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

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 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	**82-3640549**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1616 Eastlake Avenue E., Suite 208 Seattle, Washington	**98102**
(Address of principal executive offices)	**(Zip Code)**

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

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

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

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

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

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑
As of September 10, 2021, the registrant had 39,387,386 shares of common stock ($0.0001 par value) outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements (unaudited)

ICOSAVAX, INC.

Condensed Balance Sheets
(in thousands, except share and par value data)

	June 30, 2021 (Unaudited)	December 31, 2020 (Note 2)
Assets		
Current assets:		
Cash	$ 110,585	$ 13,114
Restricted cash	1,179	2,384
Prepaid expenses and other current assets	4,119	662
Total current assets	115,883	16,160
Property and equipment, net	561	10
Deferred offering costs	2,265	—
Total assets	$ 118,709	$ 16,170
Liabilities, convertible preferred stock, and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 3,111	$ 1,918
Accrued and other current liabilities	1,825	1,532
Deferred revenue	1,179	2,384
Total current liabilities	6,115	5,834
Long-term convertible promissory note	—	4,947
Embedded derivative liability	—	1,604
Other noncurrent liabilities	279	426
Total liabilities	6,394	12,811
Commitments and contingencies *(Note 2)*		
Convertible preferred stock, $0.0001 par value; 89,908,215 and 54,039,749 shares authorized at June 30, 2021 and December 31, 2020, respectively; 89,908,215 and 32,198,879 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively; $150,837 and $30,007 aggregate liquidation preference at June 30, 2021 and December 31, 2020, respectively	151,613	30,062
Stockholders' deficit:		
Common stock, $0.0001 par value; 134,329,408 and 78,000,000 shares authorized at June 30, 2021 and December 31, 2020; 3,741,667 and 3,596,936 shares issued as of June 30, 2021 and December 31, 2020, respectively; 3,072,402 and 2,639,026 shares outstanding as of June 30, 2021 and December 31, 2020, respectively	2	2
Additional paid-in capital	2,201	393
Accumulated deficit	(41,501)	(27,098)
Total stockholders' deficit	(39,298)	(26,703)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 118,709	$ 16,170

See accompanying notes to financial statements

ICOSAVAX, INC.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Grant revenue	$ 1,904	$ —	$ 3,905	$ —
Operating expenses:				
Research and development	8,277	4,666	13,830	7,586
General and administrative	2,221	541	3,312	1,153
Total operating expenses	10,498	5,207	17,142	8,739
Loss from operations	(8,594)	(5,207)	(13,237)	(8,739)
Other income (expense):				
Change in fair value of embedded derivative liability	—	—	(205)	—
Loss on extinguishment of convertible promissory note	—	—	(754)	—
Interest and other income (expense)	42	9	(207)	70
Total other income (expense)	42	9	(1,166)	70
Net loss and comprehensive loss	$ (8,552)	$ (5,198)	$ (14,403)	$ (8,669)
Net loss per share, basic and diluted	$ (2.86)	$ (2.45)	$ (5.00)	$ (4.23)
Weighted-average common shares outstanding, basic and diluted	2,985,183	2,119,312	2,878,163	2,047,803

See accompanying notes to financial statements

ICOSAVAX, INC.

Condensed Statements of Convertible Preferred Stock and Stockholders' Deficit

(Unaudited)

(in thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2020	32,198,879	$ 30,062	2,639,026	$ 2	$ 393	$ (27,098)	$ (26,703)
Issuance of Series A-1 convertible preferred stock for cash of $0.9615 per share net of $95,000 of issuance costs	21,944,874	21,005	—	—	—	—	—
Issuance of Series B-1 convertible preferred stock for cash of $2.82172 per share net of $346,000 in issuance costs	32,958,612	92,654	—	—	—	—	—
Issuance of Series B-2 convertible preferred stock from convertible note	2,805,850	7,917	—	—	—	—	—
Shares released from restriction upon vesting of early-exercised stock options	—	—	100,238	—	63	—	63
Exercise of common stock options	—	—	35,143	—	29	—	29
Vesting of shares of restricted common stock	—	—	117,369	—	—	—	—
Stock-based compensation	—	—	—	—	276	—	276
Net loss and comprehensive loss	—	—	—	—	—	(5,851)	(5,851)
Balance at March 31, 2021	89,908,215	151,638	2,891,776	2	761	(32,949)	(32,186)
Issuance costs incurred related to Series A-1 convertible preferred stock	—	(1)	—	—	—	—	—
Issuance costs incurred related to Series B-1 convertible preferred stock	—	(24)	—	—	—	—	—
Shares released from restriction upon vesting of early-exercised stock options	—	—	63,257	—	32	—	32
Vesting of shares of restricted common stock	—	—	117,369	—	—	—	—
Stock-based compensation	—	—	—	—	1,408	—	1,408
Net loss and comprehensive loss	—	—	—	—	—	(8,552)	(8,552)
Balance at June 30, 2021	89,908,215	$ 151,613	3,072,402	$ 2	$ 2,201	$ (41,501)	$ (39,298)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
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	—	—	25,641	—	1	—	1
Vesting of shares of restricted common stock	—	—	117,369	—	—	—	—
Stock-based compensation	—	—	—	—	54	—	54
Net loss and comprehensive loss	—	—	—	—	—	(3,471)	(3,471)
Balance at March 31, 2020	32,198,879	30,062	2,044,666	1	55	(11,715)	(11,659)
Stock-based compensation	—	—	—	—	63	—	63
Net loss and comprehensive loss	—	—	—	—	—	(5,198)	(5,198)
Balance at June 30, 2020	32,198,879	$ 30,062	$ 2,044,666	$ 1	$ 118	$ (16,913)	$ (16,794)

See accompanying notes to financial statements

ICOSAVAX, INC.

Condensed Statements of Cash Flows
(Unaudited)
(in thousands)

	Six Months Ended June 30,	
	2021	**2020**
Operating activities:		
Net loss	$ (14,403)	$ (8,669)
Adjustments to reconcile net loss to cash used in operating activities:		
Stock-based compensation	1,684	117
Depreciation	17	—
Non-cash interest expense	264	—
Change in fair value of embedded derivative liability	205	—
Loss on extinguishment of convertible promissory note	754	—
Changes in operating assets and liabilities:		
Prepaids and other current assets	(3,457)	(385)
Accounts payable	359	130
Accrued and other current liabilities	(396)	724
Deferred revenue	(1,205)	—
Net cash used in operating activities	(16,178)	(8,083)
Investing activities:		
Purchases of property and equipment	(568)	(5)
Net cash used in investing activities	(568)	(5)
Financing activities:		
Proceeds from issuance of convertible preferred stock, net of issuance costs	113,634	—
Proceeds from exercise of stock options, including early exercise	120	66
Payment of deferred offering costs	(742)	—
Net cash provided by financing activities	113,012	66
Net increase (decrease) in cash and restricted cash	96,266	(8,022)
Cash and restricted cash at beginning of period	15,498	23,079
Cash and restricted cash at end of period	$ 111,764	$ 15,057
Supplemental disclosure of noncash activities		
Conversion of convertible note (including accrued interest) and embedded derivative liability for Series B-2 convertible preferred stock	$ 7,917	$ —
Unpaid initial public offering costs	$ 1,524	$ —
Purchases of property and equipment included in accounts payable	$ 151	$ 5

See accompanying 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 one-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 preferred stock. Accordingly, all share and per share amounts for all periods presented in the accompanying condensed financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split and adjustment of the 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 approximately $190.6 million, after deducting underwriting discounts and commissions and estimated offering expenses. Upon the closing of the IPO, all 89,908,215 shares of the then outstanding preferred stock automatically converted into 21,634,898 shares of common stock.

Liquidity

The Company had an accumulated deficit of $41.5 million, cash of $110.6 million, and restricted cash of $1.2 million at June 30, 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 condensed 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 June 30, 2021, the Company has funded its operations through the issuance of convertible promissory notes and sale of its convertible preferred stock. On August 2, 2021, the Company completed its IPO and received net proceeds of $190.6 million.

