator shall have the right to temporarily close the parking facility or certain areas therein in order to perform necessary repairs, maintenance and improvements to the parking facility;

23.07 Landlord or the Operator shall have the right to temporarily close the parking facility or certain areas therein in order to perform necessary repairs, maintenance and improvements to the parking facility;

23.08 Landlord may elect to provide parking cards or keys to control access to the parking facility. In such event, Landlord shall provide Tenant with one card or key for each pass that Tenant is leasing hereunder, provided that Landlord shall have the right to require Tenant or its employees to place a deposit on such access cards or keys and to pay a fee for any lost or damages cards or keys.

# 24. Miscellaneous.

24.01 <u>Measurement of Floor Area</u>. Landlord and Tenant stipulate and agree that the Rentable Floor Area of the Premises originally leased to Tenant shall be conclusively deemed to be as specified in <u>Article 1</u> and that the Rentable Floor Area of the Building is as specified in <u>Article 1</u> as of the date hereof. Any change in the Rentable Floor Area of the Premises on account of expansion shall be conclusively deemed to be as specified in any applicable expansion provisions under <u>Exhibit F</u> (if any) or in any amendment hereafter executed by Landlord and

-37-

Tenant in connection with such expansion (if any). Any other change in the Rentable Floor Area of the Premises on account of casualty, condemnation, or the like shall be determined in accordance with the measurement standard that was originally used to determine the stipulated Rentable Floor Area for the space in question and Tenant's Base Rent shall be adjusted accordingly to reflect such change in Rentable Floor Area. Any change in the Rentable Floor Area of the Building on account of casualty, condemnation, or the like shall be determined from time to time by Landlord based on area computations supplied by Landlord's architect, which determinations shall be conclusive, in such event Tenant's Share shall be adjusted accordingly if such change results in a Rentable Floor Area reduction of greater than five percent (5%). References in this Lease to floor area measurements and square footage shall mean Rentable Floor Area unless the reference explicitly provides otherwise.

24.02 <u>No Recording of Lease; Confidentiality</u>. Neither party shall not record this Lease or any memorandum or notice without the other party's prior written consent. If this Lease is terminated before the Term expires, upon Landlord's written request the parties shall execute, deliver and record an instrument acknowledging such termination date of this Lease. Landlord and Tenant acknowledge that this Lease contains confidential information and that each party shall keep such information confidential and shall not disclose such confidential information to any person or entity other than (i) such party's legal, accounting and/or professional consultants as well as any lenders, prospective purchasers and other parties on a "need to know" basis, provided they are instructed to maintain such information in confidence or (ii) as may be necessary to comply with applicable laws and regulations (including, without limitation, SEC compliance and reporting obligations).

Governing Law, Etc. This Lease shall be interpreted and enforced in accordance with the Laws 24.03of the State of Washington and Landlord and Tenant hereby irrevocably consent to the jurisdiction and proper venue of such State. This Lease contains all of the agreements and understandings between Landlord and Tenant with respect to the Premises and supersedes all prior writings and dealings between them with respect thereto, including all lease proposals, letters of intent and other documents. Neither party is relying upon any warranty, statement or representation not contained in this Lease. If any term or provision of this Lease shall to any extent be void or unenforceable, the remainder of this Lease shall not be affected. This Lease may be amended only by a writing signed by all of the parties hereto. The titles are for convenience only and shall not be considered a part of the Lease. Where the phrases "persons acting under Tenant" or "persons claiming under Tenant" or similar phrases are used, such persons shall include subtenants, sub-subtenants, and licensees, and all employees, agents, independent contractors and invitees of Tenant or of such other parties. The enumeration of specific examples of or inclusions in a general provision shall not be construed as a limitation of the general provision. If Tenant is granted any extension option, expansion option, or other right or option, the exercise of such right or option (and notice thereof) must be unconditional to be effective, time always being of the essence to the exercise of such right or option; and if Tenant purports to condition the exercise of any option or to vary its terms in any manner, then the option granted shall be void and the purported exercise shall be ineffective. Unless otherwise stated herein, any consent or approval required hereunder may be given or withheld in the sole absolute discretion of the party whose consent or approval is required. Nothing herein shall be construed as creating the relationship between Landlord and Tenant of principal and agent, or of partners or joint venturers, or any relationship other than landlord and tenant. If there is more than one Tenant or if Tenant is comprised of more than one

-38-

party or entity, the obligations imposed upon Tenant shall be joint and several obligations of all such parties and entities, any requests or demands from any one person or entity comprising Tenant shall be deemed to have been made by all such persons or entities, and notices to any one person or entity comprising Tenant shall be deemed to have been given to all such persons and entities. Tenant's covenants contained in this Lease are independent and not dependent, and Tenant hereby waives the benefit of any statute or judicial law to the contrary. Tenant's covenant to pay Rent is independent of every other covenant in this Lease. Tenant's obligation to pay Rent shall not be discharged or otherwise affected by any law or regulation now or hereafter applicable to the Premises, or any other restriction on Tenant's use, or (except as expressly provided in this Lease) any casualty or taking, or any failure by Landlord to perform any covenant contained herein, or any other occurrence; and no termination or abatement remedy that is not expressly provided for in this Lease for any breach or failure by Landlord to perform any obligation under this Lease shall be implied or applicable as a matter of law.

24.04 Representations. Tenant represents and warrants to Landlord, and agrees, that each individual executing this Lease on behalf of Tenant is authorized to do so on behalf of Tenant and that the entity(ies) or individual(s) constituting Tenant, or which may own or control Tenant, or which may be owned or controlled by Tenant, or any of Tenant's affiliates, or any of their respective partners, members, shareholders or other equity owners, and their respective employees, officers, directors, representatives or agents are not and at no time will be (i) in violation of any Laws relating to terrorism or money laundering, or (ii) among the individuals or entities with whom U.S. persons or entities are restricted from doing business under regulations of the Office of Foreign Assets Control ("OFAC") of the Department of the Treasury (including those named on OFAC's Specially Designated Nationals and Blocked Persons List for the purpose of identifying suspected terrorists or on the most current list published by the U.S. Treasury Department Office of Foreign Assets Control at its official website, http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx or any replacement website or other replacement official publication of such list) or under any statute, executive order (including the September 24, 2001, Executive Order Blocking Property and Prohibiting Transactions with Persons Who Commit, Threaten to Commit, or Support Terrorism, known as Executive Order 13224), or other governmental action and Tenant will not Transfer this Lease to, contract with or otherwise engage in any dealings or transactions or be otherwise associated with such persons or entities.

24.05 <u>Waiver of Trial by Jury; No Other Waiver</u>. Landlord and Tenant hereby waive any right to trial by jury in any proceeding based upon a breach of this Lease. No failure by either party to declare a default immediately upon its occurrence, nor any delay by either party in taking action for a default, nor Landlord's acceptance of Rent with knowledge of a default by Tenant, shall constitute a waiver of the default, nor shall it constitute an estoppel. The delivery of keys to Landlord or to Landlord's property manager shall not operate as a termination of this Lease or a surrender of the Premises.

24.06 <u>Time Periods</u>. Whenever a period of time is prescribed for the taking of an action by Landlord or Tenant (other than the payment of the Security Deposit (if any) or Rent or the inability to perform due to shortage in, or inability to obtain, funds), the period of time for the performance of such action shall be extended by the number of days that the performance is actually delayed due to strikes, acts of God, pandemics, shortages of labor or materials, war,

-39-

terrorist acts, governmental action or inaction, civil disturbances and other causes beyond the reasonable control of the performing party ("Force Majeure").

24.07 <u>Transfer of the Property</u>. Landlord shall have the right from time to time to transfer and assign, in whole or in part, all of its rights and obligations under this Lease and in the Building and Property. From and after the date of transfer, Landlord shall be released from any further obligations hereunder and Tenant agrees to look solely to the successor in interest of Landlord for the performance of such obligations, to the extent that any successor pursuant to a voluntary, third party transfer (but not as part of an involuntary transfer resulting from a foreclosure or deed in lieu thereof) shall have assumed Landlord's obligations under this Lease from and after the date of the transfer.

24.08 <u>Submission</u>. The submission of this Lease to Tenant or a summary of some or all of its provisions for examination does not constitute a reservation of or option for the Premises or an offer to lease, and no legal obligations shall arise with respect to the Premises or other matters herein unless and until such time as this Lease is executed and delivered by Landlord and Tenant and approved by the holder of any mortgage on the Building having the right to approve this Lease.

24.09 <u>Broker</u>. Landlord and Tenant each represent that they have dealt directly with and only with the Broker (described in <u>Article 1</u>) as a broker, agent or finder in connection with this Lease. Excepting the Broker, Landlord and Tenant shall indemnify and hold the other (including Landlord and Tenant Related parties, respectively) harmless from all claims of any other brokers, agents or finders claiming to have represented Tenant in connection with this Lease. Any assistance rendered by any agent or employee of Landlord in connection with this Lease or any subsequent amendment or modification or any other document related hereto has been or will be made as an accommodation to Tenant solely in furtherance of consummating the transaction on behalf of Landlord, and not as agent for Tenant. Landlord shall pay a commission to the Broker pursuant to a separate written agreement between Landlord and the Broker.

24.10 <u>Survival</u>. The expiration of the Term, whether by lapse of time, termination or otherwise, shall not relieve either party of any obligations that accrued prior to or which may continue to accrue after the expiration or termination of this Lease.

24.11 Quiet Enjoyment. This Lease is subject to all easements, restrictions, agreements, and encumbrances of record to the extent in force and applicable. Landlord covenants that Tenant, on paying the Rent and performing the tenant obligations in this Lease, shall peacefully and quietly have, hold and enjoy the Premises, free from any claim by Landlord or persons claiming under Landlord, but subject to all of the terms and provisions hereof, provisions of Law, and rights of record to which this Lease is or may become subordinate. This covenant is in lieu of any other so-called quiet enjoyment covenant, either express or implied. This covenant shall be binding upon Landlord and its successors only during its or their respective periods of ownership of the Building.

24.12 <u>Reservations</u>. This Lease does not grant any rights to light or air over or about the Building. Landlord excepts and reserves exclusively to itself any and all rights not specifically granted to Tenant under this Lease. Landlord reserves the right to make changes to the Property, Building and Common Areas as Landlord deems appropriate. Wherever this Lease requires Landlord to provide a customary service or to act in a reasonable manner (whether in incurring an

expense, establishing a rule or regulation, providing an approval or consent, or performing any other act), this Lease shall be deemed also to provide that whether such service is customary or such conduct is reasonable shall be determined by reference to the practices of owners of buildings that (i) are comparable to the Building in size, age, class, quality and location, (ii) at Landlord's option, have been, or are being prepared to be, certified under the U.S. Green Building Council's Leadership in Energy and Environmental Design (LEED) rating system or a similar rating system, and (iii) leased on a so-called triple net basis.

REIT Provisions. Tenant and Landlord intend that all amounts payable by Tenant to Landlord 24.13shall qualify as "rents from real property," and will otherwise not constitute "unrelated business taxable income" or "impermissible tenant services income," all within the meaning of Section 856(d) of the Internal Revenue Code of 1986, as amended (the "Code") and the U.S. Department of Treasury Regulations promulgated thereunder (the "**Regulations**"). In the event that Landlord determines that there is any risk that any amount payable under this Lease may not qualify as "rents from real property" or will otherwise constitute impermissible tenant services income within the meaning of Section 856(d) of the Code and the Regulations, Tenant agrees to (a) cooperate with Landlord by entering into such amendment or amendments as Landlord deems necessary to qualify all amounts payable under this Lease as "rents from real property," and (b) permit (and, upon request, to acknowledge in writing) an assignment of the obligation to provide certain services under the Lease, and, upon request, to enter into direct agreements with the parties furnishing such services (which shall include, but not be limited to, a taxable REIT subsidiary of Landlord). Notwithstanding the foregoing, Tenant shall not be required to take any action pursuant to the preceding sentence (including acknowledging in writing an assignment of services pursuant thereto) if such action would result in (i) Tenant incurring more than de minimis additional liability under this Lease, or (ii) more than a de minimis negative change in the quality or level of Building operations or services rendered to Tenant under this Lease. For the avoidance of doubt: (A) if Tenant does not acknowledge in writing an assignment as described in clause (b) above (it being agreed that Tenant shall not unreasonably withhold, condition or delay such acknowledgment so long as the criteria in clauses (i) and (ii) hereinabove are satisfied), then Landlord shall not be released from liability under this Lease with respect to the services so assigned; and (B) nothing in this Section 24.13 shall limit or otherwise affect Landlord's ability to assign its entire interest in this Lease to any party as part of a conveyance of Landlord's ownership interest in the Building.

24.14 <u>Execution</u>. This Lease may be executed in one or more counterparts and, when executed by each party, shall constitute an agreement binding on all parties notwithstanding that all parties are not signatories to the original or the same counterpart provided that all parties are furnished a copy or copies thereof reflecting the signature of all parties. Either party, or both, may execute and deliver this Lease by using electronic signature technology (e.g., DocuSign or other comparable electronic signature software). Transmission of a facsimile or by email of a.pdf copy of the signed counterpart of the Lease shall be deemed the equivalent of the delivery of a "wet ink" original, and any party so delivering a facsimile or.pdf copy of the signed counterpart of the Lease by email transmission shall in all events deliver to the other party an original signature promptly upon request.

24.15 <u>Joint and Several</u>. If there is more than one Tenant, the obligations imposed upon Tenant under this Lease shall be joint and several.

-41-

24.16 Water Sensors. Tenant shall, at Tenant's sole cost and expense, be responsible for promptly installing web-enabled wireless water leak sensor devices designed to alert the Tenant on a twenty-four (24) hour seven (7) day per week basis if a water leak is occurring in the Premises (which water sensor device(s) located in the Premises shall be referred to herein as "Water Sensors"). The Water Sensors shall be installed in any areas in the Premises where water is plumbed and utilized by Tenant (such as sinks, pipes, faucets, water heaters, coffee machines, ice machines, water dispensers and water fountains) (the "Sensor Areas"). Tenant shall, at Tenant's sole cost and expense, pursuant to Article 9 of this Lease keep any Water Sensors located in the Premises (whether installed by Tenant or someone else) in good working order, repair and condition at all times during the Lease Term and comply with all of the other provisions of Article 9 of this Lease. Notwithstanding any provision to the contrary contained herein, Landlord has neither an obligation to monitor, repair or otherwise maintain the Water Sensors, nor an obligation to respond to any alerts it may receive from the Water Sensors or which may be generated from the Water Sensors. Upon the expiration of the Lease Term, or immediately following any earlier termination of this Lease, Landlord reserves the right to require Tenant, at Tenant's sole cost and expense, to remove all Water Sensors installed by Tenant, and repair any damage caused by such removal; provided, however, if the Landlord does not require the Tenant to remove the Water Sensors as contemplated by the foregoing, then Tenant shall leave the Water Sensors in place together with all necessary user information such that the same may be used by a future occupant of the Premises (e.g., the Water Sensors shall be unblocked and ready for use by a third-party). If Tenant is required to remove the Water Sensors pursuant to the foregoing and Tenant fails to complete such removal and/or fails to repair any damage caused by the removal of any Water Sensors, Landlord may do so and may charge the cost thereof to Tenant.

24.17 <u>Subdivision</u>. Landlord reserves the right to subdivide all or a portion of the Building or Property. Tenant agrees to execute and deliver, upon demand by Landlord and in the form requested by Landlord, any additional documents needed to conform this Lease to the circumstances resulting from a subdivision and any all maps in connection therewith. Notwithstanding anything to the contrary set forth in this Lease, the separate ownership of any buildings and/or Common Areas by an entity other than Landlord shall not affect the calculation of Tenant's Share of Expenses and Taxes.

24.18 <u>Light, Air and View</u>. No diminution of light, air or view by any structure, whether or not erected by Landlord, shall entitle Tenant to any reduction of Rent, result in any liability of Landlord to Tenant, or in any other way affect this Lease or Tenant's obligations hereunder.

24.19 <u>Building Name, Address and Signage</u>. Subject to Tenant's rights under <u>Section 8.04</u>, Landlord shall have the right at any time, to change the name and/or address of the Building and to install, affix and maintain any and all signs on the exterior and on the interior of the Building as Landlord may, in Landlord's sole discretion, desire.

24.20 <u>Transportation Management</u>. Tenant shall fully comply with all present or future government-mandated programs intended to manage parking, transportation or traffic, and in connection therewith, Tenant shall take responsible action for the transportation planning and management of all employees located at the Premises by working directly with Landlord, any governmental transportation management organization or any other transportation-related committees or entities. Such programs may include, without limitation: (i) restrictions on the

number of peak-hour vehicle trips generated by Tenant; (ii) increased vehicle occupancy; (iii) implementation of an in-house ridesharing program and an employee transportation coordinator; (iv) working with employees and any Building or area-wide ridesharing program manager; (v) instituting employer-sponsored incentives (financial or in-kind) to encourage employees to rideshare; and (vi) using flexible work shifts for employees.

# 24.21 <u>Sustainability</u>.

# 24.21.1 <u>Sustainable Building Operations</u>.

This Building is or may become in the future certified under the Green a. Building Initiative's Green Globes™ for Continual Improvement of Existing Buildings (Green Globes<sup>M</sup>-CIEB), the U.S. Green Building Council's Leadership in Energy and Environmental Design (LEED) rating system, or operated pursuant to Landlord's sustainable building practices. Landlord's sustainability practices address whole-building operations and maintenance issues including chemical use; indoor air quality; energy efficiency; water efficiency; recycling programs; exterior maintenance programs; and systems upgrades to meet green building energy, water, Indoor Air Quality, and lighting performance standards. Notwithstanding the foregoing, Tenant shall not be required to comply with any Green Building Initiatives or other rating systems as set forth above until the Building is certified as such, and Tenant shall only be required to comply with such Green Building Initiatives with respect to any upgrades, alterations or improvements made by Tenant after the Building is certified as set forth above. In no event shall Tenant be required to make changes, improvements and/or other repairs or replacements to the Premises in order to make the Premises compliant with the above stated initiatives and rating systems. All construction and maintenance methods and procedures, material purchase, and disposal of waste must be in compliance with minimum standards and specifications, in addition to all applicable laws.

b. Tenant shall use proven energy and carbon reduction measures, including energy efficient bulbs in task lighting; use of lighting controls; daylighting measures to avoid over-lighting interior spaces; closing shades on the south side of the Building to avoid over heating the space; turning off lights and equipment at the end of the work day; and purchasing, with respect to any new equipment that Tenant purchases for the Premises, ENERGY STAR® qualified equipment including but not limited to lighting, office equipment, commercial and residential quality kitchen equipment, vending and ice machines; purchasing products certified by the U.S. EPA's Water Sense® program. Tenant shall not be required to replace any existing equipment used by Tenant as of the date of this Lease which Tenant intends to install in the Premises in order to comply with this provisions of this <u>Section</u> <u>24.22(b)</u>.

24.21.2 Tenant covenants and agrees, at its sole cost and expense: (a) to comply with all present and future laws, orders and regulations of the Federal, State, county, municipal or other governing authorities, departments, commissions, agencies and boards regarding the collection, sorting, separation, and recycling of garbage, trash, rubbish and other refuse (collectively, "**trash**"); (b) to comply with Landlord's recycling policy as part of Landlord's sustainability practices where it may be more stringent than applicable law; (c) to sort and separate

|US-DOCS\129492181.2||

its trash and recycling into such categories as are provided by law or Landlord's sustainability practices; (d) that each separately sorted category of trash and recycling shall be placed in separate receptacles as directed by Landlord; (e) that Landlord reserves the right to refuse to collect or accept from Tenant any waste that is not separated and sorted as required by law, and to require Tenant to arrange for such collection of Tenant's sole cost and expense, utilizing a contractor satisfactory to Landlord; and (f) that Tenant shall pay all costs, expenses, fines, penalties or damages that may be imposed on Landlord or Tenant by reason of Tenant's failure to comply with the provisions of this <u>Section 24.21.2</u>.

Landlord and Tenant have executed this Lease in two or more counterparts as of the Effective Date of this Lease set forth above.

# LANDLORD:

BOREN LOFTS OWNER (DE) LLC, a Delaware limited liability Company

By: <u>/s/ Brian Barriero</u> Name: <u>Brian Barriero</u> Title: <u>Vice President, Operations</u>

By: <u>/s/ Kristen E. Binck</u> Name: <u>Kristen E. Binck</u> Title: <u>Vice President</u>

## TENANT:

ICOSAVAX, INC., a Delaware corporation

By: <u>/s/ Adam Simpson</u> Name: Adam Simpson Title: Chief Executive Officer

-44-

US-DOCS\129492181.2||

# CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

#### Exhibit 10.19

#### **NON-EXCLUSIVE LICENSE AGREEMENT**

#### BETWEEN

#### ICOSAVAX, INC.

AND

#### **UNIVERSITY OF WASHINGTON**

FOR

#### **COMPUTATIONALLY DESIGNED NANOPARTICLES AND FLU VACCINES BASED UPON SUCH DESIGNS**

#### UW COMOTION AGREEMENT REF. [\*\*\*]

Icosavax Inc. / University of Washington Non-Exclusive License Agreement UW CoMotion Ref. [\*\*\*]

|US-DOCS\130755718.2||

Page **1** of **33** 

#### TABLE OF CONTENTS

Background	1
1. Definitions	2
2. License and Option Grant	
3. Section Reserved	
4. Applications and Patents	10
5. Commercialization	11
6. Payments, Reimbursements, Reports, and Records	12
7. Infringement	13
8. Licensed Rights Validity	15
9. Termination	15
10. Release, Indemnification, and Insurance	17
11. Warranties	19
12. Damages	20
13. General Provisions	20
Exhibit A 27	
Exhibit B 29	
Icosavax Inc. / University of Washington	
Non-Exclusive License Agreement	
UW CoMotion Ref. [***]	
	Page <b>1</b> of <b>33</b>

|US-DOCS\130755718.2||

#### NON-EXCLUSIVE LICENSE AGREEMENT

This Non-Exclusive License Agreement (this "Agreement"), effective as of the date of last signature (the "Effective Date"), is made and entered into between the University of Washington, a public institution of higher education and an agency of the state of Washington, ("University"), and Icosavax, Inc., a for profit corporation under the laws of Delaware ("Company").

#### BACKGROUND

A. Certain innovations relating to computationally designed two-component icosahedral protein nanoparticles; two-component tetrahedral protein nanoparticles; and methods of multivalent antigen presentation on designed protein nanomaterials were made in the University laboratory of Dr. David Baker, a faculty member in the Department of Biochemistry and an employee of the Howard Hughes Medical Institute ("**HHMI**"), with members of the Baker lab as co-inventors, including Dr. Neil King, as well as by Dr. Neil King as "**Principal Investigator**" in his own lab while an employee and faculty member of University in the Department of Biochemistry. Such other inventions (without involvement of HHMI or Dr. Baker) relating to nanoparticle vaccine candidates for the influenza virus were made via a collaboration by Dr. King working at University and the Vaccine Research Center at the National Institute of Allergy and Infectious Diseases of the National Institutes of Health ("NIH").

B. HHMI assigned its rights in such innovations for which Dr. Baker is an inventor (identified as [\*\*\*] [\*\*\*] and [\*\*\*] in Exhibit A "License Schedule" to this Agreement) to University, subject to the HHMI License (as defined herein). University now solely owns certain intellectual property rights in innovations and co-owns certain intellectual property rights as listed in Exhibit A "License Schedule" to this Agreement. University and the U.S. Department of Health and Human Services, as represented by the National Institute of Allergy and Infectious Diseases of the NIH, (herein collectively referred to as "**NIH**") have executed an interinstitutional agreement, dated November 12, 2019, that authorizes University to assume sole responsibility for both the patent prosecution and licensing of co-owned patent applications [\*\*\*] and [\*\*\*]. Thus, University has the right to license to others certain rights to use and practice such intellectual property. University is willing to grant those rights so that such innovations may be developed for use in the public interest.

C. The innovations licensed under this Agreement were funded in part by the Bill and Melinda Gates Foundation ("**BMGF**") pursuant to those certain grant agreements between BMGF and University of Washington Foundation dated [\*\*\*] entitled [\*\*\*] and [\*\*\*] entitled [\*\*\*], as amended and pursuant to which University made certain global access commitments to BMGF.

