

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

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the quarterly period ended September 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 001-41058

**Vaxxinity, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**86-2083865**  
(I.R.S. Employer  
Identification No.)

**1717 Main St, Ste 3388**  
**Dallas, TX 75201**  
**(254) 244-5739**

(Registrant's telephone number, including area code)

Not Applicable

(Former name, former address and former fiscal year, if changed since last report)

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
<b>Class A Common Stock, par value \$0.0001 per share</b>	<b>VAXX</b>	<b>The Nasdaq Global Market</b>

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, smaller reporting company, or an emerging growth company. See 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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).

As of December 17, 2021, the registrant had 111,519,983 shares of \$0.0001 par value Class A common stock outstanding and 13,874,132 shares of \$0.0001 par value Class B common stock outstanding.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

- the effects of the COVID-19 pandemic on business operations, the initiation, development and operation of our clinical trials and patient enrollment of our clinical trials.

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

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

As used in this Quarterly Report on Form 10-Q, unless otherwise specified or the context otherwise requires, the terms “we,” “our,” “us,” the “Company” refer to Vaxxinity, Inc. and its subsidiaries. All brand names or trademarks appearing in this Quarterly Report are the property of their respective owners.

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**PART I. Financial Information**

**Item 1. Financial Statements**

**VAXXINITY, INC.**  
**CONDENSED COMBINED CONSOLIDATED BALANCE SHEETS**  
*(in thousands, except share and per share amounts)*  
*(unaudited)*

	<u>December 31,</u> <u>2020</u>	<u>September 30,</u> <u>2021</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 31,143	\$ 89,375
Accounts receivable	26	
Amounts due from related parties	361	380
Prepaid expenses and other current assets	4,144	14,299
Total current assets	35,674	104,054
Deferred offering costs	2,254	6,189
Property and equipment, net	12,158	11,382
Licensed intellectual property, net		13,217
Restricted cash	55	74
Total assets	<u>\$ 50,141</u>	<u>\$ 134,916</u>
<b>Liabilities, convertible preferred stock, and stockholders' deficit</b>		
Current liabilities:		
Accounts payable	\$ 1,017	\$ 3,905
Amounts due to related parties	8,004	21,216
Accrued expenses and other current liabilities	610	5,134
Notes payable	619	425
Notes payable with related parties	2,294	
Convertible notes payable	10,356	
Convertible notes with related parties, net of discount	14,324	
Total current liabilities	37,224	30,680
Other liabilities		
Simple agreement for future equity	24,335	
Notes payable	10,699	10,366
Warrant liability	400	
Other long-term liabilities	2,383	240
Total liabilities	<u>75,041</u>	<u>41,286</u>
Commitments and contingencies (Note 14)		
Convertible preferred stock:		
Series seed stock	10,383	
Series seed-1 stock	20,903	
Series seed-2 stock	11,315	
Series A-1 stock	4,640	
Series A-2 stock	15,234	
Series A stock		128,206
Series B stock		122,791
Total convertible preferred stock	<u>62,475</u>	<u>250,997</u>
Stockholders' deficit:		
Class A common stock	272	255
Treasury stock	(23)	
Additional paid-in capital	4,682	23,668
Accumulated deficit	(92,306)	(181,290)
Total stockholders' deficit	<u>(87,375)</u>	<u>(157,367)</u>
Total liabilities, convertible preferred stock, and stockholders' deficit	<u>\$ 50,141</u>	<u>\$ 134,916</u>

Note: Derived from audited Financial Statements as of December 31, 2020.

The accompanying notes are an integral part of the condensed combined consolidated financial statements.