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 unaudited condensed financial statements as of June 30, 2021 and for the three and six months ended June 30, 2021 and 2020 have been prepared in conformity with generally accepted accounting principles ("GAAP") in the United States of America for interim financial information and pursuant to Article 10 of Regulation S-X of the Securities Act of 1933, as amended (the

"Securities Act"). Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. These unaudited condensed financial statements include only normal and recurring adjustments that the Company believes are necessary to fairly state the Company's financial position and the results of its operations and cash flows. The results for the three and six months ended June 30, 2021 are not necessarily indicative of the results expected for the full fiscal year or any subsequent interim period. The condensed balance sheet at December 31, 2020 has been derived from the audited financial statements at that date but does not include all disclosures required by GAAP for complete financial statements. Because all of the disclosures required by GAAP for complete financial statements are not included herein, these unaudited condensed financial statements and the notes accompanying them should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2020 included in the Company's final prospectus for its IPO filed pursuant to Rule 424(b)(4) under the Securities Act, with the Securities and Exchange Commission (the "SEC") on July 22, 2021.

Use of Estimates

The Company's significant accounting policies are described in Note 2, "Summary of significant accounting policies," of the Company's audited financial statements for the year ended December 31, 2020 included in the Company's final prospectus for its IPO filed with the SEC. There have been no material changes to the significant accounting policies previously disclosed in those audited financial statements.

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.

Deferred Offering Costs

At June 30, 2021, the Company has deferred offering costs consisting of legal, accounting and other fees and costs directly attributable to its IPO. Deferred offering costs of $2.3 million that were recorded within long-term assets on the condensed balance sheet at June 30, 2021 were offset against the proceeds received upon completion of the IPO in August 2021.

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.

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 is remeasured on a recurring basis. Any changes in fair value are reflected as change in 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.

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 434,250 and 488,226 shares as of June 30, 2021 and December 31, 2020, respectively. As of June 30, 2021 and December 31, 2020, the Company recorded $279,000 and $283,000, respectively, associated with shares issued with repurchase rights as other noncurrent liabilities in the accompanying condensed balance sheets.

Commitments and Contingencies

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

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

The Company has not recorded any such liabilities at either June 30, 2021 or December 31, 2020.

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):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Numerator:				
Net Loss	$ (8,552)	$ (5,198)	$ (14,403)	$ (8,669)
Denominator:				
Weighted-average common shares outstanding, basic and diluted	3,741,667	3,468,027	3,708,083	3,464,529
Less: Weighted average unvested common stock	(756,484)	(1,348,715)	(829,920)	(1,416,726)
Weighted average shares used to compute net loss per share, basic and diluted	2,985,183	2,119,312	2,878,163	2,047,803
Net loss per share, basic and diluted	$ (2.86)	$ (2.45)	$ (5.00)	$ (4.23)

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.

	As of June 30,	
	2021	2020
Series A convertible preferred stock	54,143,753	32,198,879
Series B convertible preferred stock	35,764,462	—
Common stock options	5,131,318	698,107
Unvested common stock	669,013	1,280,201
Total	95,708,546	34,177,187

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 condensed financial statements and related disclosures.

There were no other significant updates to the recently issued accounting standards other than as disclosed herewith for the three and six months ended June 30, 2021. Although there are several other new accounting pronouncements issued or proposed by the FASB, the Company does not believe any of those accounting pronouncements have had or will have a material impact on its financial position or operating results.

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		
	Total	**(Level 1)**	**(Level 2)**	**(Level 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 June 30, 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
Probability of financing	100%
Probability of dissolution	0%
Time to liquidity (years)	0%
Discount rate	7.6%

The Company adjusted the carrying value of the derivative liability within the convertible promissory note to the estimated fair value at each reporting date, with any related increases or decreases in the fair value recorded as change in fair value of derivative liability in the statements of operations and comprehensive loss.

For the period from January 1, 2020 to June 30, 2020 and for the three and six months ended June 30, 2020, there was no change in the fair value of the derivative liability recognized in the statements of operations and comprehensive loss.

For the three and six months ended June 30, 2021 the Company recognized $0 and $205,000, respectively, of other expense in the statements of operations and comprehensive loss related to increases in the fair value of the 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 notes of $754,000 in other expense in the condensed statements of operations and comprehensive loss for the six months ended June 30, 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):

	Convertible Promissory Note
Fair value at December 31, 2020	$ (1,604)
Change in fair value of embedded derivative liability	(205)
Reclassification of derivative liability into convertible stock resulting from conversion of convertible promissory note	1,809
Fair value at June 30, 2021	$ —

4. Grant Agreement

Bill & Melinda Gates Foundation Grant Agreement

In support of the Company's development of a SARS-CoV-2 vaccine, 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 supports 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 a SARS-CoV-2 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 both December 31, 2020 and June 30, 2021, the Company's current restricted cash and deferred revenue balances on the condensed balance sheet represent funds received from BMGF and its estimate of costs to be reimbursed and revenue to be recognized, respectively, in the next twelve months under the Grant Agreement.

During the three and six months ended June 30, 2020, no funding had been received from BMGF. During the three and six months ended June 30, 2021, the Company received $0 and $2.7 million, respectively from BMGF.

During the three and six months ended June 30, 2021, the Company recognized revenue from the Grant of $1.9 million and $3.9 million, respectively and has recognized approximately $5.5 million in revenue since the inception of the Grant Agreement.

In July 2021, the Company received the final $3.3 million payment from the Grant Agreement.

5. Accrued and other current liabilities

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

	As of June 30, 2021	As of December 31, 2020
Taxes payable	$ —	$ 91
Accrued PTO	256	137
Accrued bonus	570	696
Accrued liabilities	999	608
Total accrued and other current liabilities	$ 1,825	$ 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 three months ended June 30, 2021 and 2020, the Company paid $0 in fees associated with the license and during the six months ended June 30, 2021 and 2020, the Company paid $25,000 and $0, respectively, in fees associated with the license, which were recorded as research and development expenses.

License Agreements with University of Washington

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, and certain other limited rights retained by University of Washington.

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 $1.35 million per indication, up to a maximum of $6.75 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 the University of Washington have been fulfilled, or the Company may terminate the entirety of the agreement upon written notice thereof to the University of Washington.

During the three and six months ended June 30, 2021 and 2020, the Company paid $5,000 and $5,000, respectively, in fees associated with the license, which were expensed as incurred.

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 an academic entity, University of Washington (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 Howard Hughes Medical Institute, and certain other limited rights retained by the University of Washington.

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 the University of Washington have been fulfilled, or the Company may terminate the entirety of the agreement upon written notice thereof to the University of Washington.

During the three and six months ended June 30, 2021 and 2020, the Company reimbursed the University of Washington for patent expenses under the UW 2018 Agreement and UW 2020 Agreement as amended of $40,000, $67,000, $13,000, and $56,000, respectively, which were expensed as incurred.

During the three and six months ended June 30, 2021 and 2020, the Company did not incur any other fees or make any payments associated with the UW 2020 Agreement as amended.

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 $775,000 with respect to future development and regulatory based milestones, and up to $3.75 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 the three and six months ended June 30, 2021, the Company has not incurred 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 a 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, IPO, or qualified Series B financing had not occurred prior to the maturity date at a price equal to an amount determined by dividing $140 million by the fully diluted capitalization of the Company at the time of conversion, or (iv) repaid upon a change in control for an amount equal to the issue price plus accrued and unpaid interest or an amount as would have been payable if the noteholders had optionally converted into shares of Series A-3 preferred stock. The Convertible Promissory Note was converted in March 2021 in connection with the Series B financing.

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

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

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

	Six Months Ended June 30, 2021
Coupon Interest at 6%	$ 86
Accretion of discount and amortization of issuance costs	178
Total interest expense on Convertible Promissory Note	$ 264

The company incurred no interest expense related to the Convertible Promissory Note in the three months ended June 30, 2021.

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 million and $0.8 million in other expense in the condensed statements of operations and comprehensive loss for the three and six months ended June 30, 2021, respectively, which included the unamortized debt issuance costs.

8. Convertible Preferred Stock and Stockholders' Deficit

Stockholders' Deficit

Under the Amended and Restated Certificate of Incorporation dated March 19, 2021, the Company had a total of 224,237,623 shares of capital stock authorized for issuance, consisting of 134,329,408 shares of common stock, par value of $0.0001 per share, and 89,908,215 shares of convertible preferred stock, par value of $0.0001 per share.

Convertible Preferred Stock—Series A-1

On August 15, 2019, the Company entered into a Series A convertible preferred stock purchase agreement (the "Series A Purchase Agreement"). Under the agreement, the Company issued 27,249,085 shares of Series A-1 convertible preferred stock ("Series A-1"), in an initial closing, at $0.9615 per share for total proceeds gross of $26.2 million.