D. University and Company entered into the Exclusive License Agreement [\*\*\*], such agreement effective as of June 29, 2018, as amended, and also entered into the License and Exclusive Option Agreement [\*\*\*], as amended, (collectively "**Other License Agreements**"), pursuant to which University granted to Company a license under certain licensed know-how and certain licensed patents in certain fields of use (such terms defined in the Other License Agreements).

Icosavax Inc. / University of Washington Non-Exclusive License Agreement UW CoMotion Ref. [\*\*\*]

Page **1** of **33** 

|US-DOCS\130755718.2||

E. Company desires to expand the scope of the licensed field and accordingly, Company desires that University grant it a non-exclusive license under such intellectual property rights for the Flu Field of Use (as defined herein), and University is willing to grant such a non-exclusive license for the Flu Field of Use, on the terms set forth in this Agreement.

## AGREEMENT

The Parties agree as follows:

## 1. **DEFINITIONS**

"Acquisition" means (a) the sale by Company of all, or substantially all of, its assets in transaction to a Third Party at arm's length, (b) the sale, transfer, or exchange by the shareholders, partners, or equity owners of Company of a majority interest in Company's outstanding stock in an arm's length transaction to a Third Party, or (c) the merger of Company with a Third Party at arm's length; provided, however, that in no event will (y) any bona fide equity financing for the primary purpose of raising capital for corporate purposes, or (z) any license, or any option to obtain a license, relating to all or substantially all of Company's rights (whether such rights pertain to this Agreement or to Company's rights more generally) that is granted to a Third Party (whether or not collaborative or partnership activities also will be conducted), be considered an Acquisition under this Agreement. For the avoidance of doubt, the Parties agree that any license or option to obtain a license, as stipulated in (z) above, shall be considered a Sublicense if such license or option to obtain a license rights under this Agreement.

"Combination Product" means a product sold in a form containing a Licensed Product and at least one other product, component, or ingredient which could be sold separate and apart from the Licensed Product and which is not required for the function of the Licensed Product.

"**Confidential Information**" means any information or materials of a Party not generally known to the public, including any information comprised of those materials and Company's business plans or reports. Confidential Information does not include any information that: (a) is, or becomes, part of the public domain through no fault of receiving Party; (b) is known to receiving Party prior to the disclosure by the disclosing Party, as evidenced by documentation; (c) is publicly released as authorized under this Agreement by University, its employees or agents; (d) is subsequently obtained on a non-confidential basis by receiving Party from a Third Party who is authorized to have and disclose such information; or (e) is independently developed by receiving Party without reliance on any portion of the Confidential Information received from the disclosing Party and without any breach of this Agreement as evidenced by documentation.

"Distributor" means a distributor, reseller or OEM to which a Licensed Party sells a Licensed Product for resale of Licensed Product by the Distributor, and where Distributor has no other rights with respect to the Licensed Rights other than to resell or otherwise distribute Licensed Products (including but not limited to integrated or bundled with other products or services), and for which resale or distribution such Licensed Party receives no further consideration (including but not limited to royalties and/or commissions) beyond the price for the initial sale of Licensed Product to the Distributor.

Icosavax Inc. / University of Washington Non-Exclusive License Agreement UW CoMotion Ref. [\*\*\*]

|US-DOCS\130755718.2||

Page 2 of 33

"Event of Force Majeure" means an unforeseeable act that prevents or delays a Party from performing one or more of its duties under this Agreement and that is outside of the reasonable control of the affected Party. An Event of Force Majeure includes acts of war or of nature, insurrection and riot, and labor strikes. An Event of Force Majeure does not include a Party's inability to obtain a Third Party's consent to any act or omission, unless the inability was caused by a separate Event of Force Majeure.

"Flu Field of Use" means prophylactic and/or therapeutic treatments for influenza.

"Improvements" means patentable inventions that (a) are owned by University after the Effective Date and not encumbered by third party rights that would prevent delivery to Company, (b) would require a license under the Licensed Rights to practice, (c) were developed in whole or in part in the laboratory of the Principal Investigator (including without limitation together with NIH), and identified to UW CoMotion as Improvements to patents subject to this license, and (d) do not include an HHMI employee as an inventor under the applicable patent law.

"Licensed Know-How" means University knowledge or intangible work that: (a) was developed in whole or in part in the laboratory of Principal Investigator (including without limitation together with NIH), (b) exists as of the Effective Date, (c) is relevant to utilizing any of the Licensed Patents, (d) is unpublished, (e) is not subject to patent or copyright protection, and (f) is not covered by Third Party rights that would prevent delivery to Company.

"Licensed Party" mean Company or any of its Sublicensees.

"Licensed Patents" means (a) the patents and patent applications listed in Exhibit A1.1 "Licensed Patents", all (b) divisions, continuations, and claims in continuations-in-part that are entitled to claim priority to, or that share a common priority claim with, and are directed to subject matter specifically described in, any item listed on Exhibit A1.1 "Licensed Patents"; (c) claims of extensions, renewals, substitutes, re-examinations and re-issues of any of the items in (a) or (b) that are directed to subject matter specifically described in any items listed on Exhibit A1.1; and (d) claims of foreign counterparts of any of the items in (a), (b), or (c) that are directed to subject matter specifically described in any items listed on Exhibit A1.1, wherever and whenever filed.

"Licensed Product" means any method, process, composition, product, service, or component part thereof that would, but for the granting of the rights set forth in this Agreement, infringe a Valid Claim contained in the Licensed Patents.

"Licensed Rights" means all rights granted to Company under Article 2 "License Grant" of this Agreement.

"Net Sales" means the gross amount received by a Licensed Party from Distributors, customers, end users and other Third Parties for sales, leases, and other dispositions of Licensed Products in the Flu Field of Use, less [\*\*\*]. On sales of Licensed Products by made in other than an arm's length transaction, the value of the Net Sales attributed to such transaction will be equal to the Net Sales that would have been received in an arm's length transaction, based on sales of like quantity and quality of Licensed Products sold on or about the time of the transaction. Net Sales does not include sale, lease, disposition or other transfer of Licensed Products among or between Company, Subsidiaries and Sublicensees for the purpose of subsequent resale to a Third Party, but does include subsequent resale to such Third Party. For

Icosavax Inc. / University of Washington Non-Exclusive License Agreement UW CoMotion Ref. [\*\*\*]

US-DOCS\130755718.2||

Page **3** of **33** 

avoidance of doubt Net Sales are calculated on sales by a Licensed Party to Distributor, and not on the subsequent sale by Distributor.

Net Sales of Combination Products will be calculated by multiplying actual Net Sales of such Combination Products by the fraction A/(A+B), where "A" is the Net Sales price of the Licensed Product if sold or performed separately, and "B" is the Net Sales price of the other product, component or ingredient in the Combination Product if sold separately. If, on a country-by-country basis, the other product, component or ingredient in the Combination Product is not sold separately in said country, Net Sales for the purpose of determining running royalties of the Combination Product shall be calculated by multiplying actual Net Sales of the Combination Product by the fraction A/C where "A" is the Net Sales price of the Licensed Product, if sold separately, and "C" is the Net Sales price of the Combination Product. If, on a country-by-country basis, neither the Licensed Product, nor the other product, component or ingredient in the Combination Product. If, on a country-by-country basis, neither the Licensed Product, nor the other product, component or ingredient in the Combination Product, is sold separately in said country, Net Sales for the purpose of determining running royalties of the Combination Product, is sold separately in said country. Net Sales for the purpose of determining running royalties of the Combination Product, is sold separately in said country. Net Sales for the purpose of determining running royalties of the Combination Product shall be determined in good faith by the Parties. A Combination Product may include a Licensed Product and any separate product, component or ingredient or service developed by or in-licensed by a Licensed Party from a Third Party provided it is a Combination Product as defined in this Agreement.

"New Patent Applications" means patents and patent applications which claim Improvements and that the Company elects under Section 2.4 "Improvements" to include in the Licensed Patents.

"Parties" means University and Company and "Party" means either University or Company.

"Patent Expenses" means all reasonable costs (including attorneys' and application fees) incurred by University and/or NIH in accordance with this Agreement to apply for, prosecute and maintain Licensed Patents, including but not limited to the costs of interferences, oppositions, inter partes review and re-examinations. Costs for interferences, oppositions, inter partes review and expensive patent-related proceedings will be incurred in consultation with Company, pursuant to the processes of Article 4 "Applications and Patents". Patent Expenses also include reimbursement for in-house costs to apply for, prosecute and maintain Licensed Patents; provided they are for activities that would otherwise have been performed by outside counsel at an equal or greater expense.

"**Performance Milestone**" means the milestone described in Section A2 "Performance Milestone" of attached Exhibit A "License Schedule".

"**Performance Milestone Date**" means the date by which the Performance Milestone is to be achieved as set forth in Section A2 "Performance Milestones" of attached Exhibit A "License Schedule", as such date may be extended pursuant to Section 5.1 "Performance Milestone" or as otherwise agreed upon by the Parties.

"Permitted Sublicense" means any arm's length agreement with a Third-Party commercialization partner, manufacturer, contract research organization or contract researcher/developer with whom a Licensed Party contracts for commercialization, manufacture, research or development of Licensed Products on Licensed Party's behalf, and where such Third Party has no other rights with respect to the Licensed Rights other than to manufacture, research and/or develop on behalf of Licensed Party.

Icosavax Inc. / University of Washington Non-Exclusive License Agreement UW CoMotion Ref. [\*\*\*]

|US-DOCS\130755718.2||

Page 4 of 33

"Permitted Sublicensee" means a Third Party holding a Permitted Sublicense.

"Sales Report" means a report in substantially the form set forth in Exhibit B "Royalty Report Form".

"Sublicense" means the grant by a Licensed Party to a Third Party of any license, option, first right to negotiate, or other right granted under the Licensed Rights, in whole or in part. The grant of the right to resell to a Distributor and the grant of a license or other right to use a Licensed Product to an end-user, where the end user has no other rights with respect to the Licensed Rights other than to be an end user of the Licensed Product, will not be a Sublicense and will be treated solely under Net Sales.

"Sublicensee" means a Third Party holding a Sublicense under the Licensed Rights.

"Sublicense Consideration" means all consideration, including but not limited to [\*\*\*]; but [\*\*\*]. For avoidance of doubt, consideration paid to Company by Sublicensees for the following shall not be deemed Sublicense Consideration: [\*\*\*]. For clarity, University acknowledges and agrees that, if Company should enter into an agreement with a Third Party that includes a Sublicense as part, but not all, of the subject matter of such agreement, then the total non-royalty consideration paid to Company under such Third-Party agreement will not be deemed Sublicense Consideration merely because a Sublicense is granted (since only a portion of the consideration received is for the grant of the Sublicense).

"Territory" means worldwide.

"Third Party" means an individual or entity other than University and Company.

"Valid Claim" means (a) a claim in an issued, unexpired United States or granted foreign patent included in the Licensed Patents that: (i) has not been held invalid, unpatentable, or unenforceable by a decision of a court or other governmental agency of competent jurisdiction and not subject to appeal (ii) has not been admitted to be invalid or unenforceable through reissue, inter partes review, disclaimer, or otherwise, (iii) has not been lost through an interference, reexamination, or reissue proceeding; or (b) a pending claim of a pending patent application included in the Licensed Patents.

Icosavax Inc. / University of Washington Non-Exclusive License Agreement UW CoMotion Ref. [\*\*\*]

|US-DOCS\130755718.2||

Page 5 of 33

Additional Definitions. The following terms have the meanings set forth in the corresponding sections of this Agreement, as described below.

Defined Term	Section
"Accountants"	6.5.1
"Act"	13.3.3
"Agreement"	Preamble
"BMGF"	Background
"Claim"	10.2
"Company"	Preamble
"Dispute Notice"	13.4
"Effective Date"	Preamble
"ННМІ"	Background
"HHMI Claims"	10.2
"HHMI Indemnitees"	10.2
"HHMI License"	2.8
"Indemnitee"	10.2
"Initial Notice Period"	9.8
"Other License Agreements"	Background
"Principal Investigator"	Background
"Sell-Off Period"	9.6
"Subsidiaries"	2.7
"University"	Preamble

2. LICENSE GRANT. Subject to the terms and conditions of this Agreement:

#### 2.1 Patent License.

2.1.1 <u>Non-exclusive license</u>. University hereby grants to Company a non-exclusive license under the Licensed Patents to make, have made on Company's behalf, use, offer to sell, sell, offer to lease or lease, import, or otherwise offer to dispose of Licensed Products in the Territory in the Flu Field of Use. Unless otherwise terminated under Article 9 "Termination", the term of this non-exclusive patent license will begin on the Effective Date and will continue until the date on which all Valid Claims expire or are held invalid or unenforceable by a court of competent jurisdiction from which no appeal can be taken. To the extent applicable, such non-exclusive license is subject to rights of HHMI described in Section 2.8 "HHMI Research Use Rights."

2.2 <u>Know-How License</u>. University hereby grants to Company a non-exclusive, worldwide license to use Licensed Know-How. Unless otherwise terminated under Article 9 "Termination", the term of this license will begin on the Effective Date and will continue until all rights under Licensed Patents are terminated.

2.3 <u>Sublicense Rights</u>. Company has the right, exercisable during the term of this Agreement but only after achieving the Performance Milestone and if Company is also sublicensing other intellectual property rights owned or otherwise controlled by Company, with such other intellectual property required for

Icosavax Inc. / University of Washington Non-Exclusive License Agreement UW CoMotion Ref. [\*\*\*]

|US-DOCS\130755718.2||

Page 6 of 33

commercialization of the Licensed Rights by Sublicensee, to Sublicense its Licensed Rights under this Agreement. Company may not grant Sublicensees the right to enforce Licensed Rights. Company will remain responsible for its obligations under this Agreement. Except for Permitted Sublicensees, Company will ensure that the Sublicense agreement: (a) contains terms and conditions that require Sublicensee to comply with the terms and conditions of this Agreement applicable to Sublicensees, including a release substantially similar to that provided by Company in Section 10.1 "Company's Release"; a warranty substantially similar to that provided by Company in Section 11.1 "Authority"; University disclaimers and exclusions of warranties under Sections 11.3 and 11.4 "No Known Infringement" and "Disclaimer"; and limitations of remedies and damages substantially similar to those provided by Company in Sections 12.1 "Remedy Limitation" and 12.2 "Damage Cap"; (b) specifically incorporates provisions of this Agreement regarding obligations pertaining to indemnification, use of names and insurance. Each Sublicense agreement must also contain obligations, terms and conditions in favor of HHMI or the HHMI Indemnitees, as applicable, that are identical to those undertaken by Company in favor of HHMI or the HHMI Indemnitees, as applicable, under this Agreement and intended for the protection of the HHMI Indemnitees, including, without limitation, the obligations, terms and conditions regarding indemnification, insurance and HHMI's third party beneficiary status. Company will provide University with a copy of the executed Sublicense, excluding any Permitted Sublicense agreement, within [\*\*\*] days after its execution. Company will not enter into any Sublicense agreement if the terms of such agreement are inconsistent in any material respect with the material terms of this Agreement. Any Sublicense made in violation of this Section 2.3 "Sublicense Rights" will be void and will constitute an event of default that requires remedy under Section 9.2 "Termination by University".

2.4 <u>Improvements</u>. For a period of [\*\*\*] months after the Effective Date, University will provide reasonable written notice to Company of any Improvements to the Licensed Patents. Company will have the option, exercisable within [\*\*\*] days of receipt of University's notice of such Improvement, to add such Improvements to the Licensed Patents. If Company exercises its option to add Improvements to the Licensed Patents, the Licensed Patents thereafter will include the applicable New Patent Applications, and the Parties will revise Exhibit A "License Schedule" to include such Improvements.

2.5 <u>Limitation of Rights</u>. No provision of this Agreement grants to Company, by implication, estoppel or otherwise, any rights other than the rights expressly granted it in this Agreement under the Licensed Rights, including any license rights under any other University-owned technology, copyright, know-how, patent applications, or patents, or any ownership rights in the Licensed Rights.

2.6 <u>The United States Government's Rights</u>. Inventions covered in the Licensed Patents arose, in whole or in part, from federally supported research and the federal government of the United States of America has certain rights in and to such inventions as those rights are described in Chapter 18, Title 35 of the United States Code and accompanying regulations, including Part 401, Chapter 37 of the Code of Federal Regulation. The Parties' rights and obligations under this Agreement to any government-funded inventions, including the grant of license set forth in Section 2.1 "Patent License", are subject to the applicable terms of the aforementioned United States laws. The U.S. Government is entitled, as a right, under these Chapters: (a) to a non-exclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on the behalf of the U.S. Government any of the federally funded inventions throughout the world and (b) to exercise march in rights on the federally funded inventions. Company further agrees that, to the extent required by Title 35 Section 204 of the United States Code, it will substantially manufacture in the United States of America all products embodying or produced through

Icosavax Inc. / University of Washington Non-Exclusive License Agreement UW CoMotion Ref. [\*\*\*]

|US-DOCS\130755718.2||

Page **7** of **33** 

the use of any such federally funded invention. If requested by the U.S. Government when necessary to fulfill health or safety needs, in each case to the extent required by Federal regulations, Company agrees to seek responsible sublicensees with respect to any government-funded inventions covered by this Section 2.6, on terms that are reasonable under the circumstances, for any territories that Company, its affiliates or licensees are not then exploiting such inventions or do not have plans to reasonably do so.

2.7 <u>Rights to Wholly Owned Subsidiaries of Company</u>. Company may extend rights granted to Company under this Agreement to wholly owned subsidiaries ("**Subsidiaries**") of Company, provided that (a) Company is responsible for all acts of such Subsidiaries as if they were acts of the Company, (b) such Subsidiary is bound in writing to perform all obligations to University and HHMI of this Agreement other than making payments pursuant to Article 6 "Payments, Reimbursements, Reports, and Records", as if such Subsidiary were Company, and (c) Company reports to University pursuant to Section 13.10 "Notices" that such Subsidiary will be exercising rights under this Agreement prior to such Subsidiary exercising any such rights under this Agreement. For avoidance of doubt, Company may perform any obligation of Subsidiary on Subsidiary's behalf.

2.8 <u>HHMI Research Use Rights</u>. Company acknowledges that it has been informed that the Licensed Patents were developed, at least in part, by employees of HHMI and that HHMI has a paid-up, non-exclusive, irrevocable worldwide license to exercise any intellectual property rights with respect to the Licensed Patents for research purposes, with the right to sublicense to non-profit and governmental entities, but with no other rights to assign or sublicense (the "**HHMI License**"). This license is explicitly made subject to the HHMI License.

## 3. SECTION RESERVED

## 4. APPLICATIONS AND PATENTS

4.1 <u>Pre-Agreement Patent Filings</u>. Company has reviewed the Licensed Patents and as of the Effective Date is not aware of any basis to challenge or dispute the inventorship, validity, or enforceability of any of the claims made in the Licensed Patents.

4.2 <u>Patent Prosecution Decisions</u>. University and Company will consult on the preparation, filing and prosecution of the Licensed Patents. Patent counsel will be directed to deliver to Company all written and electronic communications to and from all patent offices and foreign counsel, and provide summaries of oral communications with patent offices. Provided Company is in compliance with Section A3.6 "Patent Expense Payment" of Exhibit A "License Schedule", Company's directions regarding patent preparation, filing and prosecution will be reasonably considered, along with directions from any other licensees to the Licensed Patents, unless detrimental to University's intellectual property rights. University and Company will consult prior to deciding in which countries to pursue patent protection and provided Company is in compliance with Section A3.6 "Patent Expense Payment", patents will be filed in all countries Company designates. University will remain the client of record, and may at its own expense instruct patent counsel to take actions necessary to protect University's intellectual property rights, if in University's reasonable opinion, Company actions will result in a loss of rights; provided that for any such actions, if Company declines to reimburse University pursuant to Section A3.6 "Patent Expense Schedule", those applications and resultant patents will not be subject to this Agreement. In no event will

Icosavax Inc. / University of Washington Non-Exclusive License Agreement UW CoMotion Ref. [\*\*\*]

|US-DOCS\130755718.2||

Page 8 of 33

Company file a patent application where all of the inventors are under University or HHMI policy obligated to assign their rights in such patent application to University and/or HHMI.

## 5. COMMERCIALIZATION

5.1 <u>Performance Milestone</u>. Company will, directly or through its Subsidiaries or Sublicensees, use its commercially reasonable efforts, consistent with sound and reasonable business practices and judgment, to commercialize the Licensed Rights and to make and sell Licensed Products as soon as practicable and to maximize sales thereof. Company shall perform, or shall cause to happen or be performed, the Performance Milestone in accordance with the Performance Milestone Date.

5.2 <u>Renegotiation of Performance Milestone</u>. If Company determines that it will be unable to achieve the Performance Milestone by the Performance Milestone Date, Company will so notify University in advance of the Performance Milestone Date, and, provided Company demonstrates it is diligently pursuing commercialization of at least one Licensed Product, Company shall have the option of negotiating in good faith an appropriate new Performance Milestone and/or related Performance Milestone Date to accommodate for the reasonable length of the delay. In addition, University agrees that the Performance Milestone Date shall be extended by the number of days of delay caused by any event reasonably deemed out of the control of Company, but such extension limited in duration to no longer than [\*\*\*] year, including without limitation an Event of Force Majeure, the actions or inactions of any regulatory authority necessary for Company's plans to commercialize the Licensed Rights, or inability to enroll clinical trials due to lack of eligible participants. If the Parties are unable to agree on a renegotiated Performance Milestone [\*\*\*], then University may proceed with its termination rights under Section 9.2 "Termination by University", subject to both Company and University having the right to seek mediation under Section 13.4 "Escalation; Dispute Resolution".

5.3 <u>Commercialization Reports</u>. Throughout the term of this Agreement and during the Sell-Off Period, and within thirty (30) days of December 31<sup>st</sup> of each year, Company will deliver to University written reports of Company's and Sublicensees' efforts and plans to develop and commercialize the innovations covered by the Licensed Rights and to make and sell Licensed Products. Company will have no obligation to prepare commercialization reports in years where (a) Company delivers to University a written Sales Report with active sales, and (b) Company has fulfilled the Performance Milestone. In relation to the Performance Milestone each commercialization report will include sufficient information to demonstrate efforts towards achievement of the Performance Milestone and will set out timeframes and plans for achieving the Performance Milestone which has not yet been met.

5.4 <u>Company Information</u>. Throughout the term of this Agreement, Company shall provide the names of, and sufficient contact information to identify, any Permitted Sublicensees within [\*\*\*] days of University's written request.

## 6. PAYMENTS, REIMBURSEMENTS, REPORTS, AND RECORDS

6.1 <u>Payments</u>. Company will deliver to University the payments specified in Section A3 "Payments" of attached Exhibit A "License Schedule". Company will make such payments by check, wire transfer, or any other mutually agreed-upon and generally accepted method of payment. All checks to University will be

Icosavax Inc. / University of Washington Non-Exclusive License Agreement UW CoMotion Ref. [\*\*\*]

|US-DOCS\130755718.2||

made payable to "University of Washington" and will be mailed to the address specified in Section 13.10 "Notices" and will reference the University agreement number [\*\*\*].

All wire or electronic fund transfers must be confirmed via email referencing the above agreement number to: [\*\*\*]

Wire transfers:

Electronic Fund Transfer (ACH):

[\*\*\*]

6.2 <u>Currency and Checks</u>. All computations and payments made under this Agreement will be in United States dollars. The exchange rate for the currency into dollars as reported in *The Wall Street Journal* as the New York foreign exchange mid-range rate on the last business day of the month in which the transaction was entered into will be used for determining the dollar value of transactions conducted in non-United States dollar currencies.

6.3 <u>Late Payments</u>. University may charge Company a late fee for all amounts owed to University that are more than [\*\*\*] days overdue; provided that, for any portion of any such amount that is the subject of a bona fide, good faith dispute by Company (the mechanism of such dispute governed by Section 13.4 "Escalation; Dispute Resolution"), the late fee shall not apply to such disputed portion unless and until the dispute is decided in University's favor. The late fee will be computed as the [\*\*\*], as set forth by *The Wall Street Journal* (Western edition) on the date on which the payment is due, of the outstanding, unpaid balance. The payment of a late fee will not foreclose or limit University from exercising any other rights it may have as a consequence of the lateness of any payment.