**VAXXINITY, INC.**  
**CONDENSED COMBINED CONSOLIDATED STATEMENTS OF OPERATIONS**  
*(in thousands, except share and per share amounts)*  
*(unaudited)*

	<b>Three Months Ended</b>		<b>Nine months ended September 30,</b>	
	<b>September 30,</b>			
	<b>2020</b>	<b>2021</b>	<b>2020</b>	<b>2021</b>
Revenue	\$ 117	\$ 50	\$ 557	\$ 67
Cost of revenue	(178)	9	52	1,937
Gross profit/loss	295	41	505	(1,870)
Operating expenses:				
Research and development	7,867	23,616	12,109	54,221
General and administrative	5,122	6,700	9,453	21,130
Total operating expenses	12,989	30,316	21,562	75,351
Loss from operations	(12,694)	(30,275)	(21,057)	(77,221)
Other expense:				
Interest expense, net	331	109	737	493
Change in fair value of convertible notes	2,786		4,781	2,667
Change in fair value of warrant liability				214
Change in fair value of simple agreements for future equity	615		615	8,365
Foreign currency loss, net	39	5	48	24
Other expense, net	3,771	114	6,181	11,763
Net loss	\$ (16,465)	\$ (30,389)	\$ (27,238)	\$ (88,984)
Net loss per share, basic and diluted	(0.24)	(0.44)	(0.47)	(1.30)
Weighted average common shares outstanding, basic and diluted	68,138,651	68,728,509	58,154,956	68,667,682

The accompanying notes are an integral part of the condensed combined consolidated financial statements.

**VAXXINITY, INC.**  
**CONDENSED COMBINED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK**  
**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2020**  
*(in thousands, except share amounts)*  
*(unaudited)*

	Convertible Preferred Stock										Total
	Series Seed		Series Seed-1		Series Seed-2		Series A-1		Series A-2		
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	
<b>Balance at June 30, 2020</b>	7,831,528	\$ 10,383	22,876,457	\$ 20,903	14,615,399	\$ 11,315	—	\$ —	—	\$ —	<b>42,601</b>
Issuance of Series A-1 preferred stock, net of issuance costs of \$85							1,566,153	3,987			3,987
Conversion of Simple Agreement for Future Equity to Series A-2 preferred stock, net of issuance costs of \$41									6,307,690	15,275	15,275
<b>Balance at September 30, 2020</b>	<b>7,831,528</b>	<b>\$ 10,383</b>	<b>22,876,457</b>	<b>\$ 20,903</b>	<b>14,615,399</b>	<b>\$ 11,315</b>	<b>1,566,153</b>	<b>3,987</b>	<b>6,307,690</b>	<b>\$ 15,275</b>	<b>61,863</b>

	Convertible Preferred Stock										Total
	Series Seed		Series Seed-1		Series Seed-2		Series A-1		Series A-2		
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	
<b>Balance at December 31, 2019</b>	7,831,528	\$ 10,383	8,017,771	\$ 16,436	—	\$ —	—	\$ —	—	\$ —	<b>26,819</b>
Issuance of Series Seed-1 convertible preferred stock, net of issuance costs of \$18			14,858,686	4,467							4,467
Issuance of Series Seed-2 preferred stock, net of issuance costs of \$45					14,152,237	10,955					10,955
Conversion of Simple Agreement for Future Equity to Series Seed-2 preferred Stock					463,162	360					360
Issuance of Series A-1 preferred stock, net of issuance costs of \$373							1,566,153	3,987			3,987
Conversion of Simple Agreement for Future Equity to Series A-2 preferred stock, net of issuance costs of \$41									6,307,690	15,275	15,275
<b>Balance at September 30, 2020</b>	<b>7,831,528</b>	<b>\$ 10,383</b>	<b>22,876,457</b>	<b>\$ 20,903</b>	<b>14,615,399</b>	<b>\$ 11,315</b>	<b>1,566,153</b>	<b>3,987</b>	<b>6,307,690</b>	<b>\$ 15,275</b>	<b>61,863</b>

**VAXXINITY, INC.**  
**CONDENSED COMBINED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT**  
**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2020**  
*(in thousands, except share amounts)*  
*(unaudited)*