The Series A Purchase Agreement provided for an additional closing for the Series A-1 purchasers for the issuance of 21,840,870 shares of Series A-1 preferred stock, at a purchase price of $0.9615 per share for aggregate cash proceeds of $21.0 million, to occur no later than April 1, 2021 upon the achievement of the Closing Milestones (as defined in the Series A Purchase Agreement) or a waiver of the Closing Milestones by the Company's Board of Directors.

The Company determined that the right of the investors to purchase an additional number of shares of Series A-1 convertible preferred stock upon the achievement of the Closing Milestones, did not meet the definition of a freestanding financial instrument as the preferred shares issued at the initial closing and the future tranche right were not legally detachable and separately exercisable.

A milestone closing of 21,944,874 Series A-1 shares closed in February 2021, which was contingent on the Company achieving certain regulatory, research and development and operational milestones. With the milestone closing, the Company sold 21,944,874 shares of Series A-1 preferred stock for gross proceeds of $21.1 million.

Conversion

Each share of Series A-1 is convertible into common stock: (i) at the option of the holder, or (ii) automatically upon the closing of a public offering with a price to the public of at least $17.58933 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Company's common stock) for at least $50 million in gross proceeds. The conversion ratio of Series A-1 to common stock is currently one-for-4.1557, subject to adjustment upon any future stock splits or stock dividends, issuance of additional shares for less consideration, other distribution of payable in securities, or upon a reorganization, recapitalization, reclassification, merger or consolidation of the Company.

Dividends

The holders of the Series A-1 convertible preferred stock have preferential rights over common stockholders to non-cumulative dividends payable when declared by the Board, at the annual rate of $0.07692 per share. Dividends were not declared during the year ended December 31, 2020 or the six months ended June 30, 2021.

Voting

Series A-1 stockholders are entitled to the number of votes equal to the number of shares of common stock into which the preferred stock could be converted. In addition, the Series A-1 stockholders have certain rights whereby the Company is precluded from carrying out certain actions specified in the Company's Amended and Restated Certificate of Incorporation without the approval of the holders of a majority of the Series A-1 shares.

Liquidation

Upon the occurrence of a liquidation event, the Series A-1 stockholders have preferential rights over common stockholders as to liquidation payments of their original issuance price of $0.9615 per share, plus any dividends declared and unpaid, on a pro rata, pari passu basis. Any additional distributions after the payment of the liquidation preferences of the Series A-1 shares and Series A-2 shares will be made to the holders of common stock on a pro rata basis.

Convertible Preferred Stock—Series A-2

Under the Series A Purchase Agreement, the Company also issued 4,929,794 shares of Series A-2 in 2019 with a fair value of $4.2 million (or $0.85 per share net of issuance cost of $57,000) upon conversion of Series 1 shares with a carrying value of $3.8 million (or $1.00 per share). The $400,000 difference between the fair value of Series A-2 and the carrying value of Series 1 was recorded as a $83,000 reduction to additional paid-in capital (bringing its balance to zero) with the remainder recorded as an increase to accumulated deficit.

Conversion

Each share of Series A-2 is convertible into common stock: (i) at the option of the holder, or (ii) automatically upon the closing of a public offering with a price to the public of at least $17.58933 per share (subject to appropriate adjustment in the event of any

stock dividend, stock split, combination or other similar recapitalization with respect to the Company's common stock) for at least $50 million in gross proceeds. The conversion ratio of Series A-2 to common stock is currently one-for-4.1557, subject to adjustment.

Dividends

The holders of the Series A-2 convertible preferred stock have preferential rights over common stockholders to non-cumulative dividends payable when declared by the Board, at the annual rate of $0.061536 per share. Dividends were not declared during the year ended December 31, 2020 or the three and six months ended June 30, 2021.

Voting

Series A-2 stockholders are entitled to the number of votes equal to the number of shares of common stock into which the preferred stock could be converted.

Liquidation

Upon the occurrence of a liquidation event, the Series A-2 stockholders have preferential rights over common stockholders as to liquidation payments of their original issuance price of $0.7692 per share, plus any dividends declared and unpaid, on a pro rata, pari passu basis. Any additional distributions after the payment of the liquidation preferences of the Series A-1 shares and Series A-2 shares will be made to the holders of common stock on a pro rata basis.

Convertible Preferred Stock—Series B

On March 19, 2021, the Company entered into a preferred stock purchase agreement for the issuance of 35,764,462 shares of Series B preferred stock, $0.0001 par value per share. 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.

Conversion

Each share of Series B is convertible into common stock: (i) at the option of the holder, or (ii) automatically upon the closing of a public offering with a price to the public of at least $17.58933 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Company's common stock) for at least $50 million in gross proceeds. The conversion ratio of Series B to common stock is currently one-for-4.1557, subject to adjustment upon any future stock splits or stock dividends, issuance of additional shares for less consideration, other distribution of payable in securities, or upon a reorganization, recapitalization, reclassification, merger or consolidation of the Company.

Dividends

The holders of the Series B convertible preferred stock have preferential rights over common stockholders to non-cumulative dividends payable when declared by the Board, at the annual rate of $0.2257376 per share for Series B-1 and $0.1918768 per share for Series B-2. Dividends were not declared during the three and six months ended June 30, 2021.

Voting

Series B stockholders are entitled to the number of votes equal to the number of shares of common stock into which the preferred stock could be converted. In addition, the Series B stockholders have certain rights whereby the Company is precluded from carrying out certain actions specified in the Company's Amended and Restated Certificate of Incorporation without the approval of the holders of a majority of the Series B shares.

Liquidation

Upon the occurrence of a liquidation event, the Series B stockholders have preferential rights over common stockholders as to liquidation payments of their original issuance price of $2.82172 per share, plus any dividends declared and unpaid, on a pro rata, pari passu basis. Any additional distributions after the payment of the liquidation preferences of the Series B shares will be made to the holders of common stock on a pro rata basis.

Convertible Preferred Stock Classification

Redemption

The Series A and B convertible preferred stock is not explicitly redeemable at the option of the holder at a specified date in the future or at the option of the Company.

The Company's convertible preferred stock has been classified as temporary equity on the accompanying condensed balance sheet instead of in stockholders' deficit in accordance with authoritative guidance for the classification and measurement of redeemable securities. Upon certain change in control events that are outside of the Company's control, including liquidation, sale or transfer of control of the Company, holders of the convertible preferred stock can cause its redemption. The Company has determined not to adjust the carrying values of the convertible preferred stock to the liquidation preferences of such shares because of the uncertainty of whether or when such events would occur.

Common Stock

As of June 30, 2021 and December 31, 2020, of the 134,329,408 and 78,000,000 authorized shares of common stock, respectively, 3,741,667 and 3,596,936 shares were issued, respectively, and 3,072,402 and 2,639,026 shares were outstanding, respectively.

In December 2017, the Company entered into restricted stock purchase agreements and issued 2,580,600 shares of restricted common stock to members of management, and subject to repurchase by the Company. Any shares subject to repurchase by the Company are not deemed, for accounting purposes, to be outstanding until those shares vest. The management grants vested 20% upon issuance and the remaining 80% vest over 48 months in equal monthly installments. The grants provide for accelerated vesting upon a change in control or other contractually specified contingencies. In June 2018, 968,158 shares of the outstanding restricted shares were canceled, and the original proceeds were returned upon the departure of the founder. Given the early stage of the Company at the time of the grants, the value of all grants and the cash exchanged for the shares was de minimis.

In December 2017 and August 2018, the Company issued 77,418 and 192,276 shares, respectively of common stock to a university in connection with obtaining a licensing agreement. The shares issued to the university were fully vested upon issuance.

As of June 30, 2021 and December 31, 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, and 269,694 shares of common stock that had been issued to a university in connection with obtaining a licensing agreement.

At June 30, 2021 and December 31, 2020, 2,190,107, and 1,995,314 shares of the restricted common stock have vested, respectively. At June 30, 2021, 234,763 shares remain subject to vesting conditions and are expected to vest by December 2021.