6.4 <u>Sales Reports</u>. Within [\*\*\*] days after the last day of each calendar quarter commencing with the calendar quarter after the Company effects its first commercial sale of a Licensed Product and during the term of this Agreement and the Sell-Off Period, Company will deliver to University the Sales Report setting forth the number of and Net Sales amount (expressed in U.S. dollars) of all sales, leases, or other dispositions of Licensed Products, whether made by Company or a Sublicensee, during such calendar quarter. Included in each sales report will be the name of each Distributor, and the number and type of Licensed Product sold, leased, or otherwise provided to such Distributor. After the first commercial sale of a Licensed Product in the Territory, Company will deliver a written Sales Report to University even if Company is not required hereunder to pay to University a royalty payment during the calendar quarter. Company shall provide the names of Permitted Sublicensees within [\*\*\*] days at University's written request.

6.5 <u>Books and Records</u>. Throughout the term of this Agreement and for [\*\*\*] years after expiration or termination of this Agreement, Company, at its expense, will keep and maintain and shall cause each Sublicensee other than Permitted Sublicensees to keep and maintain complete and accurate records of all sales, leases, and other dispositions of Licensed Products and all other records related to this Agreement.

6.5.1 <u>Audit Rights</u>. Company will permit at the request of University (not to be made more than once in any given calendar year), one or more independent, certified accountants selected by University and reasonably acceptable to Company (which acceptance shall not be

Icosavax Inc. / University of Washington Non-Exclusive License Agreement UW CoMotion Ref. [\*\*\*]

|US-DOCS\130755718.2||

Page 10 of 33

unreasonably withheld or delayed) ("Accountants") to have access to Company's records and books of account pertaining to calculation of Net Sales and payment of any other amounts owed under this Agreement. Accountants' access will be during ordinary working hours to audit Company's records for any payment period ending prior to such request, the correctness of any Sales Report or payment made under this Agreement, or to obtain information as to the payments due for any period in the case of failure of Company to report or make payment under the terms of this Agreement or to verify Company's compliance with its payment obligations hereunder. Accountants will sign Company's standard non-disclosure agreement provided it is reasonable to the industry in which Company operates. Company shall cause each Sublicensee, other than Permitted Sublicensees, that manufactures, sells, leases, or otherwise disposes of Licensed Products on behalf of Company to grant University the rights to inspect and audit Sublicensee's records.

6.5.2 <u>Scope of Disclosure</u>. Accountants will not disclose to University any information relating to the business of Company except that which is necessary to inform University of: (a) the accuracy or inaccuracy of Company's Sales Reports and payments; (b) compliance or noncompliance by Company with the terms and conditions of this Agreement; or (c) the extent of any inaccuracy or noncompliance. A copy of the Accountants' report will be provided to Company.

6.5.3 <u>Accountant Copies</u>. If Accountants believe there is an inaccuracy in any of Company's payments or noncompliance by Company with any terms and conditions, Accountants will have the right to make and retain copies (including photocopies) of any pertinent portions of the records and books of account.

6.5.4 <u>Costs of Audit</u>. If Company's payments calculated for any calendar quarter are under-reported by more than [\*\*\*], then the costs of any audit and review initiated by University will be borne by Company; otherwise, University shall bear the costs of any audit initiated by University.

## 7. INFRINGEMENT

7.1 <u>Notice of Third Party's Infringement</u>. If a Party learns of substantial, credible evidence that a Third Party is infringing the Licensed Rights, that Party will promptly deliver written notice of the possible infringement to the other Party, describing in detail all relevant information to which that Party has access or control suggesting infringement of the Licensed Rights.

7.2 <u>University's Right to Enforce</u>. During the term of this Agreement, University in conjunction with its co-owner NIH has the right to respond to, defend, and prosecute in its own name, and at its own expense, actions or suits relating to the Licensed Rights. University will keep Company reasonably informed of any matters relating to the defense or prosecution of actions or suits relating to the Licensed Rights.

7.6 <u>No Obligation to Institute Action</u>. University is not obligated under this Agreement to institute or prosecute a suit against any alleged infringer of the Licensed Rights.

Icosavax Inc. / University of Washington Non-Exclusive License Agreement UW CoMotion Ref. [\*\*\*]

|US-DOCS\130755718.2||

Page **11** of **33** 

#### 8. LICENSED RIGHTS VALIDITY

8.1 <u>Notice and Investigation of Third-Party Challenges</u>. If any Third Party challenges the validity or enforceability of any of the Licensed Rights, the Party having such information will immediately notify the other Party.

8.2 <u>Third Party Actions</u>. In the event of a Third-Party legal action challenging the validity or enforceability of any Licensed Rights, University, in conjunction with its co-owner NIH, in its sole discretion will have the right to assume and control the sole defense of the claim at University's expense. University will keep Company reasonably informed of any matters relating to any Third-Party legal action challenging the validity or enforceability of the Licensed Rights, including any settlement discussions with respect thereto.

8.3 <u>Enforceability of Licensed Rights</u>. Notwithstanding challenge by any Third Party, any Licensed Right will be enforceable under this Agreement until such Licensed Right is determined to be invalid.

#### 9. TERMINATION

9.1 <u>End of Term</u>. This Agreement will expire, unless terminated earlier as provided in this Article 9 "Termination", without further action by the Parties, when all Licensed Rights have terminated pursuant to Article 2 "License Grant", and all obligations due to University based on the exercise of such Licensed Rights have been fulfilled.

9.2 <u>Termination by University</u>. If Company materially breaches or fails to perform one or more of its material duties under this Agreement, University may deliver to Company a written notice of default, which notice will (a) state that it is a notice of default, (b) state that University intends to terminate this Agreement if the default is not cured in [\*\*\*] days, and (c) identify the material duty or duties to which such default relates. Subject to Section 13.4 "Escalation; Dispute Resolution", University may terminate this Agreement by delivering to Company a written notice of termination if the default has not been cured within [\*\*\*] days of the delivery to Company of the notice of default; provided, however, if Company can reasonably demonstrate to University that it is proceeding diligently and in good faith to cure such default but cannot do so within such [\*\*\*] day period, University will extend such cure period for another [\*\*\*] day period, or such longer period approved by University. In addition, University may terminate this Agreement in part pursuant to Section 5.2 "Renegotiation of Performance Milestone".

9.3 <u>Events of Default</u>. University may terminate this Agreement by delivering to Company a written notice of termination at least [\*\*\*] days prior to the date of termination if Company (i) permanently ceases operations; (ii) voluntarily files or has filed against it a petition under applicable bankruptcy or insolvency laws that Company fails to have released within [\*\*\*] days after filing; (iii) proposes any dissolution, composition, or financial reorganization with creditors or if a receiver, trustee, custodian, or similar agent is appointed; (iv) makes a general assignment for the benefit of creditors; or (v) if Company challenges the validity of the Licensed Patents.

9.4 <u>Disputing Events of Default</u>. Notwithstanding the foregoing, if Company disputes that a default has occurred as contemplated above or that a default has not been cured, Company may use the dispute resolution mechanism outlined in Section 13.4 "Escalation; Dispute Resolution".

Icosavax Inc. / University of Washington Non-Exclusive License Agreement UW CoMotion Ref. [\*\*\*]

|US-DOCS\130755718.2||

Page 12 of 33

9.5 <u>Termination by Company</u>. Company may terminate this Agreement at any time by delivering to University a written notice of termination at least [\*\*\*] days prior to the effective date of termination. In addition, Company may propose to terminate certain of its Licensed Rights hereunder by delivering to University a written notice of termination accompanied by a proposed written amendment to this Agreement at least [\*\*\*] days prior to the effective date of termination of such Licensed Rights. For clarity, such amendment will become effective upon execution of such amendment by University and Company and shall not be unreasonably withheld or delayed.

9.6 Effect of Termination. Upon termination of this Agreement, the Licensed Rights granted (including any and all rights granted under the Licensed Rights to Sublicensees including Permitted Sublicensees) will terminate. However, no end-user rights shall terminate as a result of termination of this Agreement. Company's obligations that have accrued prior to the effective date of termination or expiration of this Agreement (including but not limited to the obligations under Article 6 "Payments, Reimbursements, Reports, and Records") will survive termination of this Agreement. Sublicenses will terminate unless converted into a direct license with University pursuant to Section 9.8 "Sublicenses After Termination". Notwithstanding any such termination of this Agreement, subject to being in compliance with Article 6 and Article 10 "Release, Indemnification, and Insurance", Company and any Sublicensees and Distributors may sell or otherwise dispose of existing inventory of Licensed Products for a period of [\*\*\*] days after the effective date of termination of this Agreement ("Sell-Off Period"), provided, however, that the terms of this Agreement shall apply to the Sell-Off Period as if this Agreement had not terminated. Company will provide notification if Company, or any Sublicensees or Distributors, will be exercising their rights to continue selling inventory pursuant to the Sell-Off Period.

9.7 <u>Final Report to University</u>. Within [\*\*\*] days after the end of the calendar quarter following either the expiration or termination of either this Agreement or the Sell-Off Period, whichever is later, Company will submit a final Sales Report to University. Any payment obligations accrued prior to such termination or expiration, including those incurred but not yet paid, will become due and payable at the same time as this final Sales Report is due to University.

9.8 <u>Sublicenses After Termination</u>. At any time within [\*\*\*] days following termination of this Agreement, Sublicensee may notify University pursuant to Section 13.10 "Notices" that it wishes to enter into a direct license with University in order to retain its rights to the Licensed Rights granted to it under its Sublicense (such [\*\*\*] day period following receipt of notice of termination, the "**Initial Notice Period**"). Following University's receipt of Sublicensee's notice, University shall offer Sublicensee a license agreement the terms of which will be substantially similar to the terms of this Agreement; *provided, however*, that the offered scope of the direct license, licensed territory, and duration of the license grant will be the same as (not merely substantially similar to) the scope of the license, licensed territory and duration of the license grant will be the same as (not merely substantially similar to) the scope of the license, licensed territory and duration of the license granted to scope of the direct license, licensed territory and duration of the license will be the same as the corresponding terms granted by Company to such Sublicensee). For the sake of clarity, the financial terms, including without limitation, the running royalty rate, will be identical to the corresponding financial terms set forth in this Agreement. Notwithstanding the foregoing, each Sublicensee's right to enter into such direct license will be conditioned upon:

Icosavax Inc. / University of Washington Non-Exclusive License Agreement UW CoMotion Ref. [\*\*\*]

|US-DOCS\130755718.2||

Page 13 of 33

9.8.1 <u>Written Notification to University</u>. Such Sublicensee informing University in writing, pursuant to Section 13.10 "Notices", that it wishes to enter into such direct license with University, within the Initial Notice Period;

9.8.2 <u>Sublicensee in Good Standing</u>. Such Sublicensee being in good standing with Company under its Sublicense such that Sublicensee is not in material breach of the Sublicense;

9.8.3 <u>Valid Sublicense</u>. Such Sublicense having been validly entered into by Company and Sublicensee pursuant to the terms of Section 2.3 "Sublicense Rights";

9.8.4 <u>Sublicensee Certification that Conditions are Satisfied</u>. Such Sublicensee using reasonable efforts to certify or otherwise demonstrate that the conditions set forth in Subsections 9.8.1 "Written Notification to University", 9.8.2 "Sublicensee In Good Standing", and 9.8.3 "Valid Sublicense" have been met within [\*\*\*] days of expiration of the Initial Notice Period (or within such longer period of time as University agrees is reasonable under the circumstances, based on the nature and extent of any documentation reasonably requested by University); and

9.8.5 <u>Time Limitations</u>. Unless mutually agreed by the Parties in writing, execution of a direct license with Sublicensee will be completed not later than [\*\*\*] days from the end of the Initial Notice Period.

Except as set forth in Subsection 9.8.5 "Time Limitations", University may, at its sole discretion, waive any of the requirements in Subsections 9.8.1 through 9.8.4. If all of the conditions set forth in this Section 9.8 "Sublicenses After Termination" are met, then Sublicensee will be granted such direct license by University. If any condition set forth in this Section 9.8 "Sublicenses After Termination" is not met, then after expiration of any time period granted to Sublicensee with respect to meeting such condition (for example and to the extent applicable, the Initial Notice Period and/or the periods described in Subsections 9.8.4 "Sublicensee Certification that Conditions are Satisfied" and 9.8.5 "Time Limitations"), Sublicensee will not practice Licensed Rights except as provided for in Section 9.6 "Effect of Termination" and University will be free to license or not license Licensed Rights to such Sublicensee according to University's sole discretion.

#### 10. RELEASE, INDEMNIFICATION, AND INSURANCE

10.1 <u>Company's Release</u>. Company hereby releases University and its regents, officers, employees, and agents forever from any and all suits, actions, claims, liabilities, demands, damages, losses, or expenses (including reasonable attorneys' and investigative expenses) relating to or arising out of (a) the manufacture, use, lease, sale, or other disposition of a Licensed Product; or (b) the assigning or sublicensing of Company's rights under this Agreement.

#### 10.2 Indemnification.

10.2.1 Company will indemnify, defend, and hold harmless University and its regents, officers, employees, and agents (each, an "**Indemnitee**") from all Third Party suits, actions, claims, liabilities, demands, damages, losses, or expenses (including reasonable attorneys' and investigative expenses), based on University's role in developing or licensing Licensed Rights and

Icosavax Inc. / University of Washington Non-Exclusive License Agreement UW CoMotion Ref. [\*\*\*]

|US-DOCS\130755718.2||

Page 14 of 33

relating to or arising out of Company's or Sublicensees' exercise of any rights with respect to Licensed Products, including, without limitation, personal injury, property damage, breach of contract and warranty and products-liability claims relating to a Licensed Product and claims brought by a Sublicensee (each, a "**Claim**"), provided that the Company will not have obligations to the extent resulting from the University's or gross negligence or willful misconduct. In the event of a Claim, the Indemnitee against whom a Claim is brought will: (a) give Company written notice of the Claim within a reasonable period of time after such Indemnitee receives notice thereof along with sufficient information for Company to identify the Claim; and (b) cooperate and provide such assistance (including, without limitation, testimony and access to documentation within the possession or control of such Indemnitee) as Company may reasonably request in connection with Company's defense, settlement and satisfaction of the Claim. Company will pay or reimburse all costs and expenses reasonably incurred by such Indemnitee to provide any such cooperation and assistance. Any settlement that would admit liability on the part of University or that would involve any relief other than the payment of monetary damages will be subject to the approval of University, such approval not to be unreasonably withheld.

10.2.2 HHMI, and its trustees, officers, employees, and agents (collectively, "**HHMI Indemnitees**"), will be indemnified, defended by counsel acceptable to HHMI, and held harmless by Company from and against any claim, liability, cost, expense, damage, deficiency, loss, or obligation, of any kind or nature (including, without limitation, reasonable attorneys' fees and other costs and expenses of defense) (collectively, "**HHMI Claims**"), based upon, arising out of, or otherwise relating to this Agreement or any Sublicense, including without limitation any cause of action relating to product liability. The previous sentence will not apply to any HHMI Claim that is determined with finality by a court of competent jurisdiction to result solely from the gross negligence or willful misconduct of an HHMI Indemnitee. Notwithstanding any other provision of this Agreement, Company's obligation to defend, indemnify and hold harmless the HHMI Indemnitees under this paragraph will not be subject to any limitation or exclusion of liability or damages or otherwise limited in any way.

#### 10.3 <u>Company's Insurance</u>.

10.3.1 <u>General Insurance Requirement</u>. Throughout the term of this Agreement, or during such period as the Parties will agree in writing, Company will maintain in full force and effect commercial general liability (CGL) insurance and product liability insurance, with single claim limits at an amount customary to Company's business for activities and/or products of a similar nature. Such insurance policy will include coverage for claims that may be asserted by University or HHMI against Company under Section 10.2 "Indemnification". The insurance coverage and limits required by this section are not a limitation on Company's liability or obligation to indemnify or defend University or HHMI or their respective Indemnitees. Such insurance policy will name the Board of Regents of the University of Washington and HHMI as an additional insured and will require the insurer to deliver written notice to University a t the address set forth in Section 13.10 "Notices", at least [\*\*\*] days prior to the termination of the policy. Company will deliver to University a copy of the certificate of insurance for such policy.

10.3.2 <u>Clinical Trial Liability Insurance</u>. Within [\*\*\*] days prior to the initiation of human clinical trials with respect to Licensed Product(s), Company will provide to University certificates

Icosavax Inc. / University of Washington Non-Exclusive License Agreement UW CoMotion Ref. [\*\*\*]

|US-DOCS\130755718.2||

Page **15** of **33** 

evidencing the existence and amount of clinical trials liability insurance. Company will issue irrevocable instructions to its insurance agent and to the issuing insurance company to notify University of any discontinuance or lapse of such insurance not less than [\*\*\*] days prior to the time that any such discontinuance is due to become effective. Company will provide University a copy of such instructions upon their transmittal to the insurance agent and issuing insurance company. Company will further provide University, at least annually, proof of continued coverage.

#### 11. WARRANTIES

11.1 <u>Authority</u>. Each Party represents and warrants to the other Party that it has full power and authority to execute, deliver, and perform this Agreement, and that no other proceedings by such Party are necessary to authorize the Party's execution or delivery of this Agreement.

11.2 <u>Documents</u>. University represents and warrants that: all University personnel, including employees, students, consultants and contractors, who University is aware as of Effective Date have contributed to the Licensed Patents as of Effective Date have either (a) been party to a for-hire relationship with University that affords University sufficient ownership of all Licensed Patents to provide this license of University's rights to Company, or (b) executed assignment documents in favor of University as prescribed either by University policies or by agreement with HHMI to provide University sufficient ownership of the Licensed Patents to provide this license of University represent to company.

11.3 <u>No Known Infringement</u>. As of the Effective Date, to the best of University's CoMotion office's knowledge, (a) no claim has been made or is threatened charging University with infringement of, or claiming that the Licensed Rights infringe any Third Party rights; and (b) no proceedings have been instituted, or are pending or threatened, which challenge the University's rights in respect to the Licensed Patents or other Licensed Rights.

11.4 <u>Disclaimer</u>. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN SECTIONS 11.1 "AUTHORITY", 11.2 "DOCUMENTS", AND 11.3 "NO KNOWN INFRINGEMENT" UNIVERSITY DISCLAIMS AND EXCLUDES ALL WARRANTIES, EXPRESS AND IMPLIED, CONCERNING EACH LICENSED RIGHT AND EACH LICENSED PRODUCT, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF NON-INFRINGEMENT AND THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. University innovation has been developed as part of research conducted at University. University innovation is experimental in nature and is made available "AS IS," without obligation by University to provide accompanying services or support except as specified in this Agreement. The entire risk as to the quality and performance of University innovation is with Company.

11.5 <u>Intellectual Property Disclaimers</u>. University expressly disclaims any warranties concerning and makes no representations: (a) that the Licensed Patent(s) will be approved or will issue; (b) concerning the validity or scope of any Licensed Right; or (c) that the practice of Licensed Rights, or the manufacture, use, sale, lease or other disposition of a Licensed Product will not infringe or violate a Third Party's patent, copyright, or other intellectual property right.

Icosavax Inc. / University of Washington
Non-Exclusive License Agreement
UW CoMotion Ref. [***]

|US-DOCS\130755718.2||

Page 16 of 33

#### 12. DAMAGES

12.1 <u>Remedy Limitation</u>. EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, (A) IN NO EVENT WILL UNIVERSITY BE LIABLE FOR PERSONAL INJURY OR PROPERTY DAMAGES ARISING IN CONNECTION WITH THE ACTIVITIES CONTEMPLATED IN THIS AGREEMENT AND (B) IN NO EVENT WILL EITHER PARTY BE LIABLE FOR LOST PROFITS, LOST BUSINESS OPPORTUNITY, INVENTORY LOSS, WORK STOPPAGE, LOST DATA OR ANY OTHER RELIANCE OR EXPECTANCY, INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, OF ANY KIND. FOR THE AVOIDANCE OF DOUBT, IN NO EVENT WILL COMPANY BE LIABLE FOR PERSONAL INJURY OR PROPERTY DAMAGES ARISING IN CONNECTION WITH THE ACTIVITIES OF ANY THIRD PARTY LICENSEE OF UNIVERSITY UNDER ANY AND ALL LICENSES GRANTED BY UNIVERSITY TO SUCH THIRD PARTY UNDER THE LICENSED PATENTS TO MAKE, HAVE MADE ON SUCH THIRD PARTY'S BEHALF, USE, OFFER TO SELL, SELL, OFFER TO LEASE OR LEASE, IMPORT, OR OTHERWISE OFFER TO DISPOSE OF LICENSED PRODUCTS IN THE TERRITORY IN THE FLU FIELD OF USE.

12.2 Damage Cap. IN NO EVENT WILL UNIVERSITY'S TOTAL LIABILITY FOR THE BREACH OR NONPERFORMANCE OF THIS AGREEMENT EXCEED [\*\*\*] OF PAYMENTS PAID TO UNIVERSITY UNDER ARTICLE 6 "PAYMENTS, REIMBURSEMENTS, REPORTS, AND RECORDS". THIS LIMITATION WILL APPLY TO CONTRACT, TORT, AND ANY OTHER CLAIM OF WHATEVER NATURE.

#### **13.** GENERAL PROVISIONS

13.1 <u>Amendment and Waiver</u>. This Agreement may be amended from time to time only by a written instrument signed by the Parties. No term or provision of this Agreement will be waived, and no breach excused, unless such waiver or consent is in writing and signed by the Party claimed to have waived or consented. No waiver of a breach will be deemed to be a waiver of a different or subsequent breach.

13.2 <u>Assignment</u>. The rights and licenses granted by University in this Agreement are personal to Company and Company will not assign its interest or delegate its duties under this Agreement without the written consent of University, which consent will not to be unreasonably withheld or delayed; any such assignment or delegation made without written consent of University will not release Company from its obligations under this Agreement. Notwithstanding the foregoing, Company, without the prior approval of University, may assign all, but no less than all, of its rights and delegate all, but no less than all, of its duties under this Agreement to a Third Party provided that: (a) the assignment is made to such Third Party as a part of and in connection with an Acquisition, (b) Company obtains from such Third Party written agreement to honor all obligations under this Agreement accrued by Company before Acquisition and all obligations under this Agreement to accrue by such Third Party assignee after Acquisition, and (c) Company provides written notice to University of the Acquisition, together with a substitution of parties document or copy of the assignment confirming compliance with (b) above, no later than [\*\*\*] days after the close of the Acquisition. Any assignment made in violation of this Section 13.2 is void and will constitute an act of breach that requires remedy under Section 9.2 "Termination by University". This Agreement will inure to the benefit of Company and University and their respective permitted assignees and trustees.

Icosavax Inc. / University of Washington Non-Exclusive License Agreement UW CoMotion Ref. [\*\*\*]

|US-DOCS\130755718.2||

Page 17 of 33

## 13.3 <u>Confidentiality</u>.

13.3.1 <u>Form of Transfer</u>. Confidential Information may be conveyed in tangible or intangible form. Disclosing Party must clearly mark its Confidential Information "confidential". If disclosing Party communicates Confidential Information in non-written form, it will reduce such communications to writing, clearly mark it "confidential", and provide a copy to receiving Party within [\*\*\*] days of original communication at the address in Section 13.10 "Notices". Any business information delivered by Company as required under this Agreement shall be deemed marked "confidential", whether or not such confidential marking appears.

13.3.2 <u>No Unauthorized Disclosure of Confidential Information</u>. Beginning on the Effective Date and continuing throughout the term of this Agreement and thereafter for a period of [\*\*\*] years, receiving Party will not disclose or otherwise make known or available to any Third Party any disclosing Party Confidential Information, without the express prior written consent of disclosing Party. Notwithstanding the foregoing, receiving Party will be permitted to disclose Confidential Information of disclosing Party to (i) actual or potential investors, lenders, consultants, advisors, collaborators, Sublicensees, or development partners, which disclosure will be made under conditions of confidentiality and limited use and (ii) its attorney or agent as reasonably required and (iii) to employees and trustees of HHMI to fulfill University's obligations to HHMI or who have a need to know. In no event will receiving Party incorporate or otherwise use disclosing Party. Receiving Party will restrict the use of disclosing Party's Confidential Information to uses exclusively in accordance with the terms of this Agreement. Receiving Party will use reasonable procedures to safeguard disclosing Party's Confidential Information in the case where Company is the receiving Party, Company's confidentiality obligations will also apply equally to Sublicensees.