	Stockholders' Deficit										
	Common Stock		Common Stock (Class A)		Common Stock (Class B)		Treasury Stock		Paid-in Capital	Accumulated Deficit	Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
<b>Balance at June 30, 2020</b>	71,289,721	\$ 271	—	\$ —	—	\$ —	(3,169,093)	\$ (23)	4,855	\$ (63,121)	\$ (58,818)
Issuance of common stock upon exercise of stock options			68,069						19		19
Stock-based compensation expense									291		291
Reclassification of common stock to Class A common stock	(60,290,572)	(271)	60,290,572	271							—
Reclassification of common stock to Class B common stock	(10,999,149)				10,999,149						—
Net loss										(16,465)	(16,465)
<b>Balance at September 30, 2020</b>	—	\$ —	60,358,641	\$ 271	10,999,149	\$ —	(3,169,093)	\$ (23)	4,365	\$ (79,586)	\$ (74,973)

	Stockholders' Deficit										
	Common Stock		Common Stock (Class A)		Common Stock (Class B)		Treasury Stock		Additional Paid-in Capital	Accumulated Deficit	Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
<b>Balance at December 31, 2019</b>	37,953,692	\$ 270	—	\$ —	—	\$ —	(3,169,093)	\$ (23)	3,591	\$ (52,348)	\$ (48,510)
Issuance of common stock upon exercise of stock options	213,271		68,069						79		79
Vesting of restricted stock	121,282		1								1
Issuance of common stock for C19 Shareholders	33,001,476										—
Stock-based compensation expense									695		695
Reclassification of common stock to Class A common stock	(60,290,572)	(271)	60,290,572	271							—
Reclassification of common stock to Class B common stock	(10,999,149)				10,999,149						—
Net loss										(27,238)	(27,238)
<b>Balance at September 30, 2020</b>	—	\$ —	60,358,641	\$ 271	10,999,149	\$ —	(3,169,093)	\$ (23)	4,365	\$ (79,586)	\$ (74,973)

The accompanying notes are an integral part of the condensed combined consolidated financial statements.



**VAXXINITY, INC.**  
**CONDENSED COMBINED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK**  
**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2021**  
*(in thousands, except share amounts)*  
*(unaudited)*

**Convertible Preferred Stock**

	Series A		Series B		Total
	Shares	Amount	Shares	Amount	
<b>Balance at June 30, 2021</b>	<b>62,223,095</b>	<b>\$ 128,206</b>	<b>15,365,574</b>	<b>\$ 122,843</b>	<b>\$ 251,049</b>
Additional issuance costs of Series B convertible preferred stock				(52)	(52)
<b>Balance at September 30, 2021</b>	<b>62,223,095</b>	<b>\$ 128,206</b>	<b>15,365,574</b>	<b>\$ 122,791</b>	<b>\$ 250,997</b>

**Convertible Preferred Stock**

	Series Seed		Series Seed-1		Series Seed-2		Series A-1		Series A-2		Series A		Series B		Total
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	
<b>Balance at December 31, 2020</b>	7,831,528	\$ 10,383	22,876,457	\$ 20,903	14,615,399	\$ 11,315	1,871,511	\$ 4,640	6,307,690	\$ 15,234	—	\$ —	—	\$ —	62,475
Exchange of Series Seed, Series seed-1, Series seed-2, Series A-1 and Series A-2 for Series A	(7,831,528)	(10,383)	(22,876,457)	(20,903)	(14,615,399)	(11,315)	(1,871,511)	(4,640)	(6,307,690)	(15,234)	53,502,585	62,475	—	—	—
Conversion of convertible notes to Series A preferred											3,624,114	27,379			27,379
Conversion of notes payable with related party to Series A convertible preferred											423,230	2,138			2,138
Conversion of SAFEs to Series A convertible preferred											4,539,060	35,600			35,600
Conversion of Warrants to Series A convertible preferred											134,106	614			614
Issuance of Series B convertible preferred stock, net of issuance costs of \$133													15,365,574	122,791	122,791
<b>Balance at September 30, 2021</b>	<b>—</b>	<b>\$ —</b>	<b>—</b>	<b>\$ —</b>	<b>—</b>	<b>\$ —</b>	<b>—</b>	<b>\$ —</b>	<b>—</b>	<b>\$ —</b>	<b>62,223,095</b>	<b>\$ 128,206</b>	<b>15,365,574</b>	<b>\$ 122,791</b>	<b>\$ 250,997</b>