Common stock reserved for future issuance consisted of the following:

	As of June 30, 2021
Convertible preferred stock	21,634,898
Common stock options granted and outstanding	5,131,318
Shares available for issuance under the 2017 equity incentive plan	874,732
Total common stock reserved for issuance	27,640,948

As of June 30, 2021, the Company's convertible preferred stock consisted of the following ($ amounts in thousands):

	Share Authorized and Outstanding	Shares Issued and Outstanding	Shares of Common Stock Issuable upon Conversion	Aggregate Liquidation Preference	Carry Value
Series A-1	49,193,959	49,193,959	11,837,711	$ 47,300	$ 46,917
Series A-2	4,949,794	4,949,794	1,191,082	3,807	4,150
Series B-1	32,958,612	32,958,612	7,930,924	93,000	92,654
Series B-2	2,805,850	2,805,850	675,181	6,730	7,917
Total	89,908,215	89,908,215	21,634,898	$ 150,837	$ 151,638

As of December 31, 2020, the Company's convertible preferred stock consisted of the following ($ amounts in thousands):

	Share Authorized and Outstanding	Shares Issued and Outstanding	Shares of Common Stock Issuable upon Conversion	Aggregate Liquidation Preference	Carry 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

Stock Options

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

The 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. The number of shares of common stock, which may be granted under the Plan, shall not exceed 7,130,414. All existing grants are subject to a time-based vesting period which will generally be four years. On the first anniversary of the grant date of each existing grant, 25% of the grant will vest with the remaining 75% to vest in equal monthly installments over the remaining 36 months provided the participant has a continuing service relationship with the Company. 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 Plan cannot exceed ten years. 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, and generally vest over a period of four years.

A summary of the status of the options issued under the Plan as of June 30, 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	$ 0.83	9.02	—
Authorized increase in plan shares	22,634,965	—	—	—	—
Granted	(4,634,622)	4,634,622	4.79	—	—
Exercised (including early)	—	(144,731)	0.83	—	$ 511,000
Balance at June 30, 2021	18,541,754	5,131,318	$ 4.41	9.64	$ 15,555,681
Vested and expected to vest as of June 30, 2021		5,131,318	$ 4.41	9.64	
Vested and exercisable at June 30, 2021		149,659	$ 0.86	8.55	$ 984,245

Exercisable options in the table above reflect the number of options vested as of the date reported. The plan permits early exercises of options. Cash received for early exercise of unvested options is carried as an other noncurrent liability in the accompanying condensed balance sheet and totaled $279,000 at June 30, 2021.

The aggregate intrinsic value in the table above is calculated as the difference between the exercise price of the underlying options and the estimate fair value of the Company's common stock for all options that were in-the-money as of June 30, 2021.

The weighted-average grant date fair value of employee option grants during the six months ended June 30, 2021 was $5.55 per share.

Stock-Based Compensation Expense

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Research and development	$ 427	$ 29	$ 540	$ 55
General and Administrative	981	34	1,144	62
Total	$ 1,408	$ 63	$ 1,684	$ 117

The Company recognizes compensation expense for options granted to employees and the board of directors based on their grant date fair value. During the three and six months ended June 30, 2021, the Company granted 3,413,872 and 4,634,622 options, respectively, with a grant date fair value of $20.8 million and $25.5 million, respectively. During the three and six months ended June 30, 2020, the Company granted 114,952 and 199,173 options, respectively, with a grant date fair value of $121,000 and $210,000, respectively. 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:

	Six Months Ended June 30,	
	2021	**2020**
Risk-free rate of interest	0.53% - 1.23%	0.46%-1.40%
Expected term (years)	5.48 - 6.49 years	5.97 - 6.08 years
Expected stock price volatility	86.0% - 88.4%	80.2% - 83.9%
Dividend yield	0%	0%

As of June 30, 2021, the unrecognized compensation cost related to outstanding stock options was $24.5 million and is expected to be recognized as expense over a weighted-average period of approximately 3.6 years.

9. Income Taxes

There was no provision for income taxes recorded during the three and six months ended June 30, 2021 or 2020. The Company's deferred tax assets continue to be reduced by a full valuation allowance.

We are subject to income taxes in the United States and our effective tax rate is calculated quarterly based upon current assumptions relating to the full year's estimated operating results and various tax-related items. Each quarter an estimate of the annual effective tax rate is updated should we revise our forecast of earnings based upon our operating results. If there is a change in the estimated effective annual tax rate, a cumulative adjustment is made. Our effective tax rate was 0% for the three and six months ended June 30, 2021 and 2020. The difference between the effective tax rate of 0% and the U.S. federal statutory rate of 21% for the three and six months ended June 30, 2021 and 2020 was primarily due to recognizing a full valuation allowance on deferred tax assets.

As of June 30, 2021, we determined that, based on an evaluation of the four sources of income and all available evidence, both positive and negative, including our latest forecasts and cumulative losses in recent years, it was more likely than not that none of our deferred tax assets would be realized and therefore we continued to record a full valuation allowance. No current tax liability or expense has been recorded in the financial statements.

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 the three and six months ended June 30, 2021 or 2020.

11. Subsequent Events

Grant Agreement Milestone

As discussed in Note 4, the Company received the final $3.3 million in restricted cash from the Grant Agreement with BMGF in July 2021.

2021 Stock Incentive Plan

During 2021, the Company's stockholders approved the 2021 Stock Incentive Plan (the "2021 Plan"), which became effective in July of 2021. The 2021 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. The number of shares of the Company's common stock 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 Stock Incentive Plan.

2021 Employee Stock Purchase Plan

During 2021, the Company's stockholders approved the 2021 Employee Stock Purchase Plan (the "ESPP"), which became effective in July of 2021. The ESPP initially provides participating employees with the opportunity to purchase up to an aggregate of 400,000 shares of the Company's common stock.

Automatic Conversion Waiver and Reverse Stock Split

In July 2021, the Company effected a one-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 condensed 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.

Initial Public Offering

On August 2, 2021, the Company completed an 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 approximately $190.6 million, after deducting underwriting discounts and commissions and estimated 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.

Changes to Authorized Common Stock and Preferred Stock

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.

Modification to Accelerate Unvested Stock Options

In August 2021, as a result of the death of Tadataka (Tachi) Yamada, M.D., the Company's former Chairman, the Company determined to accelerate the vesting of all of Dr. Yamada's previously unvested stock options, representing approximately 600,000 shares, with exercise prices ranging from $0.83 to $5.90 per share.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis and the unaudited interim condensed consolidated financial statements included in this Quarterly Report on Form 10-Q should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2020 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in the Prospectus dated July 28, 2021 filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the Securities Act), with the Securities and Exchange Commission (SEC) on July 30, 2021 (the Prospectus).

Forward-Looking Statements

This Quarterly Report contains forward-looking statements within the meaning of 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 Quarterly Report, including statements regarding our future results of operations and financial position, business strategy, research and development plans, the anticipated timing, costs, design and conduct 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 Quarterly 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 Quarterly Report and are subject to a number of risks, uncertainties and assumptions, including those described in Part II, Item 1A, "Risk Factors" of this Quarterly 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.

Overview

We are a biopharmaceutical company leveraging our innovative 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 RSV, and IVX-241, a vaccine candidate designed to target hMPV. There are currently no vaccines approved for either RSV or hMPV, which are two common causes of pneumonia in older adults. We recently initiated a clinical trial of IVX-121 in Belgium, with interim topline data expected in the first half of 2022. Assuming favorable results from the IVX-121 clinical trial and favorable preclinical data for IVX-241, we plan to submit an IND to the FDA in the first half of 2022 and, thereafter, initiate a Phase 1 clinical trial for our combination vaccine candidate, IVX-A12. Additionally, we are developing two SARS-CoV-2 vaccine candidates, IVX-411 and IVX-421, and initiated a Phase 1/2 clinical trial of IVX-411 in Australia in June 2021, with proof-of-concept data expected in the first half of 2022. Part 1 of this trial, in adults who have neither had COVID-19 nor been vaccinated with a licensed COVID-19 vaccine, has completed dosing, and Part 2 of this trial, in adults who have previously completed a vaccine regimen using a licensed COVID-19 vaccine, has now been initiated.

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 ongoing and planned preclinical studies and clinical trials. Our operations to date have been funded primarily through the sale and issuance of convertible promissory notes and our convertible preferred stock. From our inception through June 30, 2021, we had raised a total of $150.3 million to fund our operations, comprised of gross proceeds from the sale and issuance of convertible promissory notes and our convertible preferred stock. As of June 30, 2021, we had cash of $110.6 million and restricted cash of $1.2 million. In August 2021, we completed our initial public offering (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 and received net proceeds of approximately $190.6 million.