13.3.3 Access to University Information. University is an agency of the state of Washington and is subject to the Washington Public Records Act, RCW 42.56 et seq., ("Act"), and no obligation assumed by University under this Agreement will be deemed to be inconsistent with University's obligations as defined under the Act and as interpreted by University in its sole discretion. If University receives a request for public records under the Act for documents containing Company Confidential Information, and if University concludes that the documents are not otherwise exempt from public disclosure, University will provide Company notice of the request before releasing such documents. Such notice will be provided in a timely manner to afford Company sufficient time to review such documents and/or seek a protective order, at Company's expense utilizing the procedures described in RCW 42.56.540. University will have no other obligation to protect Company Confidential Information from disclosure in response to a request for public records.

13.3.4 <u>Disclosure as Required by Law</u>. Either Party will have the right to disclose the other Party's Confidential Information as required by law or valid court order, provided that such Party will inform the Party who owns such Confidential Information prior to such disclosure, will cooperate with the owner Party's efforts to limit or avoid disclosure, and will limit the scope and recipient of disclosure to that required by such law or court order.

Icosavax Inc. / University of Washington Non-Exclusive License Agreement UW CoMotion Ref. [\*\*\*]

|US-DOCS\130755718.2||

Page 18 of 33

Escalation; Dispute Resolution. If (i) Company disputes that a default has occurred as contemplated in Section 13.4 9.2 "Termination by University", or that a default has not been cured, or (ii) Company wishes to dispute termination of this Agreement resulting from a failed renegotiation of a new Performance Milestone as contemplated under Section 5.2 "Renegotiation of Performance Milestone", or (iii) Company disputes in good faith any amounts that are owed to University under this Agreement, and a late fee for such disputed amount has been charged to Company under Section 6.3 "Late Payments", then Company may provide University with a written dispute notice ("Dispute Notice"). In the case of (i) and (ii) above such Dispute Notice must be received by University prior to expiration of the [\*\*\*]-day cure period referenced in Section 9.2 "Termination by University", stating the basis of Company's disagreement with respect to such default or cure. In the case of (iii) above such Dispute Notice must be received by University within [\*\*\*] days of being charged a late fee for such disputed amount. If Company disputes that a default has occurred as contemplated in Section 9.3 "Events of Default", then Company may provide University with a Dispute Notice within [\*\*\*] days of University sending the notice of termination referenced in Section 9.3 "Events of Default". Upon receipt of a Dispute Notice, University's right to terminate this Agreement or demand payment of late fees will be suspended and all rights under this Agreement will continue unaffected provided the dispute resolution process in this Section 13.4 "Escalation; Dispute Resolution" is being exercised. Any dispute will first be escalated to Company's Chief Executive Officer or to a representative from Company's Board of Directors, and to University's Vice President for Innovation Strategy, representatives of which will be instructed to work in good faith to attempt to reach a mutually acceptable resolution of the dispute that would avoid termination of this Agreement. If the representatives are unable to reach such resolution of the dispute within thirty (30) days of delivery of the Dispute Notice, an independent, neutral mediator acceptable to both Parties (acting reasonably) will be appointed. The Parties will submit their dispute to mediation according to such parameters as they may mutually agree in writing. The Parties agree to discuss their differences in good faith and to attempt in good faith, with facilitation by the mediator, to reach an amicable resolution of the dispute within [\*\*\*] days after the mediator's appointment. If the Parties are not able to agree on resolution of the dispute within such period, or within [\*\*\*] days of the Dispute Notice, whichever is earlier, including agreeing on a new Performance Milestone pursuant to Section 5.2 "Renegotiation of Performance Milestone" if that is the subject of the dispute, then the dispute resolution process of this Section 13.4 "Escalation; Dispute Resolution" will be complete and either Party may pursue any other action that is legally available to it. Notwithstanding the foregoing, no dispute affecting the rights or property of HHMI shall be subject to the dispute resolutions provisions set forth above.

13.5 <u>Consent and Approvals</u>. Except as otherwise expressly provided in this Agreement, all consents or approvals required under the terms of this Agreement must be in writing and will not be unreasonably withheld or delayed.

13.6 <u>Construction</u>. The headings preceding and labeling the sections of this Agreement are for the purpose of identification only and will not in any event be employed or used for the purpose of construction or interpretation of any portion of this Agreement. As used herein and where necessary, the singular includes the plural and vice versa, and masculine, feminine, and neuter expressions are interchangeable, and the word "including" shall mean "including, without limitation."

13.7 <u>Enforceability</u>. If a court of competent jurisdiction adjudges a provision of this Agreement unenforceable, invalid, or void, such determination will not impair the enforceability of any of the remaining provisions hereof and the provisions will remain in full force and effect.

Icosavax Inc. / University of Washington Non-Exclusive License Agreement UW CoMotion Ref. [\*\*\*]

|US-DOCS\130755718.2||

Page **19** of **33** 

13.8 <u>Third-Party Beneficiaries</u>. Except as identified in Section 13.22 "Express Third-Party Beneficiary", no provision of this Agreement, express or implied, confers upon any person other than the Parties to this Agreement, HHMI and Sublicensees (Sublicensees solely for purposes of enforcing Sections 9.8 "Sublicenses After Termination" and 13.22) any rights, remedies, obligations, or liabilities hereunder. No Sublicensee will have a right to enforce or seek damages under this Agreement other than as set forth in Section 13.22. The Parties agree that no amendment or modification to Section 9.8 or Section 13.22.2 shall apply to a Sublicensee without the prior written consent of that Sublicensee, if such amendment occurs after the date of execution of the applicable Sublicense.

13.9 <u>Language</u>. Unless otherwise expressly provided in this Agreement, all notices, reports, and other documents and instruments that a Party elects or is required by the terms of this Agreement to deliver to the other Party will be in English.

13.10 <u>Notices</u>. All notices, requests, and other communications that a Party is required or elects to deliver will be in writing and will be delivered personally, or by facsimile or electronic mail (provided such delivery is confirmed), or by a recognized overnight courier service or by United States mail, first-class, certified or registered, postage prepaid, return receipt requested, to the other Party at its address set forth below or to another address as a Party may designate by notice given under this Section 13.10:

If to University:	UW CoMotion [***]
If to Company:	lcosavax, lnc. [***]

13.11 <u>Proprietary Markings and Provision of Inert Sample Licensed Product</u>. To the extent commercially feasible, Company will mark all material forms of Licensed Products or packaging pertaining thereto made and sold by Company in the United States with patent marking conforming to 35 U.S.C. §287(a), as amended from time to time. All Licensed Product(s) shipped to or sold in other countries will be marked in such a manner as to provide notice to potential infringers pursuant to the patent law and practice of the country of manufacture or sale. In addition, Company agrees upon request to supply to UW and its co-owner NIH, inert samples of the Licensed Products being offered for sale, or their packaging, for educational and display purposes only.

#### 13.12 Use of Names.

13.12.1 No provision of this Agreement grants Company or Sublicensee any right or license to use the name or trademarks of University or the names or identities of any member of the faculty (provided that Dr. Baker is subject to Subsection 13.12.2), staff, or student body of University. Except as provided herein, Company will not use, and will not permit a Sublicensee to use, any such trademarks, names, or identities without University's and, as the case may be, such member's prior written approval. Notwithstanding the foregoing, Company and University may provide factual information regarding the existence of this Agreement.

13.12.2 Company acknowledges that under HHMI policy, Company may not use the name of HHMI or of any HHMI employee (including Dr. Baker) in a manner that reasonably could constitute an endorsement of a commercial product or service; but that use for other purposes, even if commercially

Icosavax Inc. / University of Washington Non-Exclusive License Agreement UW CoMotion Ref. [\*\*\*]

|US-DOCS\130755718.2||

Page **20** of **33** 

motivated, is permitted provided that (1) the use is limited to accurately reporting factual events or occurrences, and (2) any reference to the name of HHMI or any HHMI employees in press releases or similar materials intended for public release is approved by HHMI in advance.

13.13 <u>Publicity</u>. In accordance with Section 13.12, University will have the right to report in its customary publications and presentations that University and Company have entered into a license agreement for the technology covered by the Licensed Rights and University may use Company logos in such publications and presentations provided that University does not modify Company's logos and does not through such use imply any endorsement by Company of University. The Parties will cooperate with one another to review and respond to any press release or similar communication proposed by the other Party regarding the non-confidential subject matter of this Agreement. The specific content and timing of such press releases or similar communication is subject to mutual agreement by the Parties, which will not be unreasonably withheld.

13.14 <u>Relationship of Parties</u>. In entering into, and performing their duties under, this Agreement, the Parties are acting as independent contractors and independent employers. No provision of this Agreement will create or be construed as creating a partnership, joint venture, or agency relationship between the Parties. No Party will have the authority to act for or bind the other Party in any respect.

## 13.15 <u>Relationship with Principal Investigator(s)</u>.

13.15.1 Company acknowledges that Principal Investigator is employed by University and has certain pre-existing obligations to University, including obligations with respect to disclosure and ownership of intellectual property and obligations arising from sponsored research agreements between University and Third Parties. Accordingly, Company agrees that to the extent that any consulting agreement between Company and Principal Investigator is inconsistent with any of Principal Investigator's obligations to University, including the reporting of all inventions developed while employed by University (regardless of where arising) and including contractual obligations arising under any sponsored research agreements between University and Third Parties, then Principal Investigator's obligations to university and Third Parties, then Principal Investigator's obligations to university and to such extent any inconsistent provisions of such consulting agreement will be deemed inapplicable and unenforceable.

13.15.2 Company acknowledges that Dr. Baker, an inventor on certain of the Licensed Patents, is employed by HHMI, as well as a member of the faculty of University, and has certain pre-existing obligations to HHMI and University, including obligations with respect to disclosure and ownership of intellectual property and obligations arising from sponsored research agreements between University and Third Parties. Accordingly, Company agrees that to the extent that any consulting agreement between Company and Dr. Baker is inconsistent with any of his obligations to HHMI and/or University, including the reporting of all inventions developed while employed by HHMI (regardless of where arising) or contractual obligations to HHMI and/or University will prevail and to such extent any inconsistent provisions of such consulting agreement will be deemed inapplicable and unenforceable.

13.16 <u>Security Interest</u>. In no event will Company grant, or permit any person to assert or perfect, a security interest in the Licensed Rights; however, Company may grant or permit a security interest in the Company's rights under this Agreement.

Icosavax Inc. / University of Washington Non-Exclusive License Agreement UW CoMotion Ref. [\*\*\*]

|US-DOCS\130755718.2||

Page 21 of 33

13.17 <u>Survival</u>. The obligations specified in Article 6 "Payments, Reimbursements, Reports, and Records" will survive termination of this Agreement provided Reports will not be required for any period in which there are no Net Sales other than the final report due under Section 9.7 "Final Report to University". Article 1 "Definitions" and the obligations and rights set forth in Section 2.8 "HHMI Research Use Rights", Section 5.3 "Commercialization Reports" (as applicable to any Sell-Off Period), Article 9 "Termination", Article 10 "Release, Indemnification, and Insurance", Article 11 "Warranties", Article 12 "Damages", Section 13.3 "Confidentiality", Section 13.4 "Escalation; Dispute Resolution", but only with respect to any disputes arising before the effective date of termination or expiration), Section 13.17 "Survival", Section 13.19 "Applicable Law", Section 13.20 "Forum Selection", Section 13.21 "Entire Agreement", and Section 13.22 "Express Third-Party Beneficiary" will survive the termination or expiration of this Agreement.

13.18 <u>Collection Costs and Attorneys' Fees</u>. If a Party fails to perform an obligation or otherwise breaches one or more of the terms of this Agreement, the other Party may recover from the non-performing breaching Party all its costs (including actual attorneys' and investigative fees) to enforce the terms of this Agreement.

13.19 <u>Applicable Law</u>. The internal laws of the state of Washington will govern the validity, construction, and enforceability of this Agreement, without giving effect to the conflict of laws principles thereof.

13.20 <u>Forum Selection</u>. Any suit, claim, or other action to enforce the terms of this Agreement will be brought exclusively in the state and federal courts of King County, Washington. Company hereby submits to the jurisdiction of that court and waives any objections it may have to that court asserting jurisdiction over Company or its assets and property.

13.21 <u>Entire Agreement</u>. This Agreement (including all attachments, exhibits, and amendments) is the final and complete understanding between the Parties concerning licensing of the Licensed Rights in the Flu Field of Use and this Agreement supersedes any and all prior or contemporaneous negotiations, representations, and agreements, whether written or oral, concerning the Licensed Rights in the Flu Field of Use, the Parties acknowledging that the Other License Agreements memorialize the final and complete understanding of the Parties regarding its subject matter, including the distinct Fields of Use. Notwithstanding anything to the contrary in this Agreement, nothing in this Agreement will limit, alter or amend any of the rights granted by University to Company pursuant to the Other License Agreements. Confidential Information disclosed under this Agreement will be governed by the terms of this Agreement. This Agreement may not be modified in any manner, except by written agreement signed by an authorized representative of both Parties.

#### 13.22 Express Third-Party Beneficiary.

13.22.1 HHMI is not a party to this Agreement and has no liability to Company, any Sublicensee, or user of anything covered by this Agreement, but HHMI is an intended third-party beneficiary of this Agreement and certain of its provisions are for the benefit of HHMI and are enforceable by HHMI in its own name.

Icosavax Inc. / University of Washington Non-Exclusive License Agreement UW CoMotion Ref. [\*\*\*]

|US-DOCS\130755718.2||

13.22.2 Notwithstanding anything to the contrary in this Agreement, each Sublicensee is an intended third-party beneficiary of this Agreement, but solely for purposes of enforcing Section 9.8 "Sublicenses After Termination" in its own name.

13.23 <u>Counterparts</u>. This Agreement may be executed in counterparts, each of which (including signature pages) will be deemed an original, but all of which together will constitute one and the same instrument. A facsimile, scanned, or photocopied signature (and any signature duplicated in another similar manner) identical to the original will be considered an original signature.

**IN WITNESS WHEREOF**, the Parties have caused this Agreement to be duly executed by their respective authorized representatives.

University o	of Washington	lcosavax, Ir	າເ.	
Ву:	/s/ Dennis A. Hanson	Ву:	/s/ Adam K. Simpson	
Name:	Dennis A. Hanson Associate Director, Innovation	_ Name:	Adam K. Simpson	
Title:	Development	Title:	Chief Executive Officer	
Date:	9/16/2021	_ Date:	9/16/2021	
	Iniversity of Washington icense Agreement Ref. [***]			Page <b>23</b> of <b>33</b>
US-DOCS\13	0755718.2			

## Exhibit A License Schedule

#### A1. Licensed Rights:

	A1.1	Licensed	Patents:
--	------	----------	----------

[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]

A2. Performance Milestone (Section 5.1 "Performance Milestone"): Subject to any extension pursuant to Section 5.2 "Renegotiation of Performance Milestone" of the Agreement, and Company's right to renegotiation of Performance Milestone Date, Company will perform, or shall cause to happen or be performed, the following Performance Milestone:

Icosavax Inc. / University of Washington Non-Exclusive License Agreement UW CoMotion Ref. [\*\*\*]

|US-DOCS\130755718.2||

Page 24 of 33

	Performance Milestone and Performance Milestone Date in the Flu Field of Use
A2.1 Performance Milestone	Company shall have initiated (first person dosed) a first in human clinical trial for a Licensed Product in the Flu Field of Use by [***]

#### A3. Payments (Section 6.1):

A3.1 Upfront License Fee. Company shall pay to University within thirty (30) days of the Effective Date US [\*\*\*] as an upfront license fee. This upfront license fee shall be non-refundable and not creditable against future payment obligations.

A3.2 <u>Minimum Annual Fees</u>. Company will pay minimum annual fees for the term of this Agreement to be creditable against running royalty payments for the preceding calendar year on a non-cumulative basis and to be due in full and payable on January 31st of each year beginning on January 31st following the second anniversary of the Effective Date and continuing during the term of this Agreement according to the following schedule:

Calendar Year	Minimum Annual Fee
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

A3.2.1 If this Agreement is terminated prior to the payment of a minimum annual fee in any given year the amount due for that minimum annual fee payment will be prorated on the basis of the number of full quarters that have elapsed prior to termination since the last payment of a minimum annual fee.

A3.3 <u>Running Royalty Payments</u>. Company will pay to University within [\*\*\*] days after the last day of each calendar quarter during the term of this Agreement an amount equal to [\*\*\*] of Net Sales in the Flu Field of Use during such quarter as a running royalty payment.

A3.3.1 <u>Stacking or Third-Party Royalty</u>. If a Licensed Party is required to pay royalties to a Third Party based on such Licensed Party's manufacture, use, offer for sale, sale or import of Licensed Product, subject to one or more patents of such Third Party, then the royalty Company pays to University may be reduced by [\*\*\*] of the royalty actually paid to the Third Party; provided that [\*\*\*]

Icosavax Inc. / University of Washington Non-Exclusive License Agreement UW CoMotion Ref. [\*\*\*]

|US-DOCS\130755718.2||

Page 25 of 33

of Licensed Product, and provided that the royalty amount paid to the University shall not fall below [\*\*\*] of Net Sales.

A3.3.2 <u>Only One Royalty</u>. Company will not be required to pay duplicate royalties on Net Sales of any Licensed Product under this Agreement if Company is required to pay royalties on such Net Sales under the Other License Agreements, but shall still report and account for Net Sales of Licensed Product under this Agreement in a Sales Report as stipulated in section 6.4. By way of example, and without limitation, if Net Sales include sales of a product that includes a product that is subject to the Other License Agreements and a Licensed Product that is subject to this Agreement, then the royalty rate with respect to such combination product will be [\*\*\*] of Net Sales, subject to any modifications for Third Party royalties as set forth in Sections A3.2.1 (of this Agreement and the Other License Agreements).

A 3.4 <u>Sublicense Consideration</u>. Within [\*\*\*] days of the end of each calendar quarter during the term of this Agreement, Company will pay to University [\*\*\*] of any Sublicense Consideration received by Company during such calendar quarter unless reduced by achievement of defined milestones by Company or its Sublicensees prior to execution of the particular Sublicense in accordance with the schedule below. A further reduction of the percentage of Sublicense Consideration payable to University under this Agreement will be negotiated in good faith between the Parties where, in addition to the Sublicense of any rights granted to Company hereunder, Company or its Sublicensee also grants a Sublicensee a license or sublicense under a Third Party's intellectual property rights that are or would be infringed by Licensed Product(s) (treating pending patent applications as if they were issued patents), but only to the extent that the total aggregate consideration for such combined license is treated as Sublicense Consideration.

	Milestone Has Been Achieved at the Date of Execution of the Sublicense	Sublicense Consideration Percentage
A3.4.1	[***]	[***]
A3.4.2	[***]	[***]

A3.5 <u>Financial Milestones</u>. Company will pay to University the following non-cumulative, non-creditable, and non-refundable milestone achievement payments within [\*\*\*] days of achieving the corresponding milestone, whether achieved by Company or a Sublicensee:

Icosavax Inc. / University of Washington Non-Exclusive License Agreement UW CoMotion Ref. [\*\*\*]

|US-DOCS\130755718.2||

Page 26 of 33

	Milestone
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

A3.6 <u>Patent Expense Payment</u>. Company will pay, or reimburse University for paying, all Patent Expenses on a pro rata basis with any other licensees of Licensed Patents, incurred before, on or after the Effective Date, within [\*\*\*] days of its receipt of University's invoice for such Patent Expenses. University reserves the right to request advance payments for certain Patent Expenses, at University's discretion.

A3.6.1 Notwithstanding Sections 4.2 and 4.3 of this Agreement, if at any time Company is not fully reimbursing University for Patent Expenses, or fails to provide advance payment when requested, University shall make patent filing, prosecution, and maintenance decisions, including choosing in which countries to prosecute patents, in its sole discretion and Company shall have no rights to provide instruction or to take over patent prosecution. University shall reasonably consider input provided by Company, but have no obligation to act on such input.

Icosavax Inc. / University of Washington Non-Exclusive License Agreement UW CoMotion Ref. [\*\*\*]

|US-DOCS\130755718.2||

Page **27** of **33** 

#### Exhibit B

# [\*\*\*]

Icosavax, Inc. / University of Washington Non-Exclusive License Agreement UW CoMotion Ref. [\*\*\*]

|US-DOCS\130755718.2||

Page 28 of 33

#### **Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-258287) pertaining to the 2017 Equity Incentive Plan, 2021 Incentive Award Plan, and 2021 Employee Stock Purchase Plan of Icosavax, Inc. of our report dated March 30, 2022, with respect to the financial statements of Icosavax, Inc. included in this Annual Report (Form 10-K) of Icosavax, Inc for the year ended December 31, 2021.

/s/ Ernst & Young LLP

Seattle, Washington March 30, 2022

#### CERTIFICATION

I, Adam Simpson, certify that:

1. I have reviewed this Annual Report on Form 10-K of Icosavax, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) [omitted];

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

|US-DOCS\129967066.2||

Date: March 30, 2022

/s/ Adam Simpson

Adam Simpson President and Chief Executive Officer (principal executive officer)

|US-DOCS\129967066.2||

#### CERTIFICATION

I, Thomas Russo, certify that:

1. I have reviewed this Annual Report on Form 10-K of Icosavax, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) [omitted];

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

US-DOCS\129967148.2||

Exhibit 31.2

Date: March 30, 2022

/s/ Thomas Russo

Thomas Russo Chief Financial Officer (principal financial officer)

|US-DOCS\129967148.2||

# CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Icosavax, Inc. (the "Company") for the year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 30, 2022

By:

/s/ Adam Simpson

Adam Simpson President and Chief Executive Officer (principal executive officer)

US-DOCS\129967206.2||

# CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Icosavax, Inc. (the "Company") for the year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1)The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2)The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 30, 2022

By:

/s/ Thomas Russo

Thomas Russo

Chief Financial Officer (principal financial officer)

US-DOCS\129967237.2||

# 12 Months Ended

<b>Document and Entity</b> <b>Information - USD (\$)</b>	Dec. 31, 2021	Mar. 28, Jun. 2022 2021
Cover [Abstract]		

<u>Cover [Abstract]</u>	
Document Type	10-К
Amendment Flag	false
Document Annual Report	true
Document Transition Report	false
Document Period End Date	Dec. 31, 2021
Document Fiscal Year Focus	2021
Current Fiscal Year End Date	12-31
Document Fiscal Period Focus	FY
Entity Registrant Name	ICOSAVAX, INC.
Entity Central Index Key	0001786255
Entity File Number	001-40655
Entity Tax Identification	82 2(40540
Number	82-3640549
Entity Current Reporting	Yes
<u>Status</u>	105
Entity Well-known Seasoned	No
Issuer	
Entity Voluntary Filers	No
Entity Shell Company	false
Entity Filer Category	Non-accelerated Filer
Entity Interactive Data Current	Yes
Entity Small Business	true
Entity Emerging Growth	true
Company	little
Entity Ex Transition Period	true
Entity Address Address Line1	1616 Eastlake Avenue E.
Entity Address, Address Line	Suite 208
<u>Two</u>	
Entity Address City Or Town	Seattle
Entity Address, State and	WA
Province	
Entity Incorporation State	DE
Country Code	
Entity Address Postal Zip	98102
<u>Code</u>	727 0005
Local Phone Number	737-0085
City Area Code	
Security12b Title	Common Stock, \$0.0001 par value per
Trading Symbol	ICVX

share

Security Exchange Name	NASDAQ	
Entity Common Stock, Shares		39,724,980
<u>Outstanding</u>		39,724,980
Entity Public Float		\$ 0
Auditor Name	Ernst & Young LLP	
Auditor Location	Seattle, Washington	
Auditor Firm ID	42	
Documents Incorporated by	Certain sections of the registrant's definitive proxy statement for the	
<u>Reference</u>	2022 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.	