**VAXXINITY, INC.**  
**CONDENSED COMBINED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT**  
**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2021**  
*(in thousands, except share amounts)*  
*(unaudited)*

	Stockholders' Deficit							
	Common Stock (Class A)		Common Stock (Class B)		Additional Paid-in Capital	Accumulated Deficit	Stockholders' Deficit	
	Shares	Amount	Shares	Amount				
<b>Balance at June 30, 2021</b>	54,845,535	\$ 255	13,874,132	\$ —	\$ 8,825	\$ (150,901)	\$ (141,821)	
Issuance of common stock upon exercise of stock options	54,841				59		59	
Stock-based compensation expense					1,464		1,464	
Common Stock Warrants (See Note 4)					13,320		13,320	
Net loss						(30,389)	(30,389)	
<b>Balance at September 30, 2021</b>	<b>54,900,376</b>	<b>\$ 255</b>	<b>13,874,132</b>	<b>\$ —</b>	<b>\$ 23,668</b>	<b>\$ (181,290)</b>	<b>\$ (157,367)</b>	

	Stockholders' Deficit								
	Common Stock (Class A)		Common Stock (Class B)		Treasury Stock		Additional Paid-in Capital	Accumulated Deficit	Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount			
<b>Balance at December 31, 2020</b>	60,360,523	\$ 272	10,999,149	\$ —	(3,169,093)	\$ (23)	\$ 4,682	\$ (92,306)	\$ (87,375)
Issuance of common stock upon exercise of stock options	82,696		6				64		70
Vesting of restricted stock	15,405								—
Reclassification of common stock to Class B common stock	(2,874,985)		2,874,983						—
Issuance of common stock upon stock grant	485,830								—
Retirement of treasury stock upon merger	(3,169,093)		(23)		3,169,093	23			—
Stock-based compensation expense							5,602		5,602
Common Stock Warrants (See Note 4)							13,320		13,320
Net loss								(88,984)	(88,984)
<b>Balance at September 30, 2021</b>	<b>54,900,376</b>	<b>\$ 255</b>	<b>13,874,132</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 23,668</b>	<b>\$ (181,290)</b>	<b>\$ (157,367)</b>

The accompanying notes are an integral part of the condensed combined consolidated financial statements.

**VAXXINITY, INC.**  
**CONDENSED COMBINED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
*(in thousands)*  
*(unaudited)*

	<b>Nine months ended</b>	
	<b>September 30,</b>	
	<b>2020</b>	<b>2021</b>
Cash flows from operating activities:		
Net loss	\$ (27,238)	\$ (88,984)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	363	928
Stock-based compensation expense	695	5,602
Non-cash interest expense	405	268
Change in fair value of convertible notes	4,781	2,667
Change in fair value of warrant liability		214
Change in fair value of simple agreement for future equity	615	8,365
Accounts receivable	(26)	26
Prepaid expenses and other current assets	(5,296)	(10,155)
Amounts due from related parties	(34)	(18)
Deferred offering costs	(541)	(3,935)
Accounts payable	821	2,888
Amounts due to related parties	2,177	13,212
Accrued expenses and other current liabilities	487	4,521
Other liabilities	122	(2,625)
Net cash used in operating activities	<u>(22,669)</u>	<u>(67,026)</u>
Cash flows from investing activities:		
Purchase of property and equipment	(1,026)	(50)
Net cash used in investing activities	<u>(1,026)</u>	<u>(50)</u>
Cash flows from financing activities:		
Proceeds from issuance of convertible notes payable	12,040	2,000
Payment of debt issuance costs for related party convertible notes	(300)	
Repayment of convertible notes	(5,500)	(2,096)
Proceeds from issuance of simple agreement for future equity	15,020	2,900
Proceeds from issuance of Series Seed-1 convertible preferred stock, net of issuance costs	4,467	
Proceeds from issuance of Series Seed-2 convertible preferred stock, net of issuance costs	10,955	
Proceeds from issuance of Series A-1 convertible preferred stock, net of issuance costs	4,360	
Repayment of note payable with related party		(100)
Proceeds from issuance of Series B convertible preferred stock, net of issuance costs		122,791
Proceeds and repayments Paycheck Protection Program	257	(257)
Proceeds from exercise of stock options	79	70
Net cash provided by financing activities	<u>41,378</u>	<u>125,308</u>
Increase in cash, cash equivalents, and restricted cash	17,683	58,232
Cash and cash equivalents at beginning of period	476	31,143
Restricted Cash	79	74
Cash, cash equivalents and restricted cash at end of period	<u>\$ 18,238</u>	<u>\$ 89,449</u>
Supplemental disclosures of non-cash investing, financing and cash flow information:		
Non-cash interest expense	425	268
Conversion of simple agreement for future equity into Series Seed 2 preferred stock	360	
Fair value of restricted stock vesting during the period	1	
Conversion of simple agreement for future equity into Series A-2 preferred stock	15,275	
Acquisition of airplane through issuance of note payable	11,500	
Fair value of warrants issued in connection with preferred stock issuance	373	
Issue of Warrant for Licensed Intellectual Property		13,320