We have incurred significant operating losses since inception. Our net loss for the six months ended June 30, 2021, was $14.4 million. As of June 30, 2021, we had an accumulated deficit of $41.5 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, protect our intellectual property and incur costs associated with being a public company.

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, or 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 three and six months ended June 30, 2021, revenue was derived from our 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 SARS-CoV-2 vaccine. We have received the full $10.0 million 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. No revenue was recognized for the three and six months ended June 30, 2020.

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 outsourced research 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;
- facilities, depreciation and other expenses, which include allocated expenses for rent and maintenance of facilities, insurance, laboratory consumables and supplies.

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

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

- the number and scope of preclinical and regulatory filing-enabling studies;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible subjects;
- the number of subjects that participate in the trials;
- the number of doses evaluated in the trials;
- the costs and timing of manufacturing our vaccine candidates;
- the drop-out or discontinuation rates of clinical trial subjects;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of subject participation in the trials and follow-up;
- the phase of development of the vaccine candidate;
- the impact of any interruptions to our operations or to those of the third parties with whom we work due to 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 three and six months ended June 30, 2021 in connection with the conversion of our convertible promissory note issued in August 2020. See Note 8 to the unaudited interim condensed financial statements included elsewhere in this Quarterly 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 Three and Six Months Ended June 30, 2020 and 2021

The following table summarizes our results of operations for the three and six months ended June 30, 2020 and 2021 (in thousands):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2021	2020	Change	2021	2020	Change
Grant revenue	1,904	$ -	$ 1,904	$ 3,905	$ -	$ 3,905
Operating expenses:						
Research and development	8,277	4,666	3,611	13,830	7,586	6,244
General and administrative	2,221	541	1,680	3,312	1,153	2,159
Total operating expenses	10,498	5,207	5,291	17,142	8,739	8,403
Loss from operations	(8,594)	(5,207)	(3,387)	(13,237)	(8,739)	(4,498)
Other income (expense)						
Change in fair value of embedded derivative liability	-	-	-	(205)	-	(205)
Loss on extinguishment of convertible promissory note	-	-	-	(754)	-	(754)
Interest and other income (expense)	42	9	33	(207)	70	(277)
Net loss and comprehensive loss	$ (8,552)	$ (5,198)	$ (3,354)	$ (14,403)	$ (8,669)	$ (5,734)

Grant Revenue

We recognized $1.9 million in grant revenue for the three months ended June 30, 2021 compared to $0 for the three months ended June 30, 2020. We recognized $3.9 million in grant revenue for the six months ended June 30, 2021, compared to $0 for the six months ended June 30, 2020. For the three and six months ended June 30, 2021, revenue was derived from the Grant Agreement we entered into in September 2020 with BMGF, under which we were awarded a grant totaling up to $10.0 million, in support of our development of a SARS-CoV-2 vaccine.

Research and Development Expenses

Research and development expenses were $8.3 million for the three months ended June 30, 2021, compared to $4.7 million for the three months ended June 30, 2020. The increase of $3.6 million was primarily due to a $2.3 million increase in direct costs related to clinical development and manufacturing, a $0.5 million increase in personnel related expenses due to increased headcount to support our development activities, a $0.4 million increase in direct costs related to non-clinical development and manufacturing, and a $0.4 million increase related to stock-based compensation expense.

For the six months ended June 30, 2021, research and development expenses were $13.8 million compared to $7.6 million for the same period in 2020. The increase of $6.2 million was primarily due to a $4.2 million increase in direct costs related to clinical development and manufacturing, a $0.8 million increase in personnel related expenses due to increased headcount to support our development activities, a $0.7 million increase in direct costs related to non-clinical development and manufacturing, and a $0.5 million increase related to stock-based compensation expense.

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):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
IVX-121	$ 1,174	$ 3,772	$ 3,352	$ 5,864
IVX-241	1,880	13	2,319	13
IVX-411	3,450	4	5,442	4
Unallocated research and development expense	1,773	877	2,717	1,705
Total research and development expense	$ 8,277	$ 4,666	$ 13,830	$ 7,586

General and Administrative Expenses

General and administrative expenses were $2.2 million for the three months ended June 30, 2021, compared to $0.5 million for the three months ended June 30, 2020. The increase of $1.7 million consisted of increased stock-based compensation expense of $0.9 million, increased professional services including legal fees of $0.4 million, and increased personnel-related expenses of $0.3 million.

General and administrative expenses were $3.3 million for the six months ended June 30, 2021, compared to $1.2 million for the six months ended June 30, 2020. The increase of $2.1 million consisted of increased stock-based compensation expense of $1.1 million, increased professional services including legal fees of $0.6 million, and increased personnel-related expenses of $0.4 million.

Other Income (Expense)

Other income (expense) was expense of $1.2 million for the six months ended June 30, 2021, compared to income of $0.1 million for the six months ended June 30, 2020. The increase of $1.1 million in expense for the six months ended June 30, 2021 was the result of a loss on extinguishment of convertible promissory note of $0.8 million, an increase in interest expense of $0.2 million, and an increase in expense recognized on the change in fair value of derivative liability 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. As of June 30, 2021, we had been financed primarily through net proceeds of approximately $149.5 million from the sale of our equity securities and convertible promissory notes. As of June 30, 2021, we had cash of $110.6 million, restricted cash of $1.2 million and an accumulated deficit of $41.5 million. In August 2021, we completed our IPO with the sale of 13,953,332 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 1,819,999 additional shares, at an IPO price of $15.00 per share and received net proceeds of approximately $190.6 million. Additionally, in July 2021, we received the final $3.3 million in restricted cash awarded under the Grant Agreement.

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 a current or future vaccine candidate is approved;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors; and
- costs associated with any products or technologies that we may in-license or acquire.

Our existing cash and restricted cash, will not be sufficient to complete development of IVX-A12, IVX-411, IVX-421 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):

	Six Months Ended June 30,	
	2021	**2020**
	(Unaudited)	
Net cash (used in) provided by		
Operating activities	$ (16,178)	$ (8,083)
Investing activities	(568)	—
Financing activities	113,012	66
Net change in cash and restricted cash	$ 96,266	$ (8,017)

Operating Activities

We have incurred significant operating losses since inception. Net cash used in operating activities for the six months ended June 30, 2021 was $16.2 million, consisting primarily of our net loss incurred during the period of $14.4 million adjusted for $4.7 million for net changes in operating assets and liabilities, and $2.9 million of non-cash charges. Non-cash charges consisted primarily of $1.7 million in stock-based compensation expense, $0.8 million loss on extinguishment of convertible promissory note, $0.2 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 $3.5 million decrease in prepaids and other current assets and a $1.2 million decrease in deferred revenue.

Net cash used in operating activities for the six months ended June 30, 2020 was $8.1 million, consisting primarily of our net loss incurred during the period of $8.7 million adjusted for net changes in operating assets and liabilities of $0.5 million, and non-cash charges of $0.1 million. Non-cash charges consisted of a decrease in accounts payable and accrued other current liabilities of $0.9 million offset by changes in operating assets consisted of a decrease in prepaid and other current assets of $0.4 million and stock-based compensation of $0.1 million.

Investing Activities

Net cash used in investing activities for the six months ended June 30, 2021 and 2020 was $0.6 million and less than $0.1 million, respectively, and related to purchases of property and equipment.

Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2021 was $113.0 million consisting of $21.0 million in proceeds related to the issuance of Series A-1 convertible preferred stock in February 2021, $92.6 million in proceeds related to the issuance of Series B-1 convertible preferred stock in March 2021, $0.1 million proceeds from exercises of stock options, including early exercises, offset by the payment of $0.7 million in deferred offering costs.

Net cash provided by financing activities for the six months ended June 30, 2020 was less than $0.1 million for the proceeds from early exercises of stock options.

Contractual Obligations and Commitments

We had no contractual obligations and commitments as of June 30, 2021 and December 31, 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 June 30, 2021 and December 31, 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 above and in the section of the Prospectus 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. There have been no significant changes in our critical accounting policies for the year ended December 31, 2020 discussed in the Prospectus.