Condensed Consolidated Balance Sheets - USD (\$) \$ in Thousands	Dec. 31 2021	, Dec. 31, 2020
Current assets:		
Cash	\$	\$
	279,082	
Restricted cash	1,642	· ·
Prepaid expenses and other current assets	/	
Total current assets	286,553	· · · · · · · · · · · · · · · · · · ·
Property and equipment, net	,	10
<u>Total assets</u>	287,629	16,170
Current liabilities:		
Accounts payable	3,899	1,918
Accrued and other current liabilities	4,757	1,532
Deferred revenue	582	2,384
Total current liabilities	9,238	5,834
Long-term convertible promissory note	0	4,947
Embedded derivative liability	0	1,604
Other noncurrent liabilities	171	426
Total liabilities	9,409	12,811
Commitments and contingencies (Note 2)		
<u>Stockholders' equity (deficit):</u>		
Preferred stock, \$0.0001 par value; 50,000,000 and no shares authorized at December 31, 2021	- 0	0
and 2020, respectively; no shares issued and outstanding at either December 31, 2021 or 2020	0	0
Common stock, \$0.0001 par value; 500,000,000 and 78,000,000 shares authorized at		
December 31, 2021 and 2020, respectively; 39,429,103 and 3,596,936 shares issued as of	5	2
December 31, 2021 and 2020, respectively; 39,175,172279 and 2,639,026 shares outstanding	5	<i>L</i>
as of December 31, 2021 and December 31, 2020, respectively		
Additional paid-in capital	372,284	
Accumulated deficit	,	)(27,098)
Total stockholders' equity (deficit)		(26,703)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	287,629	16,170
<u>Total liabilities</u>	9,409	12,811
Convertible Preferred Stock [Member]		
Current liabilities:		
Convertible preferred stock, \$0.0001 par value; no shares authorized at December 31, 2021 and	<u>t</u>	
54,039,749 shares authorized at December 31, 2020; no shares issued and outstanding at	<b>\$</b> 0	\$
December 31, 2021 and 32,198,879 shares issued and outstanding at December 31, 2020; \$0	+ ~	30,062
and \$30,007 aggregate liquidation preference at December 31, 2021 and 2020, respectively		

# **Condensed Consolidated Balance Sheets (Unaudited)** (Parenthetical) - USD (\$) **\$** in Thousands

Dec. 31, 2021 Dec. 31, 2020

5 III 1 IIOUSAIIUS		
Convertible preferred stock, aggregate liquidation preference	<u>e</u>	\$ 30,007
Preferred stock, par value	\$ 0.0001	\$ 0.0001
Preferred stock, shares authorized	50,000,000	0
Preferred stock, shares issued	0	0
Preferred stock, shares outstanding	0	0
Common stock, par value	\$ 0.0001	\$ 0.0001
Common stock, shares authorized	500,000,000	78,000,000
Common stock, shares issued	39,429,103	3,596,936
Common Stock Shares Outstanding	39,175,279	2,639,026
Convertible Preferred Stock [Member]		
Convertible preferred stock, par value	\$ 0.0001	\$ 0.0001
Convertible preferred stock, shares authorized	0	54,039,749
Convertible preferred stock, shares issued	0	32,198,879
Convertible preferred stock, shares outstanding	0	32,198,879
Convertible preferred stock, aggregate liquidation preference	<u>e</u> \$0	\$ 30,007

Statements of Operations and Comprehensive Loss -	12 Months Ended			
USD (\$) \$ in Thousands	Dec. 31, 202	21 Dec. 31, 2020		
Income Statement [Abstract]				
Grant revenue	\$ 7,802	\$ 1,616		
<b>Operating expenses:</b>				
Research and development	38,776	17,667		
General and administrative	34,887	2,659		
Total operating expenses	73,663	20,326		
Loss from operations	(65,861)	(18,710)		
Other income (expense):				
Change in fair value of embedded derivative liability	(205)	187		
Loss on extinguishment of convertible promissory note	(754)	0		
Interest and other expense	(151)	(331)		
Total other expense	(1,110)	(144)		
Net loss and comprehensive loss	\$ (66,971)	\$ (18,854)		
Net loss per share, basic and diluted	\$ (3.73)	\$ (8.40)		
Weighted-average common shares outstanding, basic and dilute	ed 17,965,894	2,245,223		

Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit) - USD (\$) \$ in Thousands	Total	Common Stock [Member]	Additional Paid In Capital [Member]	Accumulated Deficit [Member]	Convertible Preferred Stock [Member]	Convertible Preferred Stock [Member] Series A-1 Convertible Preferred Stock [Member]	Preferred Stock [Member] Series B-1
<u>Convertible preferred stock,</u> Beginning Balance (in shares)					32,198,879		
at Dec. 31, 2019					52,190,079		
Convertible preferred stock,					\$ 20.062		
Beginning Balance at Dec. 31, 2019					\$ 30,062		
Beginning Balance (in shares) at Dec. 31, 2019		1,901,656					
Beginning Balance at Dec. 31, 2019	\$ (8,243)	\$ 1		\$ (8,244)			
Shares released from	(0,243)						
restriction upon vesting of		267,894					
early-exercised stock options (in shares)							
<u>Shares released from</u>							
restriction upon vesting of	137	\$ 1	\$ 136				
early-exercised stock options							
Vesting of shares of restricted common stock		469,476					
Stock-based compensation	257		257				
Net loss and comprehensive	(18,854)			(18,854)			
loss Convertible preferred stock,							
Ending Balance (in shares) at Dec. 31, 2020					32,198,879		
Convertible preferred stock,							
Ending Balance at Dec. 31, 2020					\$ 30,062		
Ending Balance (in shares) at Dec. 31, 2020		2,639,026					
Ending Balance at Dec. 31, 2020	(26,703)	\$ 2	393	(27,098)			
Shares released from restriction upon vesting of early-exercised stock options (in shares)		344,179					
Shares released from restriction upon vesting of early-exercised stock options	203		203				

<u>Vesting of shares of restricted</u> <u>common stock</u>		469,493					
Issuance of Series convertible						21.944.874	32,958,612
preferred stock, (in shares) Issuance of Series convertible						)- )	- ) )-
preferred stock						\$ 21,004	\$ 92,630
Issuance of Series B-2							
convertible preferred stock					2,805,850		
<u>from convertible note (in</u> <u>shares)</u>					, ,		
Issuance of Series B-2							
convertible preferred stock					\$ 7,917		
from convertible note							
Initial public offering, net of issuance costs, (in shares)		13,953,332	2				
Initial public offering, net of issuance costs	190,737	\$ 1	190,736				
Conversion of convertible		21 (24 00)			(00.000.01.5)		
preferred stock into common stock, (in shares)		21,634,898	3		(89,908,215)	)	
<u>Conversion of convertible</u>							
preferred stock into common	151,613	\$ 2	151,611		\$ (151,613)		
stock							
Issuance of common stock for Employee Stock Purchase		16,606					
<u>Plan, (in shares)</u>		10,000					
Issuance of common stock for	\$ 212		212				
Employee Stock Purchase Plan	\$ 212		212				
Exercise of common stock options, (in shares)	227,333	117,745					
Exercise of common stock	¢ 00		0.0				
options	\$ 98		98				
Stock-based compensation	29,031		29,031				
Net loss and comprehensive	(66,971)	1		(66,971)			
loss Convertible preferred stock,							
Ending Balance (in shares) at					0		
Dec. 31, 2021							
Convertible preferred stock,					<b></b>		
Ending Balance at Dec. 31, 2021					\$ 0		
Ending Balance (in shares) at		00 1 = = = = =	<b>`</b>				
Dec. 31, 2021		39,175,279	)				
Ending Balance at Dec. 31, 2021	\$ 278,220	\$ 5	\$ 372,284	\$ (94,069)			

Statements of Convertible	12 Months Ended		
Preferred Stock and Stockholders' Equity (Deficit) (Parenthetical) \$ in Millions	Dec. 31, 2021 USD (\$) \$ / shares		
IPO [Member]			
Payments of Stock Issuance Costs	\$ 18.6		
Series A-1 Convertible Preferred Stock [Member]			
Issuance of convertible preferred stock per share   \$ / share	<u>s</u> \$ 0.9615		
Convertible Preferred Stock Issuance Cost	\$ 0.1		
Series B-1 Convertible Preferred Stock [Member]			
Issuance of convertible preferred stock per share   \$ / share	<u>s</u> \$ 2.82172		
Convertible Preferred Stock Issuance Cost	\$ 0.3		

Condensed Statements of		12 Months Ended		
Cash Flows - USD (\$) \$ in Thousands	Dec. 31, 202	1 Dec. 31, 2020		
<b>Operating activities:</b>				
Net loss and comprehensive loss	\$ (66,971)	\$ (18,854)		
Adjustments to reconcile net loss to cash used in operating activities:				
Stock-based compensation	29,031	257		
Depreciation	82	1		
Non-cash interest expense	264	417		
Change in fair value of embedded derivative liability	(205)	187		
Loss on extinguishment of convertible promissory note	754	0		
Changes in operating assets and liabilities:				
Prepaids and other current assets	(5,167)	(453)		
Accounts payable	1,839	1,119		
Accrued and other current liabilities	3,225	1,108		
Deferred revenue	(1,802)	2,384		
Net cash used in operating activities	(38,540)	(14,208)		
Investing activities:				
Purchases of property and equipment	(1,006)	(11)		
Net cash used in investing activities	(1,006)	(11)		
Financing activities:				
Proceeds from issuance of convertible preferred stock, net of issuance costs	113,634	0		
Proceeds from initial public offering, net of offering costs	190,738	0		
Proceeds from issuance of convertible promissory notes, net of issuance cost	<u>s</u> 0	6,464		
Proceeds from exercise of stock options, including early exercise	400	174		
Net cash provided by financing activities	304,772	6,638		
Net increase (decrease) in cash and restricted cash	265,226	(7,581)		
Cash and restricted cash at beginning of period	15,498	23,079		
Cash and restricted cash at end of period	280,724	15,498		
Supplemental disclosure of noncash activities				
Conversion of preferred stock to common stock	151,613			
Purchases of property and equipment included in accounts payable	\$ 142			

# **Description of Business**

12 Months Ended Dec. 31, 2021

Organization ConsolidationAnd Presentation OfFinancial Statements[Abstract]Description of Business

# 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, and clinical efficacy of the Company's products under development. In addition, any of the technologies covering the Company's existing products under development 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 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 \$94.1 million, cash of \$279.1 million, and restricted cash of \$1.6 million at December 31, 2021.

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 vaccines candidates, scaling up manufacturing of vaccine candidates, and preparing for its ongoing and planned 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, 2021, 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.

Summary of Significant

Accounting Policies

# 12 Months Ended Dec. 31, 2021

## 2. Summary of Significant Accounting Policies

# Basis of Presentation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in t ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Cod 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 t balances of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the rep expenses during the reporting period. Estimates are used for, but not limited to, stock-based compensation, derivative liability, the tir development accruals, and income taxes. Although these estimates are based on the Company's knowledge of current events and a in the future, actual results may materially differ from these estimates and assumptions.

The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operation condition, including expenses, clinical trials and research and development costs, will depend on future developments that are highly a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat COVID-19, as well as the local, regional, national and international markets. The Company has considered potential impacts arising from the COVID-19 pander presently aware of any events or circumstances that would require the Company to update its estimates, judgments or revise the car or liabilities.

#### Concentration of Credit Risk

Financial instruments which potentially subject the Company to significant concentration of credit risk consist of cash and resist Company is exposed to credit risk from its deposits of cash in excess of amounts insured by the Federal Deposit Insurance Corporation maintains an Insured Cash Sweep account where balances are maintained in interest bearing demand accounts. The Company has losses on its deposits of cash since inception, and management believes that the Company is not exposed to significant credit risk depositors of the respective depository institutions in which those deposits are held.

#### **Comprehensive Loss**

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances f sources. The Company's comprehensive loss was the same as its reported net loss for all periods presented.

# Fair Value of Financial Instruments

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

The carrying amounts of all cash, restricted cash, prepaid expenses and other assets, accounts payable, and accrued and ot considered to be representative of their respective fair values due to their short maturities.

The carrying values of the derivative liability of \$1.6 million (level 3 fair value) and the convertible promissory note of \$4.9 mill accompanying balance sheet at December 31, 2020 approximate fair value because they collectively converted into 2,805,850 share convertible preferred stock in March 2021.

#### Cash

Cash represents funds in the Company's operating bank account. The Company has no cash equivalents.

# **Restricted Cash**

The Company's restricted cash includes payments received under the Grant Agreement (as defined in Note 4) with the Bill & Foundation ("BMGF") under which the Company was awarded a grant of up to \$10.0 million. The Company will utilize the Grant Agre incurs expenses for services performed under the agreement. Restricted cash also includes cash collateral supporting the standby le in "Leases" below.

#### Property and equipment, net

Property and equipment, net is stated at cost, net of accumulated depreciation and is depreciated using the straight-line meth useful lives of the assets (generally two to five years).

#### Impairment of Long-Lived Assets

The Company regularly reviews the carrying value and estimated lives of its long-lived assets, including property and equipm whether indicators of impairment may exist which warrant adjustments to carrying values or estimated useful lives. Should an impair impairment loss would be measured based on the excess over the carrying amount of the asset's fair value. The Company has not r impairment losses from inception through December 31, 2021.

#### 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 embedde therefore subject to bifurcation and derivative accounting. The initial recognition of the fair value of the derivative resulted in a discount once, with a corresponding derivative liability. The discount to the convertible note was amortized using the effective interest method discount is included in interest and other income (expense) in the statements of operations and comprehensive loss. The derivative features was recorded at estimated fair value and remeasured on a recurring basis. Any changes in fair value were reflected as chan derivative liability in the statements of operations and comprehensive loss at each reporting date while such instruments were outstated liability was settled in March 2021 upon conversion of the underlying convertible note into Series B convertible preferred stock, result extinguishment of convertible promissory note.

#### Leases

At the inception of a contractual arrangement, the Company determines whether the contract contains a lease by assessing v identified asset and whether the contract conveys the right to control the use of the identified asset in exchange for consideration ov both criteria are met, the Company records the associated lease liability and corresponding right-of-use asset upon commencement implicit rate or a discount rate based on a credit-adjusted secured borrowing rate commensurate with the term of the lease. The Cor 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 a finance lease if it meets one of the following five criteria: the lease has a purchase option that is reasonably certain of being exercise 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 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 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 operating lease. Operating lease assets represent a right to use an underlying asset for the lease term and operating lease liabilities to make lease payments arising from the lease. Operating lease liabilities with a term greater than one year and their corresponding recognized on the balance sheet at the commencement date of the lease based on the present value of lease payments over the ex Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received. As the not typically provide an implicit rate, the Company utilizes the appropriate incremental borrowing rate, determined as the rate of inter would have to pay to borrow on a collateralized basis over a similar term and in a similar economic environment. Lease cost is record basis over the lease term and variable lease payments are recognized as operating expenses in the period in which the obligation for incurred. Variable lease payments primarily include common area maintenance, utilities, real estate taxes, insurance, and other oper passed on from the lessor in proportion to the space leased by the Company. The Company has elected the practical expedient to n non-lease components.

In January 2020, and amended in March 2020, the Company entered into a lab license agreement for office and lab space in The lab license agreement is twelve months and provides for renewal options. The monthly base rent is approximately \$16,000. The is considered short-term and therefore, no right-of-use asset or lease liability has been recorded.

In December 2021, the Company entered into a lease agreement for corporate office and lab space in Seattle, Washington. The possession of certain leased space at various dates in January 2022 and March 2022. The lease agreement is five years and 3 more 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 and will incover the initial term. In addition, the Company is obligated to pay for common area maintenance and other costs. Under the terms of the Company is required to maintain a standby letter of credit of \$1.1 million at the execution of the lease agreement, reduced to \$0.7 million at the second anniversary of the lease. As of December 31, 2021, the Company had space and the lease term had not commenced; therefore, no right-of-use asset or lease liability has been recognized.

# Grant Revenue

The Company's revenue consists of revenue under its Grant Agreement with BMGF (see Note 4). The Company is reimburse support development activities, including the Company's clinical trial notification ("CTN") preparations for and planned first-in-human of COVID-19 RBD VLP vaccine in Australia. The Company's Grant Agreement does not provide a direct economic benefit to BMGF, entered into an agreement with BMGF to make a certain amount of any resulting vaccine available and accessible at affordable prici low- and middle-income countries. The Company assessed this cost reimbursement agreement to determine if the agreement shoul an exchange transaction or a contribution. Such an agreement is accounted for as a contribution if the resource provider does not re value in return for the assets transferred. Contributions are recognized as grant revenue when all donor-imposed conditions have be ultimately determines if milestones under the agreement are met and if funding should continue, there may be a difference in timing and development expenses are incurred and when grant revenue is recognized.

#### Accrued Research and Development Expense

The Company is required to estimate its obligation for expenses incurred under contracts with vendors, consultants, and cont organizations, in connection with conducting research and development activities. The financial terms of these contracts are subject vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are procontracts. The Company reflects research and development expenses in its financial statements by recognizing those expenses in the services and efforts are expended. The Company accounts for these expenses according to the progress of the preclinical study or or measured by the timing of various aspects of the study, trial or related activities. The Company determines accrual estimates through underlying contracts along with preparation of financial models taking into account discussions with research and other key personneservice providers as to the progress of studies or trials, or other services being conducted. To date, the Company has had no materiits estimates of such expenses and the amounts actually incurred. During the course of a study or trial, the Company adjusts its expri actual results differ from its estimate. Nonrefundable advance payments for goods and services, including fees for process developm and distribution of clinical supplies that will be used in future research and development activities, are deferred and recognized as exthe 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 candidates, including salaries and benefits, stock-based compensation, facilities and depreciation, contracted research, consulting a expenses incurred to sustain the Company's research and development programs.

#### Interest Income

Interest income consists of interest income earned on interest bearing demand accounts.

# 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 unvested stock options are restricted and continue to vest in accordance with the original vesting schedule. The Company has the original purchase price upon any voluntary or involuntary termination. The shares purchased by the employe pursuant to the early exercise of stock options are not deemed, for accounting purposes, to be outstanding until those shares vest. The exchange for exercise and unvested shares related to stock options granted is recorded as a liability for the early exercise of stock accompanying balance sheets and will be reclassified as common stock and additional paid-in capital as the shares vest. Unvested early exercise provisions subject to repurchase by the Company totaled 253,824 and 488,226 shares as of December 31, 2021 and of December 31, 2021 and 2020, the Company had \$0.2 million and \$0.2 million respectively, of amounts related to shares issued w classified as other noncurrent liabilities in the accompanying balance sheets.

#### Stock-Based Compensation

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

The Black-Scholes option pricing model uses inputs which are assumptions that generally require judgment. These assumptions **Fair Value of Common Stock**. Prior to the Company's IPO, the grant date fair market value of the shares of common store options was historically determined by the Company's board of directors. Because there was no public market for the Company board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the fair market value, which included contemporaneous valuations performed by an independent third-party, the Company's result financial position, including its levels of available capital resources, its stage of development and material risks related to the progress of the Company's research and development activities, the Company's business conditions and projections, the lack Company's common stock and preferred stock as a private company, the prices at which the Company sold shares of its com to outside investors in arms-length transactions, the rights, preferences and privileges of the Company's redeemable convert relative to those of its common stock, the analysis of initial public offerings and the market performance of similar companies biopharmaceutical industry, the likelihood of achieving a liquidity event for the Company's securityholders, such as an initial public offerings industry, and external market conditions affecting the hiring of key personnel and the experience of management, trends a Company's IPO, the grant date fair value of the Company's IPO, the grant date fair value of the Company's IPO.

•Expected Term. The expected term represents the period that the options granted are expected to be outstanding. The expected Term and the original contractul Company has concluded that its stock option exercise history does not provide a reasonable basis upon which to estimate expected Volatility. Given the Company's limited historical stock price volatility data, the Company derived the expected average historical volatilities over a period approximately equal to the expected term of company has limited trading history for Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own 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 corresponding with the expected term of the options.

• Expected Dividend Yield. The Company never paid dividends on its common stock and do not anticipate paying any div 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 common stock a

# **Commitments and Contingencies**

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

In the event the Company becomes subject to claims or suits arising in the ordinary course of business, the Company would 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, 2021 or 2020.

# Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted 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 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 t such a determination, management considers all available positive and negative evidence, including future reversals of existing taxa differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines the be able to realize its deferred tax assets in the future in excess of their recorded amount, management would make an adjustment to valuation allowance, which would reduce the provision for income taxes. As of December 31, 2021 and 2020, the Company maintained valuation allowances against its deferred tax assets as the Co not met the "more likely than not" to be realized threshold. Changes in the valuation allowance when they are recognized in the prov 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 wheth 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 mee more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50 percent likely-than-not recognition threshold, management recognizes interest and penalties related to unrecognized tax benefit expense. Any accrued interest and penalties are included within the related tax liability. As of December 31, 2021, the Company had penalties.

# Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted-average recommon stock outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the weighted average recommon stock and common stock equivalents outstanding for the period. Common stock equivalents are only included when their er-Company's potentially dilutive securities include outstanding stock options under the Company's equity incentive plan and have bee 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 r 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

		Year Er Decemb
	2021	
Numerator:		
Net loss	\$	(66,971)
Denominator:		
Weighted-average common shares outstanding, basic and diluted	18,	587,782
Less: Weighted-average unvested common stock	()	621,888)
Weighted-average shares used to compute net loss per share, basic and diluted	17,9	965,894
Net loss per share, basic and diluted	\$	(3.73)

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

	Year E Decemb
	2021
Series A convertible preferred stock	_
Common stock options	6,591,727
ESPP shares	16,606
Unvested common stock	253,824
Total	6,862,157

# Segments

The Company has determined that it operates and manages one operating segment, which is the business of researching ar against infectious diseases. The Company's chief operating decision maker, its chief executive officer, reviews financial information of 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 guidance simplifies the accounting for income taxes by removing several exceptions in the current standard and adding guidance to 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 ra interim period that includes the enactment date. The new standard is effective for fiscal years beginning after December 15, 2021, and fiscal years beginning after December 15, 2022 for all non-public entities, with early adoption permitted, and is effective for fiscal years December 15, 2020, including interim periods within those annual periods for public entities. Early adoption is permitted. The Compa 2019-12 on January 1, 2021 and the standard did not have a material impact on its financial statements and related disclosures.

# Fair Value Disclosures [Abstract] Fair Value Disclosures

# 12 Months Ended Dec. 31, 2021

### 3. Fair Value Measurements

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

Level 1—Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted a Level 2—Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or input 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 unobs by little or no market activity).

No transfers between levels have occurred during the periods presented.

The following table summarizes financial liabilities that the Company measured at fair value on a recurring basis, classified in fair value hierarchy (in thousands):

		Fair Val	ue Meas	surements at
Т	otal	(Level	1)	(Level 2)
\$	(1,604)	\$		\$
	T <u>\$</u>	<b>Total</b> \$ (1,604)	Total (Level	

There were no assets or liabilities measured at fair value on a recurring basis as of December 31, 2021.

As further described in Note 7, the Company issued a convertible promissory note in August 2020. The convertible promissor certain features that met the definition of a derivative and were required to be bifurcated. The Company has accounted for these as comprising all the features requiring bifurcation. The fair value of the derivative liability was estimated using a scenario-based analys probability-weighted present value of the convertible promissory note payoff at maturity with and without the bifurcated features. The possible outcomes available to the noteholders, including various financing dissolution scenarios. In addition, the probabilities applie 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

	March 19, 2021	December 31, 2020
Probability of financing	100%	909
Probability of dissolution	—	109
Time to liquidity (years)	—	0.50 - 1.00
Discount rate	7.6%	8.39

The Company adjusted the carrying value of the derivative liability within the convertible promissory note to the estimated fair date, with any related increases or decreases in the fair value recorded as change in fair value of derivative liability in the statements comprehensive loss.

For the year ended December 31, 2021, the Company recognized \$0.2 million of other income in the statements of operation loss related to increases in the fair value of the embedded derivative liability.

For the year ended December 31, 2020, the Company recognized \$0.2 million of other income in the statements of operation loss related to decreases 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 promi accrued interest) and derivative liability converted into 2,805,850 shares of Series B-2 convertible preferred stock. As a result of the Company recorded a loss on extinguishment of convertible promissory note of \$0.8 million in other expense in the statements of ope comprehensive loss for the year ended December 31, 2021, which included the write off of unamortized debt issuance costs.