The accompanying notes are an integral part of the condensed combined consolidated financial statements.

**VAXXINITY, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
*(Amounts in thousands, except share and per share amounts)*  
*(unaudited)*

**1. Nature of the Business**

Vaxxinity, Inc., a Delaware corporation (“Vaxxinity”, and together with its subsidiaries, the “Company”), was formed through the combination of two separate businesses that originated from United Biomedical, Inc. (“UBI”) in two separate transactions: a spin-out from UBI in 2014 of operations focused on developing chronic disease product candidates that resulted in United Neuroscience (“UNS”), and a second spin-out from UBI in 2020 of operations focused on the development of a COVID-19 vaccine that resulted in C19 Corp. (“COVAXX”).

On February 2, 2021, Vaxxinity was incorporated for the purpose of reorganizing and combining UNS and COVAXX and on March 2, 2021, did so by acquiring all the outstanding equity interests of UNS and COVAXX pursuant to a contribution and exchange agreement (the “Contribution and Exchange Agreement”) whereby the existing equity holders of UNS and COVAXX contributed their equity interests in each of UNS and COVAXX in exchange for equity in Vaxxinity (the “Reorganization”).

The Company is a biotechnology company currently focused on developing product candidates for human use in the fields of neurology and coronaviruses utilizing its “Vaxxine Platform” — a peptide vaccine technology first developed by UBI and subsequently refined over the last two decades. The Company is engaged in the development and commercialization of rationally designed prophylactic and therapeutic vaccines to combat chronic disorders and infectious diseases with large patient populations and unmet medical need. UBI is a significant shareholder of the Company and, therefore, considered a related party.

***Impact of COVID-19 Pandemic***

In March 2020, the World Health Organization declared the outbreak of a COVID-19 pandemic. The COVID-19 pandemic is evolving, and to date, has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures.

The Company is closely monitoring the impact of the COVID-19 pandemic on all aspects of its business, including how it will impact its operations and the operations of its customers, suppliers, vendors and business partners. The Company does not yet know the full extent of potential delays or impacts on its business, its clinical trials, its research programs, healthcare systems or the global economy and it cannot presently predict the scope and severity of any potential business shutdowns or disruptions. The extent to which COVID-19 impacts its business, results of operation and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, new information that may emerge concerning the severity of COVID-19 or the effectiveness of actions to contain COVID-19 or treat its impact, among others. If the Company or any of the third parties with whom the Company engages, however, were to experience shutdowns or other business disruptions, its ability to conduct its business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on its business, results of operation and financial condition.

The Company has not incurred impairment losses in the carrying values of its assets as a result of the COVID-19 pandemic and it is not aware of any specific related event or circumstance that would require it to revise its estimates reflected in these condensed combined consolidated financial statements.

**2. Summary of Significant Accounting Policies**

***Basis of Presentation***

The accompanying unaudited interim condensed combined consolidated financial statements have been prepared pursuant to the rules and regulations of the United States Securities and Exchange Commission (“SEC”) for interim financial reporting. The condensed consolidated financial statements for the periods presented include the accounts of UNS and COVAXX that were parties to the Contribution and Exchange Agreement. All share and per share amounts, as originally recorded by each entity, have been converted to a number of shares and per share amounts using the conversion ratios determined under the Contribution and Exchange Agreement.