Applicability of JOBS Act and Smaller Reporting Company Rules

As an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (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 elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. We intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of Sarbanes-Oxley. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of the consummation of our IPO, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion, (iii) the last 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 such 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 unaudited interim condensed financial statements included for discussion of recent accounting pronouncements, if any.

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.

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 Quarterly Report.

Item 4. 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, as of the end of the period covered by this Quarterly Report, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation, our principal executive officer and principal financial officer have concluded that as of June 30, 2021, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarter ended June 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. 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 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 Quarterly Report and in the Prospectus, 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 only 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, 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
- 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 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.

Only 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 $5.3 million and $18.9 million for the years ended December 31, 2019 and December 31, 2020, respectively, and $14.4 million for the six months ended June 30, 2021. As of June 30, 2021, we had an accumulated deficit of $41.5 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. Furthermore, we expect to incur additional costs associated with operating as a public company.

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, 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 preclinical studies and clinical trials of our vaccine candidates or other potential product candidates we may choose to pursue in the future, including any modifications to our preclinical or 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 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 any current or future product candidates are 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;
- 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 grant funding or collaborations to fund the continued development, preclinical studies and clinical trials of our SARS-CoV-2 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 and only 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.

We are early in our development efforts and have only two vaccine candidates, IVX-411 and IVX-121, in clinical development and three vaccine candidates, IVX-241, IVX-421 and IVX-A12, in preclinical 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;
- 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 without certain underlying health conditions common within this age range. These restrictions could negatively impact our ability to complete clinical trials along our planned timeline and could limit our commercial potential.

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

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

The success of our business depends primarily upon our ability to identify, develop and commercialize our vaccine candidates based on our VLP platform technology. While there are a number of approved vaccines based on VLPs, we have not yet succeeded and may not succeed in demonstrating safety, purity, immunogenicity, and/or efficacy for any vaccine candidates based on our VLP platform technology in clinical trials or in obtaining marketing approval thereafter. In addition, while we believe our pipeline will 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.

In addition, we are in the process of developing combination candidates using our VLP technology, such as IVX-A12. 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.

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, 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 have not yet completed a clinical trial, 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. By contrast, adverse effects 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 and IVX-241 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 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 such 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 certain preclinical studies of certain of our vaccine candidates, we do not know whether they or our other potential vaccine candidates will perform in 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. Any 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, 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 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. Acceptance by the FDA of our planned IND will be subject to the FDA's agreement with our proposal to initiate clinical trials of IVX-A12 based upon data from our Phase 1 clinical trial of IVX-121 and preclinical data with respect to IVX-241. If the FDA does not agree with this proposal, it may require us to conduct clinical evaluation of IVX-241 before progressing to clinical evaluation of IVX-A12. The Belgian Federal Agency for Medicines and Health Products

(FAMHP), FDA or comparable foreign regulatory authorities may 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. Moreover, even if we commence clinical trials, 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 be completed on schedule, if at all. The commencement 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 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;
- 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, heath reasons or otherwise resulting from the COVID-19 pandemic;
- 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; 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 increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, 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 drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and

we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries, as we plan to 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 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 to our vaccine candidates, in which case we may need to conduct additional preclinical studies to bridge our modified vaccine candidates to earlier versions. Any resulting delays to our clinical trials could shorten any period during which we may have the exclusive right to commercialize our vaccine candidates. In such cases, our competitors may be able to bring products to market before we do, and the commercial viability of our vaccine candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

Successful and timely completion of clinical trials will require that we identify and enroll a specified number of subjects for each of our clinical trials. We may not be able to initiate or continue clinical trials for our vaccine candidates if we are unable to identify and enroll a sufficient number of eligible subjects to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Subject enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the subject population, the severity of the disease under investigation, the proximity of subjects to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the ability to obtain and maintain informed consents, the risk that enrolled subjects will not complete a clinical trial, our ability to recruit clinical trial investigators with the appropriate competencies and experience, and competing clinical trials and clinicians' and subjects' perceptions as to the potential advantages and risks of the vaccine candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating as well as any vaccine candidates under development. For our Phase 1/2 clinical trial in Australia of our SARS-CoV-2 candidate IVX-411, we intend to assess our vaccine candidate as a booster vaccine following completion of an alternative licensed vaccine regimen. We are dependent on the ability to recruit subjects that have received a full vaccine regimen of an alternative vaccine and may be delayed if the vaccine rollout in Australia is slower than anticipated and we are therefore unable to recruit subjects at our projected pace. Additionally, across our ongoing and anticipated clinical trials and target subjects, other pharmaceutical companies targeting these same diseases are recruiting clinical trial subjects from these target populations, which may make it more difficult to fully enroll our clinical trials.

In addition, the process of finding subjects may prove costly. The timing of our clinical trials depends, in part, on the speed at which we can recruit subjects to participate in our trials, as well as completion of required follow-up periods. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants. 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. 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 are correct or that we will not experience delays in enrollment, which would result in the delay of completion of such trials beyond our expected timelines.

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, similar to influenza. 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 have not evaluated any vaccine candidates in clinical trials.

We will monitor for expected and unexpected side effects in our clinical trials. 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. For example, we plan to assess reactogenicity and immunogenicity of our RSV/hMPV bivalent candidate IVX-A12 when administered concurrently with a quadrivalent influenza vaccine in our planned Phase 2 clinical trial. This could lead to unanticipated side effects or interfere with the potential immunogenicity of IVX-A12. An inability to be dosed concurrently with a quadrivalent influenza vaccine could limit the commercial potential of IVX-A12.

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 have initiated clinical trials for two of our vaccine candidates, and our other vaccine candidates in the preclinical development stage. We will need to successfully complete our 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 have not had any discussions with the FDA. Therefore, we cannot be certain how many clinical trials of our IVX-121, IVX-241, 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 plans to commence clinical development. For example, we may be required to conduct additional preclinical studies of the individual vaccine candidates comprising our combination candidate, IVX-A12, prior to testing IVX-A12 in clinical trials. We may also be required to conduct clinical testing of our hMPV candidate IVX-241 prior to testing IVX-A12, which would cause a delay in the development of our IVX-A12 candidate. 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. For certain infectious disease applications, such as SARS-CoV-2, these licenses may only be available to us in certain jurisdictions. Third parties may also have licensed or will license the same VLP technology from UW for use in infectious disease applications or jurisdictions where we do not have an exclusive license. Any adverse developments that occur during clinical trials related to these infectious disease applications conducted by third parties in other jurisdictions may result in delays, limitations or denials of regulatory approvals of our vaccine candidates, may cause regulators to require us to conduct additional clinical trials as a condition to marketing approval, may result in the withdrawal of any approvals of our vaccine candidates that we receive in the future, or may result in further restrictions on our ability to commercialize our vaccine candidates. Such adverse developments may also negatively impact the perception of our vaccine candidates, which may reduce the enrollment of subjects in our clinical trials or inhibit our ability to market our vaccine candidates in the future if approved. For example, SK Bioscience has initiated a Phase 1/2 clinical trial in South Korea, and has recently received approval from South Korea MFDS to initiate a Phase 3 clinical trial, for 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, and adverse developments related to such clinical trial 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 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 SARS-CoV-2 vaccines will impact the approval processes of other vaccine candidates for SARS-CoV-2. In addition, there is a less clearly defined regulatory path for booster vaccines, which may be our target development path for our SARS-CoV-2 vaccine candidates.

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.

We may seek an EUA from the FDA or comparable emergency authorizations from foreign regulatory authorities with respect to IVX-411 or IVX-421, 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.