The following table provides a reconciliation of the fair value of the derivative liability using Level 3 significant unobservable in

Fair value at December 31, 2019	\$
Fair value of derivative liability at issuance of convertible promissory note	
Change in fair value of derivative liability (Note 7)	
Fair value at December 31, 2020	
Change in fair value of embedded derivative liability	
Reclassification of derivative liability into convertible preferred stock resulting from conversion of convertible promissory note	
Fair value at December 31, 2021	\$

Copyright © 2022 www.secdatabase.com. All Rights Reserved. Please Consider the Environment Before Printing This Document

# **Grant Agreement [Abstract]**

Grant Agreement

# 4. Grant Agreement

# **Bill & Melinda Gates Foundation Grant Agreement**

In support of the Company's development of a 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, including the Company's regulatory filing preparations and planned Phase 1 clinical trial. Unless terminated earlier by BMGF, the Grant Agreement will continue in effect until March 31, 2022. The Company concurrently entered into a Global Access Commitments Agreement ("GACA") with BMGF as part of the Grant Agreement. Under the terms of the GACA, among other things, the Company agreed to make a certain amount of its COVID-19 vaccine available and accessible at affordable pricing to people in certain low- and middle-income countries, if the vaccine is commercialized.

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

At December 31, 2021, the Company had \$0.6 million of restricted cash and deferred revenue, and at December 31, 2020, had \$2.3 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.

During the years ended December 31, 2021 and 2020, the Company received \$6.0 million and \$4.0 million in funding, respectively, from BMGF.

During the years ended December 31, 2021 and 2020, the Company recognized revenue from the Grant Agreement of \$7.8 million and \$1.6 million, respectively, and has recognized approximately \$9.4 million in revenue since the inception of the Grant Agreement. As of December 31, 2021, the Company has received the full \$10.0 million in funding under the Grant Agreement.

# **Balance Sheet Details**

# Balance Sheet Related Disclosures [Abstract] Balance Sheet Details

# 12 Months Ended Dec. 31, 2021

# 5. Balance Sheet Details

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

	As of Dec
	2021
Laboratory equipment	\$ 856
Construction in progress	303
Property and equipment, cost	1,159
Accumulated depreciation	(83)
Property and equipment, net	\$ 1,076

Depreciation expense was \$0.1 million for the year ended December 31, 2021, and was a negligible amount for the year ended

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

	As of Dece
	 2021
Taxes payable	\$ 
Accrued paid time off	342
Accrued bonus	2,216
Other accrued liabilities	1,977
Accrued 401k	156
ESPP liability	 66
Total accrued and other current liabilities	\$ 4,757

# **License Agreements**

License Agreements [Abstract] License Agreements

# 12 Months Ended Dec. 31, 2021

# 6. License Agreements

# License Agreement with the National Institutes of Health

On June 28, 2018, the Company entered into a non-exclusive patent license agreement (the "NIH Agreement") with a U.S. government entity, the National Institutes of Health, represented by National Institute of Allergy and Infectious Disease ("NIAID"). The NIH Agreement was amended in September 2018 and September 2020. 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 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. There are milestone payments due upon the completion of certain development, regulatory, and commercial milestones for the licensed products in the future. The Company is obligated to pay aggregate potential milestone payments of up to \$2.1 million with respect to future development and regulatory based milestones, and up to \$6.5 million with respect to future sales milestones following commercialization. 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.

During the years ended December 31, 2021 and 2020, the Company paid \$0.2 million and \$0.1 million, respectively, in fees associated with the license, which were recorded as research and development expenses.

# License Agreements with University of Washington

# License Agreement with respect to RSV and Other Pathogens

On June 29, 2018, the Company entered into an exclusive license agreement with an academic entity, University of Washington (the "UW 2018 Agreement"), for an exclusive license to covered intellectual property, a non-exclusive, worldwide license to use licensed know-how, and rights to sublicense for computationally designed nanoparticles and vaccines. The UW 2018 Agreement was amended in June 2019 and again in November 2020. 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 University of Washington ("UW"). The Company issued 192,276 shares of common stock on August 1, 2018 in exchange for the UW 2018 Agreement's exclusive license. The shares issued were recorded at their estimated fair value, which is de minimis, with the related expense classified as research and development in 2018.

Under the UW 2018 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 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 \$1.4 million per indication, up to a maximum of \$6.8 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 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.

The UW 2018 Agreement will terminate when all licensed rights have been terminated and all obligations due to UW have been fulfilled, or the Company may terminate the entirety of the agreement upon written notice thereof to UW.

On July 2, 2020, the Company entered into a non-exclusive license agreement with respect to specified intellectual property with options for exclusivity in North America and Europe subject to the performance of certain development milestones, with UW (the "UW 2020 Agreement"). Under the UW 2020 Agreement, the Company also received a non-exclusive, worldwide license to use specific know-how and rights to sublicense for computationally designed nanoparticles and vaccines. The UW 2020 Agreement was amended in August 2020 and subsequently in May 2021. The Company's rights and obligations under the UW 2020 Agreement as amended 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 as amended, 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. 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 as amended 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.

The UW 2020 Agreement as amended will terminate when all licensed rights have been terminated and all obligations due to UW have been fulfilled, or the Company may terminate the entirety of the agreement upon written notice thereof to UW.

During the years ended December 31, 2021 and 2020, the Company paid \$0.2 million and \$0.3 million respectively, in fees associated with the 2018 and 2020 Agreements.

License Agreement with Respect to Influenza

In September 2021, the Company entered into a license agreement with UW ("UW Flu License Agreement"). 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. As of March 2022, the UW Flu License Agreement is applicable to the Company's preclinical influenza program. The United States federal government and HHMI have similar rights under the UW Flu 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 do 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 \$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. The Company is 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 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 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 the Company breaches or fails to perform one of the 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. The Company can terminate the UW Flu License Agreement at will with prior written notice to UW. The Company can also terminate certain of its licensed rights through an amendment to the UW Flu License Agreement.

During year ended December 31, 2021, the Company paid \$0.1 million in fees associated with the UW Flu License Agreement.

# License Agreement with the University of Texas

In June 2021, the Company entered into an exclusive patent license agreement with an academic entity, the University of Texas at Austin (the "UT Agreement"). Under the UT Agreement, the Company obtained 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 metapneumovirus infection in all vaccine fields, excluding mRNA-based vaccines. The Company is obligated to pay aggregate potential milestone payments of up to \$0.8 million with respect to future development and regulatory based milestones, and up to \$3.8 million with respect to future sales milestones following commercialization for each licensed product for so long as licensed patent rights exist and have not expired, been revoked, lapsed, or held unenforceable.

The UT Agreement will terminate upon the last expiration of the patent rights or the Company may terminate the entirety of the agreement upon written notice thereof to the University of Texas at Austin.

During year ended December 31, 2021, the Company paid a negligible amount in fees associated with the UT Agreement.

# 12 Months Ended Dec. 31, 2021

# Temporary Equity Disclosure [Abstract] Convertible Promissory Note

# 7. Convertible Promissory Note

In August 2020, the Company issued a \$6.5 million convertible promissory note ("Convertible Promissory Note"). The Conver 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 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 prinxestors for such securities, (ii) automatically converted upon initial public offering at a conversion price equal to 85% of the per sha stock in the initial public offering, (iii) optionally converted into Series A-3 preferred stock if a change in control, initial public offering, financing had not occurred prior to the maturity date at a price equal to an amount determined by dividing \$140 million by the fully di 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 a amount as would have been payable if the noteholders had optionally converted into shares of Series A-3 preferred stock. The Converse was converted in March 2021 in connection with the Series B financing.

The Convertible Promissory Note is accounted for in accordance with ASC 470-20, *Debt with Conversion and Other Options* ASC 815-15, *Derivatives and Hedging - Embedded Derivatives* ("ASC 815-15"). Under ASC 815-15, an feature is required to be bifu conditions are met: (1) economic characteristics and risks of the embedded derivative are not clearly and closely related to the econ risks of the host contract, (2) the hybrid instrument is not remeasured at fair value under otherwise applicable GAAP with changes in earnings as they occur, and (3) a separate instrument which the same terms as the embedded derivative would be considered a der 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 accounted separately for as a single embedded derivative. The initial fair value of this derivative of \$1.8 million was recorded as a lia reduction to the carrying value of the Convertible Promissory Note. The Company also incurred approximately \$36,000 of issuance Convertible Promissory Note, which were also recorded as a reduction to the Convertible Promissory Note on the balance sheet.

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

Total Convertible Promissory Note consisted of the following (in thousands):

	De
Principal amount	\$
Discount related to the derivative liability and issuance costs	
Net carrying amount of Convertible Promissory Note	\$

Interest expense incurred in connection with the Convertible Promissory Note consisted of the following year ended December

		Decembe
	20	021
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 Promaccrued interest) and derivative liability converted into 2,805,850 shares of Series B-2 convertible preferred stock at an issuance prior share. As a result of the conversion, the Company recorded a loss on extinguishment of convertible promissory notes of \$0.8 million statements of operations and comprehensive loss for the year ended December 31, 2021 which included the unamortized debt issuance prior to the statements of operations and comprehensive loss for the year ended December 31, 2021 which included the unamortized debt issuance prior to the statements of operations and comprehensive loss for the year ended December 31, 2021 which included the unamortized debt issuance prior to the statement of th

Convertible Preferred Stock and Stockholders' Equity (Deficit) Stockholders Equity Note [Abstract] Convertible Preferred Stock and Stockholders' Equity (Deficit)

# 12 Months Ended Dec. 31, 2021

Charge of

#### 8. Convertible Preferred Stock and Stockholders' Equity (Deficit)

#### **Convertible Preferred Stock**

Prior to its conversion into common stock in connection with the Company's IPO in August 2021, the Company's convertible preferred as temporary equity on the Company's balance sheets in accordance with authoritative guidance. Convertible preferred strissued and its principal terms as of December 31, 2020 consisted of the following (\$ amounts in thousands):

	Share Authorized and Outstanding	Shares Issued and Outstanding	Common Stock Issuable upon Conversion	Aggregat Liquidatio Preference
Series A-1	49,089,955	27,249,085	6,557,031	\$ 26
Series A-2	4,949,794	4,949,794	1,191,082	3
Total	54,039,749	32,198,879	7,748,113	\$ 30

In February 2021, the Company triggered a milestone closing associated with its Series A-1 convertible preferred stock resul 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 comm proportional adjustment to the existing conversion ratios for each series of the Company's convertible preferred stock in July 2021, t into a convertible preferred stock purchase agreement for the issuance of 35,764,462 shares of Series B convertible preferred stock 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 preferre 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 Promisson that the Company issued in August 2020, including accrued interest as of the date of conversion of \$0.2 million, was converted into a Series B-2 convertible preferred stock on March 19, 2021 at 85% of the offering's share price.

In connection with the Company's IPO in August 2021, all outstanding shares of the convertible preferred stock converted int common stock and the related carrying value was reclassified to common stock and additional paid-in capital. There were no shares stock outstanding as of the closing of the IPO.

In addition, on August 2, 2021, the Company amended and restated its certificate of incorporation to authorize 500,000,000 s and 50,000,000 shares of preferred stock, which shares of preferred stock are currently undesignated. The Company does not have preferred stock as of December 31, 2021.

#### Equity Incentive Plans

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

During 2021, the Company's stockholders approved the 2021 Incentive Plan (the "2021 Plan"), which became effective in Jul provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock, dividend equivulats and other stock or cash-based awards. The number of shares of the Company's common stock initially reserved for issuance u 4,600,000 shares; plus the shares of common stock remaining available for issuance under the 2017 Plan as of the effective date of as any shares subject to outstanding awards under the 2017 Plan as of the effective date of the 2021 Plan thereafter in accordance with its terms. The number of shares initially available for issuance increases annually on Januar 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 preceding calendar year and (B) a smaller number of shares as determined by our board of directors. The reserve for the 2021 Plan incentive stock of under the 2021 Plan the 2021 Plan incentive stock of the 2021 Plan the 2021 Plan incentive stock of the 2021 Plan as of the 2021 Plan incentive stock of the 2021 Plan as of the final day of preceding calendar year and (B) a smaller number of shares as determined by our board of directors. The reserve for the 2021 Plan 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 types of awards to be granted, including the number of shares subject to the awards, the exercise price and the vesting schedule. Al subject to a time-based vesting period which will generally be four years. Certain option and share awards provide for accelerated ve 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 o certain significant stockholders). Options shall not have an exercise price less than 100% of the fair market value of the Company's grant date (or 110% in the case of incentive stock options granted to certain significant stockholders), except with respect to certain significant stockholders), except with respect to certain significant stockholders).

A summary of the status of the options issued under the Company's equity incentive plans as of December 31, 2021, and info the changes in options outstanding is as follows:

Option Pool		Weighted	Weighted
Available	Options	Average	Average
for Grant	Outstanding	Exercise	Remaining

Price Per ContractuaShareTerm (Years	
541,411 641,427 \$ 0.84 9	ance at December 31, 2020 541,411
22,634,965 — —	horized increase in plan shares 22,634,965
(6,177,633) 6,177,633 8.52	Granted (6,177,633)
	Exercised (including early)
<u>16,998,743</u> <u>6,591,727</u> <u>\$ 8.04</u> <u>9</u>	ance at December 31, 2021 16,998,743
6,591,727 \$ 8.04 9	ted and expected to vest as of ecember 31, 2021
826,952 \$ 5.71 9	ted and exercisable at ecember 31, 2021
<u> </u>	

Exercisable options in the table above reflect the number of options vested as of the date reported. The 2021 Plan permits ea Cash received for early exercise of unvested options is recognized as an other noncurrent liability in the accompanying balance she million at December 31, 2021.

The aggregate intrinsic value in the table above is calculated as the difference between the exercise price of the underlying o of the Company's common stock for all options that were in-the-money as of December 31, 2021.

During the year ended December 31, 2021, the Company granted 6,177,633 options, with a grant date fair value of \$48.3 mil ended December 31, 2020, the Company granted 271,405 options, with a grant date fair value of \$0.3 million. The weighted-average of employee option grants during the years ended December 31, 2021 and 2020 were \$8.52 and \$1.06 per share, respectively.

During the year ended December 31, 2021, the Company granted 388,500 restricted stock unit ("RSU") awards, with a grant million. The weighted-average grant date fair value of RSU awards during the year ended December 31, 2021 was \$25.96. All RSU the year ended December 31, 2021 were nonvested as of December 31, 2021. There were no RSU awards granted during the year 2020.

#### **Common Stock**

As of December 31, 2021 and 2020, of the 500,000,000 and 78,000,000 authorized shares of common stock, respectively, 33,596,936 shares were issued, respectively, and 39,175,279 and 2,639,026 shares were outstanding, respectively.

As of December 31, 2021 and 2020, the Company had 2,347,629 shares of restricted common stock that had been issued to management at a price of \$0.004 per share, and 269,694 shares of common stock that had been issued to a university in connection licensing agreement.

At December 31, 2021 and 2020, 2,347,629 and 1,995,314 shares of the restricted common stock have vested, respectively. no shares were subject to vesting conditions.

Common stock reserved for future issuance consisted of the following:

A

Common stock options and restricted stock units granted and outstanding	
Shares available for issuance under the equity incentive plans	
Shares available for issuance under the 2021 Employee Stock Purchase Plan	
Total common stock reserved for issuance	

# Stock-Based Compensation Expense

Stock-based compensation expense for all equity awards and the 2021 Employee Stock Purchase Plan, has been reported in operations and comprehensive loss as follows (in thousands):

	Year E
	Decemb
	2021
Research and development	\$ 2,710
General and administrative	 26,321
Total	\$ 29,031

The Company recognizes compensation expense for options and RSU awards granted to employees and the board of directed date fair value. The compensation expense is recognized over the vesting period of 4 years on a straight-line basis.

The fair value of each stock option granted was determined using the Black-Scholes option pricing model. The assumptions using Black-Scholes option pricing model to determine the fair value of the employee and nonemployee stock option grants issued during follows:

	Year B
	Decem
	2021
Risk-free rate of interest	0.63%-1.34%
Expected term (years)	5.77 - 6.08 years
Expected stock price volatility	84.2% - 90.9%
Dividend yield	0%

As of December 31, 2021, the unrecognized compensation cost related to outstanding stock options and RSU awards was \$3 million, respectively and is expected to be recognized as expense over a weighted-average period of approximately 3.41 years.

On August 4, 2021, as a result of the death of Tadataka (Tachi) Yamada, M.D., the Company's former Chairman, the Company decided to accelerate the vesting of all of Dr. Yamada's previously unvested stock options as of the date of his death. The Company vesting of 611,639 stock options, with exercise prices ranging from \$0.83 to \$5.90 per share, resulting in incremental non-cash, stoc of \$21.0 million being recorded in 2021 as general and administrative expense.

# Employee Stock Purchase Plan

During 2021, the Company's stockholders approved the 2021 Employee Stock Purchase Plan (the "ESPP"), which became end the ESPP permits eligible employees who elect to participate in an offering under the ESPP to have up to 15% of their eligible earning certain limitations, to purchase shares of common stock pursuant to the ESPP. The price of common stock purchased under the ESP the lower of the fair market value of the common stock at the commencement date of each offering period or the relevant date of purshares of common stock initially reserved for issuance under the ESPP is 400,000 shares. The number of shares of common stock in under the ESPP increases on January 1, 2022 and each January 1 thereafter through January 1, 2031, in an amount equal to the loaggregate number of shares of common stock as determined by the Board, provided that no more than 15,000,000 shares of our commissued under the ESPP. The reserve for the ESPP increased by 1% or 394,291 shares, on January 1, 2022. As of December 31, 20 been purchased by employees under the ESPP. Stock-based compensation expense related to the ESPP for the year ended Decemmillion.

### **Income Taxes**

# Income Tax Disclosure [Abstract] Income Taxes

# 12 Months Ended Dec. 31, 2021

# 9. Income Taxes

The reconciliations of the U.S. statutory federal income tax rates to the Company's effective tax rates were as follows:

	Year	En
	Decer	
	2021	
U.S. federal statutory income tax rate	21.0%	
Adjustments for the tax effects of:		
State income taxes, net of federal tax	1.0	
Other permanent differences	(0.4) 3.1	
Research and development tax credits	3.1	
Research and development credit permanent adjustment	(0.6)	
Stock-based compensation	(0.6) (1.6)	
Uncertain tax positions	(0.8)	
Change in valuation allowance	(21.7)	
Effective income tax rate	%	,

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabiliti purposes and the amounts used for income tax purposes. The significant components of our deferred tax assets and liabilities are a

	As of Dece	
	 2021	
Deferred tax assets		
Net operating loss carryforwards	\$ 12,623	
Research and development credits	2,349	
Deferred revenue	126	
Stock-based compensation	5,192	
Other	 533	
Total deferred tax assets	20,823	
Less: deferred tax liabilities	(280)	
Less: valuation allowance	 (20,543)	
Net deferred tax assets	\$ 	

Due to the uncertainty surrounding the realization of deductible tax attributes in future tax returns, the Company has recorded against its net deferred tax assets as of December 31, 2021 and 2020. Utilization of the net operating loss carryforwards is depende income. As such, realization is not assured, and a valuation allowance has been established.

The valuation allowance for deferred tax assets was approximately \$20.5 million as of December 31, 2021, an increase of \$1 year ended December 31, 2021. The Company has total net operating loss carryforwards for U.S. federal income tax and state purp \$57.0 million and \$11.9 million, respectively, as of December 31, 2021 which begin to expire in 2037 and 2035, respectively. Federal generated after January 1, 2018 will be carried forward indefinitely. The Company has federal research and development tax credit of approximately \$3.0 million as of December 31, 2021, which begin to expire in 2037. Additionally, the Company has state research arc carryforwards of approximately \$168,000 as of December 31, 2021, which carryforward indefinitely. The operating loss carryforward development tax credits may be limited due to a change in control in the Company's ownership as defined by the Internal Revenue 0 383.

The Company files federal and state income tax returns. The Company is not currently under examination but is open to audi tax authorities for tax years beginning in 2017. The resolutions of any examinations are not expected to be material to these financia December 31, 2021, 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 (

	Year Ended D
	2021
Unrecognized tax benefits, beginning of year	\$ 263
Additions based on tax positions relating to current year	495
Additions based on tax positions relating to prior year	—
Reductions for positions of prior years	 
Unrecognized tax benefits, end of year	\$ 758

The Company does not believe it is reasonably possible that its unrecognized tax benefits will change materially in the next twelve material of the next twelve material o

# **Employee Savings Plan**

# Postemployment Benefits [Abstract] Employee Saving Plan

# 12 Months Ended Dec. 31, 2021

# 10. 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 did not make any contributions to the plan during 2021 or 2020.

Summary of Significant Accounting Policies (Policies)	12 Months Ended
Accounting Policies	Dec. 31, 2021
[Abstract]	
Basis of Presentation	Basis of Presentation
	The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Cod Accounting Standards Updates ("ASU") promulgated by the Financial Accounting Standards Board ("FASB").
Use of Estimates	Use of Estimates
	The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions to balances of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the rep expenses during the reporting period. Estimates are used for, but not limited to, stock-based compensation, derivative liability, the tir development accruals, and income taxes. Although these estimates are based on the Company's knowledge of current events and in the future, actual results may materially differ from these estimates and assumptions.
	The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operation condition, including expenses, clinical trials and research and development costs, will depend on future developments that are highly a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat COVID-19, as well as the local, regional, national and international markets. The Company has considered potential impacts arising from the COVID-19 pander presently aware of any events or circumstances that would require the Company to update its estimates, judgments or revise the car or liabilities.
Concentration of Credit Risk	Concentration of Credit Risk
	Financial instruments which potentially subject the Company to significant concentration of credit risk consist of cash and restricted exposed to credit risk from its deposits of cash in excess of amounts insured by the Federal Deposit Insurance Corporation. The Con Insured Cash Sweep account where balances are maintained in interest bearing demand accounts. The Company has not experien deposits of cash since inception, and management believes that the Company is not exposed to significant credit risk due to the final
Comprehensive Loss	respective depository institutions in which those deposits are held
	Comprehensive Loss
	Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances a sources. The Company's comprehensive loss was the same as its reported net loss for all periods presented.
Fair Value of Financial Instruments	Fair Value of Financial Instruments
	The accounting guidance defines fair value, establishes a consistent framework for measuring fair value, and expands disclo asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price re that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fa market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset
	The carrying amounts of all cash, restricted cash, prepaid expenses and other assets, accounts payable, and accrued and ot considered to be representative of their respective fair values due to their short maturities.
	The carrying values of the derivative liability of \$1.6 million (level 3 fair value) and the convertible promissory note of \$4.9 mil accompanying balance sheet at December 31, 2020 approximate fair value because they collectively converted into 2,805,850 shar convertible preferred stock in March 2021.
Cash	Cash
	Cash represents funds in the Company's operating bank account. The Company has no cash equivalents.
Restricted Cash	Restricted Cash
	The Company's restricted cash includes payments received under the Grant Agreement (as defined in Note 4) with the Bill & Foundation ("BMGF") under which the Company was awarded a grant of up to \$10.0 million. The Company will utilize the Grant Agrin incurs expenses for services performed under the agreement. Restricted cash also includes cash collateral supporting the standby in "Leases" below.
Property and equipment, net	Property and equipment, net
	Property and equipment, net is stated at cost, net of accumulated depreciation and is depreciated using the straight-line meth useful lives of the assets (generally two to five years).
Impairment of Long-Lived Assets	Impairment of Long-Lived Assets
<u>- 100010</u>	The Company regularly reviews the carrying value and estimated lives of its long-lived assets, including property and equipm whether indicators of impairment may exist which warrant adjustments to carrying values or estimated useful lives. Should an impair impairment loss would be measured based on the excess over the carrying amount of the asset's fair value. The Company has not r impairment losses from inception through December 31, 2021.