We may seek an EUA from the FDA or comparable emergency authorizations with respect to our SARS-CoV-2 vaccine candidates, IVX-411 and IVX-421. The FDA has the authority to issue an EUA during a public health emergency if it determines that, based on the totality of the scientific evidence it is reasonable to believe that the product may be effective, that the known and potential benefits of the product outweigh the known and potential risks, and that there are no adequate, approved, and available alternatives, and if other regulatory criteria are met. The FDA's standards for granting an EUA are lower than for approving BLAs in accordance with traditional review procedures, and 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 FDA's policies regarding an EUA can change unexpectedly, and the FDA may revoke an EUA if the Secretary of Health and Human Services determines that the underlying health emergency no longer exists or warrants such authorization, or if the FDA identifies safety or efficacy concerns with the authorized product. 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 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 plan to conduct certain of our clinical trials for our vaccine candidates outside the United States, including a Phase 1/1b clinical trial in Belgium of IVX-121 in adults aged 18-45 and 60-75 and our Phase 1/2 clinical trial of IVX-411 in Australia. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to certain conditions imposed by the FDA. Where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless those data are applicable to the U.S. population and U.S. medical practice; the trials were performed by clinical investigators of recognized competence; and 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. For clinical trials that are conducted only at sites outside of the United States and not subject to an IND, the FDA requires the clinical trial to have been conducted in accordance with GCPs, and the FDA must be able to validate the data from the clinical trial through an on-site inspection if it deems such inspection necessary. For such trials not subject to an IND, the FDA generally does not provide advance comment on the clinical protocols for the trials, and therefore there is an additional potential risk that the FDA could determine that the trial design or protocol for a non-U.S. clinical trial was inadequate, which could require us to conduct additional clinical trials. There can be no assurance the FDA will accept data from clinical trials conducted outside of the United States. If the FDA does not accept data from our clinical

trials of our 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, the 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 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 data should be viewed with caution until the final data are available.

In particular, we may disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as subject enrollment continues and more clinical trial data become available. Adverse differences between interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our 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, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products. Subsequently, on March 18, 2020 the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to

resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. 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. According to the guidance, the FDA intends to request such remote interactive evaluations in situations where an in-person inspection would not be prioritized, deemed mission-critical, or where direct inspection is otherwise limited by travel restrictions, but where the FDA determines that remote evaluation would be appropriate. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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 or equity 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 an 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. 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.

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 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 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. However, we may face significant challenges in this scale-up of manufacturing capabilities, 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 and in securing third-party manufacturers may materially delay or disrupt our development efforts, and increase our overall development costs.

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 or manufacturing constraints. 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 GCP 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. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. 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 drugs;
- 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 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. If we cannot successfully manage the promotion of our vaccine candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

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, hMPV and SARS-CoV-2 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, Codagenix and Meissa are currently developing vaccines against RSV for use in older adults, and may target hMPV in the future. Moderna, Pfizer/BioNTech, AstraZeneca and Janssen, along with many other companies, are currently marketing SARS-CoV-2 vaccines. We also compete with companies that have developed VLP technologies targeting SARS-Cov-2 and may target RSV or hMPV in the future. These companies include SpyBiotech, VLP Therapeutics, VBI Vaccines, Medicago and Artes Biotechnology. 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 qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

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

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

vaccine candidates. If we obtain regulatory approval of our vaccine candidates and ultimately commercialize our products in foreign markets, we would be subject to additional risks and uncertainties, including:

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

We received a grant from the Bill & Melinda Gates Foundation, which subjects certain of our vaccine candidates to pricing and other restrictions.

In September 2020, we entered into the Grant Agreement with the BMGF, pursuant to which BMGF awarded us a grant (the Grant) to help fund our development of a SARS-CoV-2 vaccine. We are using 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 SARS-CoV-2 vaccine candidates, including IVX-411, to certain pricing requirements in certain geographies, global access requirements and reporting and other covenants to ensure that such vaccine candidates are made available by us worldwide and on a nondiscriminatory basis. Such covenants may limit the prices we can charge for such vaccine candidates in low and middle income countries, and include a license to use certain of our proprietary technology related to such vaccine candidates 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 certain of our vaccine candidates targeting SARS-CoV-2, which could harm our ability to initiate or continue clinical trials of such vaccine candidates, adversely affect the development or commercialization of such vaccine candidates, 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 provide.

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

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, as well as our senior scientists and other members of our management team. 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 each member of our senior management team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. 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, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our unique company culture and continuing to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biopharmaceutical, biotechnology and other businesses, particularly in the Seattle area. Our industry has experienced a high rate of turnover of management 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 22 full-time employees as of June 30, 2021. As we continue development and pursue the potential commercialization of our vaccine candidates, as well as 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 may need to 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 any future growth effectively.

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) and teaching hospitals, as well as ownership and investment interests held by such healthcare professionals and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding payments and transfers of value provided, as well as ownership and investment interests held, during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse-midwives; 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; 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. It is unclear how the healthcare reform measures of the Biden administration, or other efforts to challenge the ACA, if any, will impact the ACA or our business.

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 December 31, 2021, 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, the former Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. 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 and marketing cost disclosure and transparency measures, and, in some cases, 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.

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. 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 patient health 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. The global data protection landscape is rapidly evolving, and

we may be affected by or subject to new, amended or existing laws and regulations in the future, including as our operations continue to expand or if we operate in foreign jurisdictions. These laws and regulations may be subject to differing interpretations, which adds to the complexity of processing personal data. Guidance on implementation and compliance practices are often updated or otherwise revised. This 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.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. 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. By way of example, the California Consumer Privacy Act (CCPA), which went into effect on January 1, 2020, gives California residents individual privacy rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. 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. The CCPA may increase our compliance costs and potential liability and many similar laws have been proposed at the federal level and in other states. Further, the California Privacy Rights Act (CPRA) recently passed in California. The CPRA 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. Other states are exploring their own laws, which may or may not be similar to CCPA or the CPRA. 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.

There also are a wide variety of privacy laws in other countries that may impact our operations, now or in the future. For example, in Europe, the General Data Protection Regulation (GDPR) imposes stringent requirements regarding the collection, use, disclosure, transfer or other processing of personal data of individuals within the European Economic Area (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. The GDPR also confers a private right of action in some circumstances on 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 things, the GDPR requires the establishment of a lawful basis for the processing of data, imposes requirements relating to the consent of the individuals to whom the personal data relates, including detailed notices for clinical trial subjects and investigators, as well as requirements regarding the security of personal data and notification of data processing obligations to the competent national data processing authorities. In addition, the GDPR increases the scrutiny of transfers of personal data from clinical trial sites located in the EEA to the United States and other jurisdictions that the European Commission does not recognize as having “adequate” data protection laws. Recent legal developments in Europe have created complexity and uncertainty regarding transfers of personal data from the EEA to the United States. For example, on July 16, 2020, the Court of Justice of the European Union (CJEU) invalidated the EU-US Privacy Shield Framework (Privacy Shield) under which personal data could be transferred from the EEA to United States entities that had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. 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. 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, following the withdrawal of the United Kingdom from the European Union and the EEA and the end of the transition period, from January 1, 2021, we have to comply with the GDPR and separately the GDPR as implemented in the United Kingdom, 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.

In many jurisdictions, enforcement actions and consequences for noncompliance are rising. In the United States, these include enforcement actions in response to rules and regulations promulgated under the authority of federal agencies and state attorneys general and legislatures and consumer protection agencies. If we fail to follow these security standards, even if no personal information is compromised, we may incur significant fines or experience a significant increase in costs. Many state legislatures have adopted legislation that regulates how businesses operate online, including measures relating to privacy, data security and data breaches. Laws in all U.S. states require businesses to provide notice to customers whose personally identifiable information has been disclosed as a result of a data breach. The laws are not consistent, and compliance in the event of a widespread data breach is costly.

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 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 potential 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.

In addition, 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. These attacks can present meaningful risks to our operations, data and commercial information. 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 that any actual or perceived disruption or security breach affects our systems (or those of our third-party collaborators, service providers, 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, and we could be subject to significant fines, penalties or liabilities for any noncompliance to certain privacy and security laws.

Further, despite the implementation of security measures, our internal technology systems (including infrastructure) and those of our current and any future CROs and other contractors, consultants and collaborators are vulnerable to damage from computer viruses, cybersecurity threats (such as denial-of-service attacks, cyber-attacks or cyber-intrusions over the Internet, hacking, phishing and other social engineering attacks), unauthorized access or use, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event 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 of the federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular categories of personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships.

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 U.S. 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, including issuing varying forms of “stay-at-home” orders, and restricting business functions outside of one’s home. 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. 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. The COVID-19 pandemic and any future epidemic disease outbreak 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 and mitigation measures have had and may continue to have, and any future epidemic disease outbreak may have, an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. The extent to which the COVID-19 pandemic impacts our results will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact.

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 field have not yet published and could impact our freedom to operate using our technology in the SARS-CoV-2 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 SARS-CoV-2 vaccine candidate, we granted BMGF a humanitarian license that allows BMGF to make our SARS-CoV-2 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 U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

We have in-licensed certain patents and patent applications that were generated through the use of U.S. government funding or grants, and we may acquire or license in the future intellectual property rights that have been generated through the use of U.S. government funding or grants. Pursuant to the Bayh-Dole Act of 1980, the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. 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 U.S. government exercises its march-in rights in our current or future intellectual property rights that are generated through the use of U.S. 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 U.S. government for the exercise of such rights. The U.S. 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 U.S. 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 U.S. 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 U.S. industry may limit our ability to contract with non-U.S. 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 U.S. 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 U.S. government, the U.S. 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, IVX-411, and IVX-421 and may permit the U.S. 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 U.S. 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 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 SARS-CoV-2 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 SARS-CoV-2 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 inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This 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 includes 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 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 August 31, 2021, our executive officers, directors and greater than 5% stockholders, in the aggregate, own approximately 51% of our outstanding common stock. As a result, such persons, acting together, will have the ability to significantly influence all matters submitted to our board of directors or stockholders for approval, including the appointment of our management, the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

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

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

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

Sales of a substantial number of shares of our common stock 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. In connection with our IPO, our directors and executive officers and holders of substantially all of our outstanding securities entered into lock-up agreements with the underwriters pursuant to which they may not, with limited exceptions, for a period of 180 days from the date of the Prospectus, offer, sell or otherwise transfer or dispose of any of our securities, without the prior written consent of Jefferies LLC, Cowen and Company, LLC and Evercore Group L.L.C. The underwriters may permit our officers, directors and other securityholders who are subject to the lock-up agreements to sell shares prior to the expiration of the lock-up agreements at any time in their sole discretion. Sales of these shares, or perceptions that they will be sold, could cause the trading price of our common stock to decline. After the lock-up agreements expire, these shares of common stock will be eligible for sale in the public market, except that shares held by our directors, executive officers and other affiliates will be subject to volume limitations under Rule 144 under the Securities Act.

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 U.S. Securities and Exchange Commission (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.

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.

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.

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 recently 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. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

Our ability to use net operating loss carryforwards and other tax attributes may be limited in connection with this 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, 2020, we had federal and state net operating loss (NOL) carryforwards of approximately $21.0 million and $2.2 million, respectively.

Under the Tax Cuts and Jobs Act (the Tax Act), federal NOL carryforwards generated in periods after December 31, 2017, may be carried forward indefinitely. The deductibility of federal NOL carryforwards, particularly for tax years beginning after December 31, 2020, may be limited. It is uncertain if and to what extent various states will conform to the Tax Act or the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act). 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 this 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 this 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 U.S. tax law may materially adversely affect our financial condition, results of operations and cash flows.

On March 27, 2020, the CARES Act was signed into law to address the COVID-19 crisis. The CARES Act is an approximately $2 trillion emergency economic stimulus package that includes numerous U.S. federal income tax provisions, including the modification of: (i) NOL rules (as discussed above), (ii) the alternative minimum tax refund and (iii) business interest deduction limitations under Section 163(j) of the Code.

The Tax Act also significantly changed the U.S. federal income taxation of U.S. corporations. The Tax Act remains unclear in many respects and has been, and may continue to be, the subject of amendments and technical corrections, as well as interpretations and implementing regulations by the IRS, which have lessened or increased certain adverse impacts of the Tax Act and may continue to do so in the future. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities. We continue to work with our tax advisors and auditors to determine the full impact the Tax Act and the CARES Act will have on us.

Congress may enact additional legislation in connection with the COVID-19 pandemic, and as a result of changes in the U.S. presidential administration and control of the U.S. Senate, additional tax legislation may also be enacted, which could have an impact on our company. We urge our investors to consult with their legal and tax advisors with respect to the Tax Act, the CARES Act, and possible changes in U.S. 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 will depend in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. If 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 reporting once that firm begin its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

We could be subject to securities class action litigation.

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

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Unregistered Sales of Equity Securities

During the quarter ended June 30, 2021, certain of our employees and consultants were granted options to purchase an aggregate of 3,413,872 shares of common stock at an exercise prices ranging from $5.90 to $7.44 per share. The stock options and the common stock issuable upon the exercise of such options as described were issued pursuant to written compensatory plans or arrangements with our employees and directors, in reliance on the exemption from the registration requirements of the Securities Act provided by Rule 701 promulgated under the Securities Act or the exemption set forth in Section 4(a)(2) under the Securities Act and Rule 506 promulgated thereunder as a transaction not involving any public offering.

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 $190.6 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.

There has been no material change in the planned use of proceeds from our initial public offering from that described in the Prospectus.

Issuer Repurchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities

Not Applicable.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation	8-K	8/2/2021	3.1	
3.2	Amended and Restated Bylaws	8-K	8/2/2021	3.2	
4.1	Specimen stock certificate evidencing the shares of common stock	S-1/A	7/22/21	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	
10.1#	Icosavax, Inc. 2021 Incentive Award Plan, form of stock option agreement thereunder, and form of restricted stock unit agreement	S-1/A	7/22/21	10.2	
10.2#	Icosavax, Inc. 2021 Employee Stock Purchase Plan	S-1/A	7/22/21	10.3	
10.3#	Non-Employee Director Compensation Program	S-1/A	7/22/21	10.4	
10.4#	Amended and Restated Employment Letter Agreement, dated July 22, 2021, by and between Adam Simpson and the Registrant	S-1/A	7/22/21	10.12	
10.5#	Amended and Restated Employment Letter Agreement, dated July 22, 2021, by and between Douglas Holtzman, Ph.D. and the Registrant	S-1/A	7/22/21	10.13	
10.6#	Amended and Restated Employment Letter Agreement, dated July 22, 2021, by and between Niranjan Kanesa-Thasan, M.D. and the Registrant	S-1/A	7/22/21	10.14	
10.7#	Amended and Restated Employment Letter Agreement, dated July 22, 2021, by and between Cassia Cearley and the Registrant	S-1/A	7/22/21	10.15	
10.8#	Amended and Restated Employment Letter Agreement, dated July 22, 2021, by and between Charles Richardson, Ph.D. and the Registrant	S-1/A	7/22/21	10.16	
10.9#	Employment Letter, dated May 25, 2021, by and between Thomas J. Russo and the Registrant	S-1	7/7/21	10.11	
10.10#	Amended and Restated Employment Letter Agreement, dated July 22, 2021, by and between Thomas J. Russo and the Registrant	S-1/A	7/22/21	10.17	
10.11#	Form of Indemnification Agreement for Directors and Officers	S-1	7/7/21	10.18	
10.12†	Patent License Agreement, dated June 2, 2021, between the Registrant and the University of Texas at Austin	S-1	7/7/21	10.24	

31.1	Certification of Chief Executive Officer of Icosavax, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X
31.2	Certification of Chief Financial Officer of Icosavax, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document	X
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X
101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document	X
101.LAB	Inline XBRL Taxonomy Label Linkbase Document	X
101.PRE	Inline XBRL Presentation Linkbase Document	X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)	X

# Indicates management contract or compensatory plan.

† Portions of this exhibit have been omitted for confidentiality purposes.

* This certification is deemed not filed for purpose of section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

SIGNATURES

Pursuant to the requirements 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:	September 13, 2021	By:	/s/ Adam Simpson
			Adam Simpson
			President and Chief Executive Officer
			(principal executive officer)
Date:	September 13, 2021	By:	/s/ Thomas Russo, CFA
			Thomas Russo, CFA
			Chief Financial Officer
			(principal financial and accounting officer)

Exhibit 31.1

CERTIFICATION

I, Adam Simpson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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.

Date: September 13, 2021

By: /s/ Adam Simpson

Adam Simpson

President and Chief Executive Officer

(principal executive officer)

Exhibit 31.2

CERTIFICATION

I, Thomas Russo, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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.

Date: September 13, 2021

By: /s/ Thomas Russo

Thomas Russo

Chief Financial Officer

(*principal financial officer*)

Exhibit 32.1

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 Quarterly Report on Form 10-Q of Icosavax, Inc. (the "Company") for the period ended June 30, 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: September 13, 2021

By: /s/ Adam Simpson

Adam Simpson

President and Chief Executive Officer

(principal executive officer)

Exhibit 32.2

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 Quarterly Report on Form 10-Q of Icosavax, Inc. (the "Company") for the period ended June 30, 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: September 13, 2021

By: /s/ Thomas Russo
Thomas Russo
Chief Financial Officer
(*principal financial officer*)