Derivative Liability, Convertible Notes Discount and Amortization

# 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 derivation subject to bifurcation and derivative accounting. The initial recognition of the fair value of the derivative resulted in a discount to the corresponding derivative liability. The discount to the convertible note was amortized using the effective interest method. The amorti included in interest and other income (expense) in the statements of operations and comprehensive loss. The derivative liability rela was recorded at estimated fair value and remeasured on a recurring basis. Any changes in fair value were reflected as change in fai liability in the statements of operations and comprehensive loss at each reporting date while such instruments were outstanding. The settled in March 2021 upon conversion of the underlying convertible note into Series B convertible preferred stock, resulting in a loss convertible promissory note

#### Leases

At the inception of a contractual arrangement, the Company determines whether the contract contains a lease by assessing v identified asset and whether the contract conveys the right to control the use of the identified asset in exchange for consideration ov both criteria are met, the Company records the associated lease liability and corresponding right-of-use asset upon commencement implicit rate or a discount rate based on a credit-adjusted secured borrowing rate commensurate with the term of the lease. The Cor 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 a finance lease if it meets one of the following five criteria: the lease has a purchase option that is reasonably certain of being exercise 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 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 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 operating lease. Operating lease assets represent a right to use an underlying asset for the lease term and operating lease liabilities to make lease payments arising from the lease. Operating lease liabilities with a term greater than one year and their corresponding recognized on the balance sheet at the commencement date of the lease based on the present value of lease payments over the ex Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received. As the not typically provide an implicit rate, the Company utilizes the appropriate incremental borrowing rate, determined as the rate of inter would have to pay to borrow on a collateralized basis over a similar term and in a similar economic environment. Lease cost is record basis over the lease term and variable lease payments are recognized as operating expenses in the period in which the obligation for incurred. Variable lease payments primarily include common area maintenance, utilities, real estate taxes, insurance, and other ope passed on from the lessor in proportion to the space leased by the Company. The Company has elected the practical expedient to n non-lease components.

In January 2020, and amended in March 2020, the Company entered into a lab license agreement for office and lab space in The lab license agreement is twelve months and provides for renewal options. The monthly base rent is approximately \$16,000. The is considered short-term and therefore, no right-of-use asset or lease liability has been recorded.

In December 2021, the Company entered into a lease agreement for corporate office and lab space in Seattle, Washington. possession of certain leased space at various dates in January 2022 and March 2022. The lease agreement is five years and 3 mor 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 and will inc over the initial term. In addition, the Company is obligated to pay for common area maintenance and other costs. Under the terms of 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. anniversary, and further reduced to \$0.7 million at the second anniversary of the lease. As of December 31, 2021, the Company had space and the lease term had not commenced; therefore, no right-of-use asset or lease liability has been recognized.

### Grant Revenue

The Company's revenue consists of revenue under its Grant Agreement with BMGF (see Note 4). The Company is reimburse support development activities, including the Company's clinical trial notification ("CTN") preparations for and planned first-in-human of COVID-19 RBD VLP vaccine in Australia. The Company's Grant Agreement does not provide a direct economic benefit to BMGF. entered into an agreement with BMGF to make a certain amount of any resulting vaccine available and accessible at affordable pric low- and middle-income countries. The Company assessed this cost reimbursement agreement to determine if the agreement shoul an exchange transaction or a contribution. Such an agreement is accounted for as a contribution if the resource provider does not re value in return for the assets transferred. Contributions are recognized as grant revenue when all donor-imposed conditions have be ultimately determines if milestones under the agreement are met and if funding should continue, there may be a difference in timing and development expenses are incurred and when grant revenue is recognized.

#### Accrued Research and Development Expense

The Company is required to estimate its obligation for expenses incurred under contracts with vendors, consultants, and contracts with vendors, contracts with v organizations, in connection with conducting research and development activities. The financial terms of these contracts are subject vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are pr contracts. The Company reflects research and development expenses in its financial statements by recognizing those expenses in t services and efforts are expended. The Company accounts for these expenses according to the progress of the preclinical study or measured by the timing of various aspects of the study, trial or related activities. The Company determines accrual estimates throug underlying contracts along with preparation of financial models taking into account discussions with research and other key personn service providers as to the progress of studies or trials, or other services being conducted. To date, the Company has had no materi its estimates of such expenses and the amounts actually incurred. During the course of a study or trial, the Company adjusts its exp actual results differ from its estimate. Nonrefundable advance payments for goods and services, including fees for process developments and distribution of clinical supplies that will be used in future research and development activities, are deferred and recognized as ex the related goods are consumed or services are performed.

# Research and Development

# Research and Development

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

Leases

# Accrued Research and

Development Expense

# Grant Revenue

### Interest Income

#### Interest Income

Interest income consists of interest income earned on interest bearing demand accounts.

# Liability For Early Exercise Of 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 unvested stock options are restricted and continue to vest in accordance with the original vesting schedule. The Company has the o unvested shares at the original purchase price upon any voluntary or involuntary termination. The shares purchased by the employe pursuant to the early exercise of stock options are not deemed, for accounting purposes, to be outstanding until those shares vest. 1 exchange for exercised and unvested shares related to stock options granted is recorded as a liability for the early exercise of stock accompanying balance sheets and will be reclassified as common stock and additional paid-in capital as the shares vest. Unvested early exercise provisions subject to repurchase by the Company totaled 253,824 and 488,226 shares as of December 31, 2021 and of December 31, 2021 and 2020, the Company had \$0.2 million and \$0.2 million respectively, of amounts related to shares issued w classified as other noncurrent liabilities in the accompanying balance sheets.

## Stock-Based Compensation

### Stock-Based Compensation

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

The Black-Scholes option pricing model uses inputs which are assumptions that generally require judgment. These assumpti •Fair Value of Common Stock. Prior to the Company's IPO, the grant date fair market value of the shares of common sto options was historically determined by the Company's board of directors. Because there was no public market for the Company board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine fair market value, which included contemporaneous valuations performed by an independent third-party, the Company's resu financial position, including its levels of available capital resources, its stage of development and material risks related to the progress of the Company's research and development activities, the Company's business conditions and projections, the lac Company's common stock and preferred stock as a private company, the prices at which the Company sold shares of its con to outside investors in arms-length transactions, the rights, preferences and privileges of the Company's redeemable convert relative to those of its common stock, the analysis of initial public offerings and the market performance of similar companies biopharmaceutical industry, the likelihood of achieving a liquidity event for the Company's securityholders, such as an initial p of the Company, given prevailing market conditions, the hiring of key personnel and the experience of management, trends a Company's industry, and external market conditions affecting the life sciences and biopharmaceutical industry sectors. Subset Company's IPO, 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 e options issued is determined using the simplified method (based on the average of the vesting term and the original contract Company has concluded that its stock option exercise history does not provide a reasonable basis upon which to estimate ex

•Expected Volatility. Given the Company's limited historical stock price volatility data, the Company derived the expected average historical volatilities over a period approximately equal to the expected term of comparable publicly traded companie peer group that were deemed to be representative of future stock price trends as the Company has limited trading history for Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its owr 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 corresponding with the expected term of the options.

•Expected Dividend Yield. The Company never paid dividends on its common stock and do not anticipate paying any div 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 common stock a

#### **Commitments and Contingencies**

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

In the event the Company becomes subject to claims or suits arising in the ordinary course of business, the Company would 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, 2021 or 2020.

#### Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred ta are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted 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 the period that includes the enactment date.

Commitments and Contingencies

Income Tax

The Company recognizes deferred tax assets to the extent that the Company believes these assets are more likely than not such a determination, management considers all available positive and negative evidence, including future reversals of existing taxa differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines th be able to realize its deferred tax assets in the future in excess of their recorded amount, management would make an adjustment to valuation allowance, which would reduce the provision for income taxes.

As of December 31, 2021 and 2020, the Company maintained valuation allowances against its deferred tax assets as the Co not met the "more likely than not" to be realized threshold. Changes in the valuation allowance when they are recognized in the prov 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 whetl 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 mee more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50 percent lik ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefi expense. Any accrued interest and penalties are included within the related tax liability. As of December 31, 2021, the Company had penalties.

# Net Loss Per Share

# Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted-average r common stock outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the weighted average net common stock and common stock equivalents outstanding for the period. Common stock equivalents are only included when their e Company's potentially dilutive securities include outstanding stock options under the Company's equity incentive plan and have bee 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 r 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

		Decemb
	2021	
Numerator:		
Net loss	\$	(66,971)
Denominator:		. ,
Weighted-average common shares outstanding, basic and diluted	18,	587,782
Less: Weighted-average unvested common stock		621,888)
Weighted-average shares used to compute net loss per share, basic and		
diluted	17,	965,894
Net loss per share, basic and diluted	\$	(3.73)

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

	Year E Decemb
	2021
Series A convertible preferred stock	
Common stock options	6,591,727
ESPP shares	16,606
Unvested common stock	253,824
Total	6,862,157
Segments	

The Company has determined that it operates and manages one operating segment, which is the business of researching ar against infectious diseases. The Company's chief operating decision maker, its chief executive officer, reviews financial information

Segments

Recent Accounting Pronouncements

#### 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 guidance simplifies the accounting for income taxes by removing several exceptions in the current standard and adding guidance to 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 r interim period that includes the enactment date. The new standard is effective for fiscal years beginning after December 15, 2021, a fiscal years beginning after December 15, 2022 for all non-public entities, with early adoption permitted, and is effective for fiscal year December 15, 2020, including interim periods within those annual periods for public entities. Early adoption is permitted. The Compa 2019-12 on January 1, 2021 and the standard did not have a material impact on its financial statements and related disclosures.

[Abstract] Computation of Basic and Diluted Net Loss Per Share 12 Months Ended Dec. 31, 2021

Year E

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

		Year Er Decemb 2021
Numerator:		2021
Net loss	\$	(66,971)
Denominator:		
Weighted-average common shares outstanding, basic and diluted		18,587,782
Less: Weighted-average unvested common stock		(621,888)
Weighted-average shares used to compute net loss per share, basic and diluted		17,965,894
Net loss per share, basic and diluted	\$	(3.73)
The following table sets forth the outstanding potentially dilutive securities that have been e because their inclusion would be anti-dilutive.	xcluded in the c	alculation of dilut

Summary of Outstanding Potentially Dilutive Securities Excluded in Calculation of Diluted Net Loss Per Share

	Decemb
	2021
Series A convertible preferred stock	_
Common stock options	6,591,727
ESPP shares	16,606
Unvested common stock	253,824
Total	6,862,157

**Fair Value Measurements 12 Months Ended** (Tables) Dec. 31, 2021 **Fair Value Disclosures** [Abstract] Fair Value, Liabilities The following table summarizes financial liabilities that the Company measured at fair value on a recurring basis, classified in Measured on Recurring Basis fair value hierarchy (in thousands): Fair Value Measurements a Total (Level 1) (Level 2 As of December 31, 2020 (1,604) \$ \$ \$ Embedded derivative liability \_\_\_\_ Fair Value Measurement The following table summarizes information about the significant unobservable inputs used in the fair value measurements for Inputs and Valuation **Techniques** December 31, March 19, 2021 2020 Probability of financing Probability of dissolution 100% 90 109 Time to liquidity (years) 0.50 - 1.00 Discount rate 7.6% 8.39 Fair Value, Liabilities The following table provides a reconciliation of the fair value of the derivative liability using Level 3 significant unobservable in Measured on Recurring Basis, Unobservable Input **Reconciliation** Fair value at December 31, 2019 \$ Fair value of derivative liability at issuance of convertible promissory note Change in fair value of derivative liability (Note 7) Fair value at December 31, 2020 Change in fair value of embedded derivative liability

note

Fair value at December 31, 2021

Reclassification of derivative liability into convertible preferred stock resulting from conversion of convertible promissory

\$

Copyright © 2022 www.secdatabase.com. All Rights Reserved. Please Consider the Environment Before Printing This Document

Balance Sheet Details (Tables)	12 Months Ended Dec. 31, 2021		
Balance Sheet Related Disclosures [Abstract] Schedule of property and equipment	Property and equipment, net, consists of the following (in thousands):		As of Dece
	Laboratory equipment Construction in progress Property and equipment, cost Accumulated depreciation Property and equipment, net	\$ <u>\$</u>	<b>2021</b> 856 <u>303</u> 1,159 (83) <u>1,076</u>
Schedule of Accrued and Other Current Liabilities	Accrued and other current liabilities consist of the following (in thousands):		As of Dece 2021
	Taxes payable	\$	
	Accrued paid time off Accrued bonus		342 2,216
	Other accrued liabilities		1,977
	Accrued 401k		156
	ESPP liability Total accrued and other current liabilities	¢	<u>66</u> 4,757
		<u>\$</u>	4,737

Convertible Promissory Note (Tables) <u>Convertible Promissory Note</u>	Dec. 31, 2021		
[Abstract] Summary of Convertible Promissory Note	Total Convertible Promissory Note consisted of the following (in thousands):		De
	Principal amount Discount related to the derivative liability and issuance costs Net carrying amount of Convertible Promissory Note		\$
Summary Of Interest Expense Of Convertible Promissory Note	Interest expense incurred in connection with the Convertible Promissory Note consisted of the f	ollowing year ende	ed Decembe Decembe
	Coupon interest at 6% Accretion of discount and amortization of issuance costs Total interest expense on Convertible Promissory Note	\$	86 177 263

## **Convertible Preferred Stock** and Stockholders' Equity (Deficit) (Tables) **Stockholders Equity Note** [Abstract] Schedule of Convertible

# **12 Months Ended**

## Dec. 31, 2021

Preferred Stock

Convertible preferred stock authorized and issued and its principal terms as of December 31, 2020 consisted of the following (\$ amo

	Share Authorized and Outstanding	Shares Issued and Outstanding	Shares of Common Stock Issuable upon Conversion	Aggregat Liquidatio Preference
Series A-1	49,089,955	27,249,085	6,557,031	\$ 26
Series A-2	4,949,794	4,949,794	1,191,082	3
Total	54,039,749	32,198,879	7,748,113	\$ 30

Summary of the Status of the

A summary of the status of the options issued under the Company's equity incentive plans as of December 31, 2021, and info Options Issued Under the Plan the changes in options outstanding is as follows:

Option Pool Available for Grant	Options Outstanding		Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractua Term (Years
541,411	641,427	\$	0.84	9
22,634,965	_			
(6,177,633)	6,177,633		8.52	
	(227,333)		0.84	
16,998,743	6,591,727	\$	8.04	9
	6,591,727	\$	8.04	9
	826,952	\$	5.71	9
	Available for Grant 541,411 22,634,965 (6,177,633)	Available for Grant         Options Outstanding           541,411         641,427           22,634,965         —           (6,177,633)         6,177,633           —         (227,333)           16,998,743         6,591,727           6,591,727	Option Pool Available for Grant         Options Outstanding           541,411         641,427           22,634,965         —           (6,177,633)         6,177,633           —         (227,333)           16,998,743         6,591,727           6,591,727         \$	Option Pool Available for Grant         Options Outstanding         Average Exercise Price Per Share           541,411         641,427         \$ 0.84           22,634,965         -         -           (6,177,633)         6,177,633         8.52           -         (227,333)         0.84           16,998,743         6,591,727         \$ 8.04

Schedule of common stock reserved for future issuance

Common stock reserved for future issuance consisted of the following:

	Α
Common stock options and restricted stock units granted and outstanding	
Shares available for issuance under the equity incentive plans	
Shares available for issuance under the 2021 Employee Stock Purchase Plan	
Total common stock reserved for issuance	

Schedule of Stock-based

Equity Awards

Stock-based compensation expense for all equity awards and the 2021 Employee Stock Purchase Plan, has been reported in Compensation Expense for All operations and comprehensive loss as follows (in thousands):

	Year E
	Decemb
	 2021
Research and development	\$ 2,710
General and administrative	26,321
Total	\$ 29,031

### Summary of Assumptions Used in Black-Scholes Model

The fair value of each stock option granted was determined using the Black-Scholes option pricing model. The assumptions Black-Scholes option pricing model to determine the fair value of the employee and nonemployee stock option grants issued during follows:

	Tear
	Decem
	2021
Risk-free rate of interest	0.63%-1.34%
Expected term (years)	5.77 - 6.08 years
Expected stock price volatility	84.2% - 90.9%
Dividend yield	0%

### **Income Taxes (Tables)**

## **Income Tax Disclosure** [Abstract] **Reconciliation of Federal** Statutory Income Tax Rate and Effective Income Tax Rate

The reconciliations of the U.S. statutory federal income tax rates to the Company's effective tax rates were as follows:

**12 Months Ended** 

Dec. 31, 2021

		Year En Decemb
	2021	
U.S. federal statutory income tax rate		21.0%
Adjustments for the tax effects of:		
State income taxes, net of federal tax		1.0
Other permanent differences		(0.4) 3.1
Research and development tax credits		`3.1 <sup>′</sup>
Research and development credit permanent adjustment		(0.6)
Stock-based compensation		(1.6)
Uncertain tax positions		(0.8)
Change in valuation allowance		(21.7)
Effective income tax rate		_%

Schedule Of Components Of Deferred Tax Assets And Liabilities

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilit purposes and the amounts used for income tax purposes. The significant components of our deferred tax assets and liabilities are a

	 As of Dece
	 2021
Deferred tax assets	
Net operating loss carryforwards	\$ 12,623
Research and development credits	2,349
Deferred revenue	126
Stock-based compensation	5,192
Other	533
Total deferred tax assets	 20,823
Less: deferred tax liabilities	(280)
Less: valuation allowance	(20,543)
Net deferred tax assets	\$ 

### Summary of Unrecognized Tax Benefits

A reconciliation of the beginning and ending amount of unrecognized tax benefits for uncertain tax positions were as follows (

	Year Ended D
	2021
Unrecognized tax benefits, beginning of year	\$ 263
Additions based on tax positions relating to current year	495
Additions based on tax positions relating to prior year	—
Reductions for positions of prior years	 
Unrecognized tax benefits, end of year	\$ 758

The Company does not believe it is reasonably possible that its unrecognized tax benefits will change materially in the next twelve n

Description of Business - Additional Information			1 Mon	ths Ended	12 Mont	hs Ended
(Detail) - USD (\$) \$ / shares in Units, \$ in Thousands	Aug. 02, 2021	Mar. 31, 2021	Aug. 31, 2021	Jul. 31, 2021	Dec. 31, 2021	Dec. 31, 2020
Subsidiary Sale Of Stock [Line Items]						
Stock split		1-for-4.1557	7	1-for-4.1557	7	
Sale of common stock					39,429,103	33,596,936
<u>Proceeds from initial public offering, net</u> of offering costs					\$ 190,738	\$ 0
Preferred stock, shares outstanding					0	0
Accumulated Deficit					\$ 94,069	\$ 27,098
Cash					279,082	\$ 13,114
Restricted Cash					\$ 1,600	
IPO [Member]						
Subsidiary Sale Of Stock [Line Items]						
Sale of common stock	12,133,333	3				
Offering price per share	\$ 15.00					
Additional shares purchasable by underwriters	1,819,999					
Proceeds from initial public offering, net of offering costs	\$ 190,700					
Preferred stock, shares outstanding	89,908,21	5			0	
Common stock converted	21,634,898	8	21,634,898	3		

# 12 Months Ended

Summary of Significant Accounting Policies - Additional Information (Details)	Dec. 31, 2021 USD (\$) Segment shares	Mar. 19, 2021 shares	Dec. 31, 2020 USD (\$) shares	Jan. 31, 2020 USD (\$)
Derivatives liability, carrying value	2 \$ 1,800,000		\$ 1,600,000	
Convertible preferred stock issued upon conversion   shares			7,748,113	
Restricted Cash	1,600,000			
Impairment losses	\$ 0			
Number of shares subject to repurchase   shares	253,824		488,226	
Liabilities with shares issued with repurchase rights	\$ 200,000		\$ 200,000	
Accrued interest and penalties	\$ O			
Number Of Reporting Units   Segment	1			
Operating Lease, Right-of-Use Asset, Statement of Financial Position [Extensible Enumeration]	Property Plant And Equipment Net		Property Plant And Equipment Net	
Lab License Agreement [Member]				
Monthly Base Rent	\$ 16,000			
Lease agreement term	12 months			
Lease agreement option to extend	The lab license agreement is twelve months and provides for renewal options.			
Right-of-use asset	\$ 0			<b>\$</b> 0
Lease liability	0			\$0
Lease Agreement [Member]				
Monthly Base Rent	\$ 200,000			
Monthly base rent yearly increase percentage	3.00%			
Lease agreement term Lease agreement option to extend	5 years 3 months The lease agreement is five years and 3 months and provides for a one-time option to extend for a period of five additional years.			
Lease term option to extend for additional years	5 years			
Minimum [Member] Property and equipment useful lives of assets Maximum [Member]	2 years			
Property and equipment useful lives of assets	5 years			

Bill And Melinda Gates		
Foundation		
Restricted Cash	\$ 10,000,000.0	
Series B [Member]		
Convertible preferred stock issued		2,805,850
upon conversion   shares		2,803,830
Standby Letters of Credit		
[Member]   Lease Agreement		
[Member]		
Standby letters of credit	1,100,000	
First Anniversary [Member]]		
Lease Agreement [Member]		
Standby letters of credit	900,000	
Second Anniversary [Member]		
Lease Agreement [Member]		
Standby letters of credit	\$ 700,000	
Promissory Note [Member]		
Convertible note		\$ 4,900,000

Summary of Significant Accounting Policies -	12 Months Ended Dec. 31, 2021 Dec. 31, 2020	
Computation of Basic and Diluted Net Loss Per Share (Details) - USD (\$) \$ / shares in Units, \$ in Thousands		
Numerator:		
<u>Net loss</u>	\$ (66,971)	\$ (18,854)
Denominator:		
Weighted-average common shares outstanding, basic and diluted	18,587,782	3,517,671
Less: Weighted average unvested common stock	(621,888)	(1,272,448)
Weighted average shares used to compute net loss per share, basic and diluted	<u>d</u> 17,965,894	2,245,223
Net loss per share, basic and diluted	\$ (3.73)	\$ (8.40)

Summary of Significant		12 Months Ended		
Accounting Policies - Summary of Outstanding Potentially Dilutive Securities Excluded in Calculation of Diluted Net Loss Per Share (Details) - shares	Dec. 31, 2021	Dec. 31, 2020		
Antidilutive Securities Excluded From Computation Of Earnings Per Share				
[Line Items]				
Anti-dilutive common equivalent shares	6,862,157	33,798,017		
ESPP Shares				
Antidilutive Securities Excluded From Computation Of Earnings Per Share				
[Line Items]				
Anti-dilutive common equivalent shares	16,606	0		
Series A				
Antidilutive Securities Excluded From Computation Of Earnings Per Share				
[Line Items]				
Anti-dilutive common equivalent shares	0	32,198,879		
Common Stock [Member]   Stock Option [Member]				
Antidilutive Securities Excluded From Computation Of Earnings Per Share				
[Line Items]				
Anti-dilutive common equivalent shares	6,591,727	641,427		
Unvested Common Stock				
Antidilutive Securities Excluded From Computation Of Earnings Per Share				
[Line Items]				
Anti-dilutive common equivalent shares	253,824	957,711		

Fair value measurements - Schedule of Fair Value	Dec. 31,
Liabilities Measured on	2020
Recurring Basis (Details)	USD (\$)
\$ in Thousands	
Fair Value Assets And Liabilities Measured On Recurring And Nonrecurring Basis [Line	
<u>Items</u> ]	
Embedded derivative liability	\$ (1,604)
Level 1	
Fair Value Assets And Liabilities Measured On Recurring And Nonrecurring Basis [Line	
<u>Items</u>	
Embedded derivative liability	0
Level 2	
Fair Value Assets And Liabilities Measured On Recurring And Nonrecurring Basis [Line	
<u>Items</u>	
Embedded derivative liability	0
Level 3	
Fair Value Assets And Liabilities Measured On Recurring And Nonrecurring Basis [Line	
Items	
Embedded derivative liability	\$ (1,604)

Fair Value Measurements - Additional Information (Detail) - USD (\$)	Mar. 19, 2021		ths Ended Dec. 31, 2020
Fair Value Assets And Liabilities Measured On Recurring And			
Nonrecurring Basis [Line Items]			
Convertible preferred stock issued upon conversion			7,748,113
Loss on extinguishment of convertible promissory note		\$ (754,000)	\$ 0
Series B2 Convertible Preferred Stock [Member]			
Fair Value Assets And Liabilities Measured On Recurring And			
Nonrecurring Basis [Line Items]			
Promissory note and derivative liability conversion into share	2,805,850		
Convertible preferred stock issued upon conversion	2,805,850		
Operating Expense [Member]			
Fair Value Assets And Liabilities Measured On Recurring And			
Nonrecurring Basis [Line Items]			
Change in fair value of embedded derivative liability		200	\$ 200
Operating Expense [Member]   Series B2 Convertible Preferred Stock			
[Member]			
Fair Value Assets And Liabilities Measured On Recurring And			
Nonrecurring Basis [Line Items]			
Loss on extinguishment of convertible promissory note		800,000	
Fair Value, Recurring [Member]			
Fair Value Assets And Liabilities Measured On Recurring And			
Nonrecurring Basis [Line Items]			
Liabilities measured at fair value		0	
Asset Measured at fair value		\$ 0	

Fair Value Measurements - Schedule of Significant Unobservable Inputs Used in the Fair Value Measurements for the Derivative Liability (Details)	Mar. 19, 2021	Dec. 31, 2020	Aug. 20, 2020
Measurement Input Probability Of Financing [Member]			
<u>Fair Value Assets And Liabilities Measured On Recurring And</u> Nonrecurring Basis [Line Items]			
Derivative liability	100	90	90
Measurement Input Probability Of Dissolution [Member]			
Fair Value Assets And Liabilities Measured On Recurring And			
Nonrecurring Basis [Line Items]			
Derivative liability	0	10	10
Measurement Input, Expected Term [Member]			
Fair Value Assets And Liabilities Measured On Recurring And			
Nonrecurring Basis [Line Items]			
Derivative liability	0		
Measurement Input, Expected Term [Member]   Minimum			
Fair Value Assets And Liabilities Measured On Recurring And			
Nonrecurring Basis [Line Items]			
Derivative liability		0.50	0.83
Measurement Input, Expected Term [Member]   Maximum			
Fair Value Assets And Liabilities Measured On Recurring And			
Nonrecurring Basis [Line Items]			
Derivative liability		1.00	1.33
Measurement Input, Discount Rate [Member]			
Fair Value Assets And Liabilities Measured On Recurring And			
Nonrecurring Basis [Line Items]			
Derivative liability	7.6	8.3	11.9

Fair Value Measurements - Schedule of Reconciliation of	12 Mont	hs Ended
the Fair Value of the Derivative Liability Using Level 3 Significant Unobservable Inputs (Details) - Level 3 - USD (\$)	Dec. 31, 2021	Dec. 31, 2020
\$ in Thousands Fair Value Assets And Liabilities Measured On Recurring And Nonrecurring Basis		
[Line Items]		
Beginning balance	\$ (1,604)	<b>\$</b> 0
Fair value of derivative liability at issuance of convertible promissory note		(1,791)
Change in fair value of derivative liability (Note 7)		187
Ending balance	0	\$ (1,604)
Change in the fair value of the derivative liability	(205)	
Reclassification of derivative liability into convertible preferred stock resulting from conversion of convertible promissory note	\$ 1,809	

Grant Agreement - Additional Information	12 Months Ended		
(Details) - USD (\$) \$ in Millions	Dec. 31, 2021 Dec. 31, 202		
<b>Grant Agreement [Line Items</b>	1		
Restricted Cash	\$ 1.6		
BMSF Grant			
Grant Agreement [Line Items	1		
Grant Received	10.0		
Funding received	6.0	\$ 4.0	
Revenue from grant	7.8	1.6	
Revenue since inception	9.4		
Restricted Cash	0.6	2.3	
Deferred revenue	\$ 0.6	\$ 2.3	

**Balance Sheet Details 12 Months Ended** (Additional Information) (Details) - USD (\$) Dec. 31, 2021 Dec. 31, 2020 **\$** in Thousands **Balance Sheet Related Disclosures [Abstract]** \$ 82

**Depreciation expenses** 

\$1

Balance Sheet Details - Schedule of property and equipment (Details) - USD (\$) \$ in Thousands	Dec. 31, 202	1 Dec. 31, 2020
<b>Property and Equipment [Line Items</b>	1	
Property and equipment, cost	\$ 1,159	\$ 11
Accumulated depreciation	(83)	(1)
Property and equipment, net, Total	1,076	10
Laboratory equipment [Member]		
<b>Property and Equipment [Line Items</b>	1	
Property and equipment, cost	856	11
Construction in progress [Member]		
<b>Property and Equipment [Line Items</b>	1	
Property and equipment, cost	\$ 303	

# Balance Sheet Details -Schedule of Accrued and Other Current Liabilities (Details) - USD (\$) \$ in Thousands

Dec. 31, 2021 Dec. 31, 2020

## **Balance Sheet Related Disclosures [Abstract]**

Taxes payable	<b>\$</b> 0	\$ 91
Accrued paid time off	342	137
Accrued bonus	2,216	696
Other accrued liabilities	1,977	608
Accrued 401k	156	0
ESPP liability	66	0
Total accrued and other current liabilities	\$ 4,757	\$ 1,532

License Agreements -		12 Months Ended		
Additional Information (Details) - USD (\$) \$ in Thousands	Dec. 31, 2021	Dec. 31, 2020	Aug. 01, 2018	
Collaborative Arrangements And Noncollaborative Arrangement				
Transactions [Line Items]				
Common stock, shares issued	39,429,103	33,596,936		
NIH Agreement				
Collaborative Arrangements And Noncollaborative Arrangement				
Transactions [Line Items]	<b>A</b> 100 000			
Payment Of License Fee	\$ 100,000			
Potential milestone payments	2,100			
Potential milestone payments	6,500			
NIH Agreement   Research and Development Expense				
Collaborative Arrangements And Noncollaborative Arrangement				
Transactions [Line Items]	• • •	<b>.</b>		
Payment Of License Fee	200	\$ 100		
U W Two Thousand And Eighteen Agreement				
Collaborative Arrangements And Noncollaborative Arrangement				
Transactions [Line Items]				
Common stock, shares issued			192,276	
Potential Payments For Future Development Regulatory And Sales Based	1,400			
Milestones				
Total Milestone Payments	6,800			
U W Two Thousand And Eighteen And U W Two Thousand And Twenty				
Agreement   License				
<u>Collaborative Arrangements And Noncollaborative Arrangement</u>				
Transactions [Line Items]	200	¢ 200		
Payment Of License Fee	200	\$ 300		
<u>U T Agreement</u>				
<u>Collaborative Arrangements And Noncollaborative Arrangement</u> <u>Transactions [Line Items]</u>				
Potential milestone payments	800			
Potential milestone payments	3,800			
UW Flu License Agreement	,			
Collaborative Arrangements And Noncollaborative Arrangement				
Transactions [Line Items]				
Payment Of License Fee	100			
Aggregate Payments Related To Development	350			
Aggregate Payments Related To Cumulative Net Sales Thresholds	\$ 6,000			
License Agreement Expiry Year	2041			

Convertible Promissory Note			1 Months Ended	12 Months Ended
- Additional Information (Details) - USD (\$)	Mar. 31 2021	, Mar. 19, 2021	Aug. 31, 2020	Dec. 31, Dec. 31, 2021 2020
Debt Conversion [Line Items]				
Convertible promissory note issued			\$ 6,500,000	
Accrued interest rate, per annum			6.00%	
Promissory note maturity period			2 years	2 years
Derivatives liability, carrying value				\$\$
				1,800,0001,600,000
Payments of Debt Issuance Costs				\$ 36,000
Debt discount interest rate, effective percentage				23.80%
Loss on extinguishment of convertible promissory note				\$ (754,000) <sup>\$</sup> 0
Convertible Promissory Note				
Debt Conversion [Line Items]				
Debt Conversion, Converted Instrument, Amount			\$	
			140,000,000	)
Loss on extinguishment of convertible promissory note				\$ 800,000
Series A3 Convertible Preferred Stock   Convertible				
Promissory Note				
Debt Conversion [Line Items]				
Share price, percentage			85.00%	
Series B2 Convertible Preferred Stock [Member]				
Debt Conversion [Line Items]				
Share price, percentage	85.00%			
Promissory note and derivative liability conversion into		2,805,850	)	
share		2,805,850	)	
Shares issued price per share		\$ 2.39846	Ď	
Minimum [Member]   Series A3 Convertible Preferred				
Stock   Convertible Promissory Note				
<b>Debt Conversion [Line Items]</b>				
Proceeds from Convertible Debt			\$	
			5,000,000.0	

Convertible Promissory Note - Summary of Convertible Promissory Note (Details) - Promissory Note [Member] \$ in Thousands	Dec. 31, 2020 USD (\$)
Summary Of Investment Holdings [Line Items]	
Principal amount	\$ 6,500
Discount related to the derivative liability and issuance costs	<u>s</u> (1,553)
Net carrying amount of Convertible Promissory Note	\$ 4,947

Convertible Promissory Note - Summary of Interest	12 Months Ended		
Expense of Convertible Promissory Note (Details) -	Dec 31 202	1 Dec. 31, 2020	
USD (\$) \$ in Thousands	Dec. 51, 202	1 Dec. 51, 2020	
<u>Convertible Promissory Note [Abstract]</u>			
Coupon interest at 6%	\$ 86	\$ 143	
Accretion of discount and amortization of issuance costs	177	274	
Total interest expense on Convertible Promissory Note	\$ 263	\$ 417	

Convertible Preferred Stock and Stockholders' Equity (Deficit) - Schedule of Convertible Preferred Stock (Details) \$ in Thousands	Dec. 31, 2020 USD (\$) shares
<u>Class Of Stock [Line Items]</u>	
Share Authorized and Outstanding	54,039,749
Shares Issued and Outstanding	32,198,879
Convertible preferred stock issued upon conversion	7,748,113
Aggregate Liquidation Preference   \$	\$ 30,007
Carrying Value   \$	\$ 30,062
Series A-1	
Class Of Stock [Line Items]	
Share Authorized and Outstanding	49,089,955
Shares Issued and Outstanding	27,249,085
Convertible preferred stock issued upon conversion	6,557,031
Aggregate Liquidation Preference   \$	\$ 26,200
Carrying Value   \$	\$ 25,912
Series A-2	
Class Of Stock [Line Items]	
Share Authorized and Outstanding	4,949,794
Shares Issued and Outstanding	4,949,794
Convertible preferred stock issued upon conversion	1,191,082
Aggregate Liquidation Preference   \$	\$ 3,807
Carrying Value   \$	\$ 4,150

Convertible Preferred Stock						1 Months	Ended		12 Mont	hs Ended
and Stockholders' Equity (Deficit) - Additional Information (Details) - USD (\$)	Aug. 04, 2021	Aug. 02, 2021	Mar. 31, 2021	Mar. 19, 2021	Aug. 31, 2021	Jul. 31, 2021	Feb. 28, 2021	Aug. 31, 2020	Dec. 31, 2021	Dec. 31, 2020
Class Of Stock [Line Items]										
Reverse Stock Split			1-for-4.1557	7		1-for-4.1557				
Preferred stock, shares issued									0	0
Preferred stock, par value									\$ 0.0001	\$ 0.0001
Preferred stock, shares outstanding									0	0
<u>Common stock, shares</u>										
authorized		500,000,000							500,000,000	78,000,000
Preferred stock, shares		50,000,000							50,000,000	0
authorized		50,000,000							50,000,000	0
<u>Proceeds from issuance of</u> <u>convertible preferred stock, net</u>									\$	¢ 0.
of issuance costs	L								113,634,000	\$ 0
Payments of Debt Issuance									<b>A A C A A</b>	
Costs									\$ 36,000	
Convertible promissory note								\$		
issued								6,500,000		
<u>Convertible preferred stock</u> Sale of common stock									16,351,336 39,429,103	3 506 036
<u>Common Stock Shares</u>										
Outstanding									39,175,279	2,639,026
Common stock, par value									\$ 0.0001	\$ 0.0001
Restricted common stock, vested									2,347,629	1,995,314
Restricted common									0	
stock,Expected to vest										
<u>Granted</u>									6,177,633	D. Ø. 257 000
Stock-based compensation Stock-based compensation									\$ 29,031,000	5 257,000
expense related to the ESPP									29,031,000	\$ 257,000
Board of Directors Chairman										
Class Of Stock [Line Items]										
Accelerated vesting of shares	611,639	)								
<u>Exercise price range, lower</u> range limit	\$ 0.83									
Exercise price range, upper range limit	\$ 5.90									
Stock-based compensation									21,000,000.	0
Stock Options [Member]										
Class Of Stock [Line Items]										
Cash Recieved For Exercise Of Non Vested Options									\$ 200,000	
Weighted-average grant date										
fair value									\$ 8.52	\$ 1.06
Granted									6,177,633	271,405
Fair Value Of Option Granted									\$ 48,300,000	0\$ 300
Employee Service										
Compensation expense recognition vesting period									3 years 4 months 28 days	4 years
Share-based Payment Arrangement, Nonvested										
Award, Option, Cost Not yet									\$ 39,400,000	0
Recognized, Amount										

Restricted Stock				
Class Of Stock [Line Items]				
Sale of common stock			269,694	269,694
Common stock, par value				\$ 0.004
Share-based Payment			¢	
Arrangement, Nonvested Award, Option, Cost Not yet			\$ 9,000,000.0	
Recognized, Amount			9,000,000.0	
Restricted Stock				
Management				
Class Of Stock [Line Items]				
Sale of common stock			2,347,629	2,347,629
Common stock, par value			\$ 0.004	
Restricted Stock Units (RSUs)				
[Member]				
Class Of Stock [Line Items]				
<u>Weighted-average grant date</u> fair value			\$ 25.96	
Granted			388,500	0
Fair Value Of Option Granted				
Employee Service			\$ 10,100,00	0
2021 Stock Incentive Plan				
Class Of Stock [Line Items]				
Convertible preferred stock			4,600,000	
Sale of common stock			50,000,000	
Stock option granted vesting			4	
period			4 years	
Stock option granted			10 years	
maximum term			10 9 0000	
Percentage Of Exercise Price			100.000/	
<u>To Fair Market Value</u> <u>Common Stock On Grant Date</u>			100.00%	
Percentage Increase In				
Common Stock Shares			5.00%	
Reserved For Future Issuance				
Increase In Common Stock				
Shares Reserved For Future			1,971,455	
Issuance				
Percentage Of Common Stock			5.00%	
Outstanding				
2021 Stock Incentive Plan   Stock Options [Member]				
Class Of Stock [Line Items]				
Percentage Of Exercise Price				
To Fair Market Value			110.00%	
Common Stock On Grant Date				
IPO [Member]				
Class Of Stock [Line Items]				
Common stock converted	21,634,898	21,634,898		
Preferred stock, shares	89,908,215		0	
outstanding				
Sale of common stock	12,133,333			
Employee Stock [Member]				
Class Of Stock [Line Items] Convertible preferred stock			400,000	
Sale of common stock			400,000	
Percentage Increase In			12,000,000	
Common Stock Shares			1.00%	
Reserved For Future Issuance				

Increase In Common Stock Shares Reserved For Future			394,291
Issuance Percentage Of Common Stock			1.00%
Outstanding			1.0070
Number of purchased shares			16,606
by the employee Stock-based compensation			
expense related to the ESPP			\$ 100,000
Series A-1 Convertible			
Preferred Stock [Member]			
Class Of Stock [Line Items]			
Convertible preferred stock,			
shares issued		21,944,874	
Series B Preferred Stock			
[Member]			
Class Of Stock [Line Items]			
Preferred stock, shares issued	35,764,462		
Proceeds from issuance of	\$		
convertible preferred stock, net	92,700,000		
of issuance costs	, _,, ,		
Convertible Preferred Stock			
[Member]			
Class Of Stock [Line Items]	¢ o ooo1		
Preferred stock, par value	\$ 0.0001		
Series B-1 Convertible			
Preferred Stock [Member]			
Class Of Stock [Line Items]	22.059.612		
Preferred stock, shares issued	32,958,612 \$ 2.82172		
Preferred stock, par value	\$ 2.82172		
Payments of Debt Issuance Costs	\$ 350,000		
Convertible promissory note			
issued	6,500,000		
Accrued Liabilities	\$ 200,000		
Series B2 Convertible	4 200,000		
Preferred Stock [Member]			
Class Of Stock [Line Items]			
Preferred stock, shares issued	2,805,850		
Promissory note and derivative			
liability conversion into share	2,805,850		
Shares issued price per share	\$ 2.39846		
Debt Conversion, Converted	85.00%		
Instrument, Rate	03.0070		

Convertible Preferred Stock and Stockholders' Equity	12 Months Ended	
(Deficit) - Summary of the Status of the Options Issued Under the Plan (Details) - USD (\$) \$ / shares in Units, \$ in	Dec. 31, 2021	Dec. 31, 2020
Thousands		
Stockholders Equity Note [Abstract]		
Option Pool Available for Grant ,Balance at December 31, 2020	541,411	
Authorized increase in plan shares	22,634,965	
Granted	(6,177,633)	
Options Outstanding, Balance at December 31, 2020	641,427	
Granted	6,177,633	
Exercise of common stock options, (in shares)	227,333	
Option Pool Available for Grant ,Balance at December 31, 2021	16,998,743	541,411
Options Outstanding, Balance at December 31, 2021	6,591,727	641,427
Weighted average exercise price per share, Balance at December 31, 202	<u>1</u> \$8.04	\$ 0.84
Vested and expected to vest as of December 31, 2021	6,591,727	
Vested and exercisable at December 31, 2021	826,952	
Weighted average exercise price per share, Balance at December 31, 202	<u>0</u> \$0.84	
Granted	8.52	
Exercised (including early)	0.84	
Vested and expected to vest as of December 31, 2021	8.04	
Vested and exercisable at December 31, 2021	\$ 5.71	
Weighted average remaining contractual term (Years)	9 years 3 months 3 day	vs 9 years 7 days
Vested and expected to vest as of December 31, 2021	9 years 3 months 3 day	/S
Vested and exercisable at December 31, 2021	9 years 18 days	
Aggregate intrinsic value, Balance at December 31, 2020	\$ 0	
Aggregate intrinsic value, Balance at December 31, 2021	101,725,631	\$ O
Exercised (including early)	1,012,104	
Vested and expected to vest as of December 31, 2021	101,725,631	
Vested and exercisable at December 31, 2021	\$ 14,199,668	

Convertible Preferred Stock and Stockholders' Equity (Deficit) - Schedule of Common Stock Reserved for Future Issuance (Details)	Dec. 31, 2021 shares
Share Based Compensation Arrangement By Share Based Payment Award [Line Items]	L
Common Stock, Capital Shares Reserved for Future Issuance	16,351,336
Common Stock Options and Restricted Stock Units [Member]	
Share Based Compensation Arrangement By Share Based Payment Award [Line Items]	L
Common Stock, Capital Shares Reserved for Future Issuance	6,980,227
Equity Incentive Plan [Member]	
Share Based Compensation Arrangement By Share Based Payment Award [Line Items]	L
Common Stock, Capital Shares Reserved for Future Issuance	8,187,715
2021 Employee Stock Purchase Plan [Member]	
Share Based Compensation Arrangement By Share Based Payment Award [Line Items]	L
Common Stock, Capital Shares Reserved for Future Issuance	1,183,394

Convertible Preferred Stock and Stockholders' Equity	12 Months Ended	
(Deficit) - Schedule of Stock- based Compensation Expense for All Equity Awards (Details) - USD (\$) \$ in Thousands	Dec. 31, 2021	Dec. 31, 2020
Class Of Stock [Line Items]		
Stock-based compensation expense related to the ESPF	\$ 29,031	\$ 257
Research and Development Expense [Member]		
Class Of Stock [Line Items]		
Stock-based compensation expense related to the ESPF	2,710	137
General and Administrative [Member]		
Class Of Stock [Line Items]		
Stock-based compensation expense related to the ESPF	\$ 26,321	\$ 120

Convertible Preferred Stock and Stockholders' Equity	12 Mor	ths Ended
(Deficit) - Summary of Assumptions Used in Black- Scholes Model (Details)	Dec. 31, 2021	Dec. 31, 2020
Class Of Stock [Line Items]		
Risk-free rate of interest, Minimum	0.63%	0.31%
Risk-free rate of interest, Maximum	1.34%	1.40%
Expected stock price volatility, Minimum	84.20%	80.20%
Expected stock price volatility, Maximum	90.90%	86.40%
Dividend yield	0.00%	0.00%
Maximum [Member]		
Class Of Stock [Line Items]		
Expected term (years)	6 years 29 days	6 years 29 days
Minimum [Member]		
Class Of Stock [Line Items]		
Expected term (years)	5 years 9 months 7 days	s 5 years 10 months 24 days

Income Taxes -	12 Months Ended		
Reconciliation of Federal Statutory Income Tax Rate and Effective Income Tax Rate (Detail)	Dec. 31, 202	1 Dec. 31, 2020	
Income Tax Disclosure [Abstract]			
U.S. federal statutory income tax rate	21.00%	21.00%	
State income taxes, net of federal tax	1.00%	0.60%	
Other permanent differences	(0.40%)	(0.30%)	
Research and development tax credits	3.10%	3.80%	
Research and Development Credit Permanent Adjustmen	<u>t</u> (0.60%)	(1.30%)	
Stock-based compensation	(1.60%)	(0.30%)	
Uncertain Tax Positions	(0.80%)	(1.00%)	
Change in valuation allowance	(21.70%)	(22.50%)	
Effective Income Tax Rate Reconciliation, Percent, Total	0.00%	0.00%	

Income Taxes - Deferred Tax Assets (Liabilities) Included in Other Assets in Consolidated Balance Sheet (Detail) - USD (\$) \$ in Thousands Deferred tax assets	Dec. 31, 202	1 Dec. 31, 2020
Net operating loss carryforwards	\$ 12,623	\$ 4,549
Research and development credits	2,349	790
Deferred revenue	126	515
Stock-based compensation	5,192	0
Other	533	226
Total deferred tax assets	20,823	6,080
Less: deferred tax liabilities	(280)	(3)

(20,543)

**\$ 0** 

Less: valuation allowance

Deferred Tax Assets, Net, Total

(6,077)

Copyright © 2022 <u>www.secdatabase.com</u>. All Rights Reserved. Please Consider the Environment Before Printing This Document

\$0

Income Taxes - Additional Information (Detail) - USD	12 Months Ended	
(\$)	Dec. 31, 2021	Dec. 31, 2020
\$ in Thousands		
<b>Operating Loss Carryforwards [Line Items]</b>		
Deferred tax assets, valuation allowance	\$ 20,543	\$ 6,077
Increase in valuation allowance	14,400	
Research and development credits	\$ 2,349	\$ 790
Federal Operating Loss Carry forwards Expiration Period	2037	
State Operating Loss Carry forwards Expiration Period	2035	
<b>Operating Loss Carry Forwards Expiration Period</b>	2037	
Federal		
<b>Operating Loss Carryforwards [Line Items]</b>		
Operating loss carryforwards	\$ 57,000	
State		
<b>Operating Loss Carryforwards [Line Items]</b>		
Operating loss carryforwards	11,900	
Research and Development Tax Credit Carryforwards   Federa	<u>ıl</u>	
<b>Operating Loss Carryforwards [Line Items]</b>		
Research and development credits	3,000	
Research and Development Tax Credit Carryforwards   State		
<b>Operating Loss Carryforwards [Line Items]</b>		
Research and development credits	\$ 168,000	

Income Taxes - Summary of Unrecognized Tax Benefits	12 Months Ended	
(Detail) - USD (\$) \$ in Thousands	Dec. 31, 2021	Dec. 31, 2020
Income Tax Disclosure [Abstract]		
Unrecognized tax benefits, beginning of year	\$ 263	\$ 84
Additions based on tax positions relating to current year	495	242
Additions based on tax positions relating to prior year	0	0
Reductions for positions of prior years	0	(63)
Unrecognized tax benefits, end of year	\$ 758	\$ 263

Employee Savings Plan - Additional Information	12 Months Ended	
(Details) - USD (\$)	Dec. 31, 202	21 Dec. 31, 2020
\$ in Thousands		
<b>Defined Contribution Plan Disclosure [Line Items</b>	1	
Employer discretionary contribution amount	\$ 0	<b>\$</b> 0
<u>Maximum</u>		
Defined Contribution Plan Disclosure [Line Items	1	
Percent of employees gross pay	90.00%	