These interim condensed combined consolidated financial statements are unaudited and, in the opinion of management, include all adjustments (consisting of normal recurring adjustments and accruals) necessary to fairly present the results of the interim periods. The condensed combined balance sheet at December 31, 2020, has been derived from the audited financial statements at that date. Operating results for the three and nine months ended September 30, 2021 and cash flows for the nine months ended September 30, 2021 are not necessarily indicative of the results that may be expected for the fiscal year ended December 31, 2021 or any other future period. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance

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with accounting principles generally accepted in the United States (“U.S. GAAP”) have been omitted in accordance with the rules and regulations for interim reporting of the SEC. These interim condensed financial statements should be read in conjunction with the financial statements and notes thereto included in our report for the year ended December 31, 2020.

***Significant Accounting Policies***

The significant accounting policies used in preparation of these condensed financial statements are disclosed in our annual financial statements for the year ended December 31, 2020. There have been no changes to the Company’s significant accounting policies during the three and nine months ended September 30, 2021.

***Emerging Growth Company Status***

The Company is an “emerging growth company” (“EGC”), as defined in the Jumpstart Our Business Startups Act (“JOBS Act”) and is permitted to and plans to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not EGCs. The Company may take advantage of these exemptions until it is no longer an EGC under Section 107 of the JOBS Act, which provides that an EGC can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. The Company has elected to avail itself of the extended transition period and, therefore, while the Company is an EGC it will not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not EGCs.

***Recently Adopted Accounting Pronouncements***

In November 2018, the Financial Accounting Standards Board (“FASB”) issued ASU 2018-18, Collaborative Arrangements (Topic 808): *Clarifying the Interaction between Topic 808 and Topic 606*, (“ASU 2018-18”). The amendments in this update clarify that certain transactions between collaborative arrangement participants should be accounted for as revenue when the collaborative arrangement participant is a customer in the context of a unit of account and precludes recognizing as revenue consideration received from a collaborative arrangement participant if the participant is not a customer. ASU 2018-18 is effective for the Company’s annual reporting periods after December 15, 2020. The Company adopted ASU 2018-18 at January 1, 2021. The adoption of this pronouncement did not have a material impact on the Company’s combined consolidated financial statements or its results of operations.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* (“ASU 2019-12”), which is intended to simplify the accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. The new standard will be effective for the Company beginning January 1, 2021. The Company adopted ASU 2019-12 at January 1, 2021. The adoption of this pronouncement did not have a material impact on the Company’s combined consolidated financial statements or its results of operations.

***Recently Issued Accounting Pronouncements***

In February 2016, the FASB issued ASU 2016-12, “Leases (Topic 842), and associated ASUs related to Topic 842, which requires organizations that lease assets to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases. The new guidance requires that a lessee recognize assets and liabilities for leases, and recognition, presentation and measure in the financial statements will depend on its classification as a finance or operating lease. In addition, the new guidance requires disclosures to help investors and other financial statement users better understand the amount, timing and uncertainty of cash flows arising from leases. The estimated impact on our existing lease agreements is approximately \$250,000.

The Company has elected to apply the transition requirements as of January 1, 2022. This approach allows for a cumulative effect adjustment in the period of adoption, and prior periods continue to be reported in accordance with historic accounting under ASC 840 “Leases.” Additionally, as an accounting policy election, the Company has chosen to not apply the standard to any existing short-term leases (term of 12 months or less) as this is optional under U.S. GAAP.

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**3. Fair Value Measurements**

The value for the Convertible Notes, SAFE and warrant liability balances as of December 31, 2020 are based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. In accordance with the Contribution and Exchange Agreement, on March 2, 2021 the Convertible Notes, SAFEs and warrants were all converted into Series A preferred stock.

The following tables present information about the Company's financial instruments measured at fair value on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values:

<b>December 31, 2020</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Liabilities</b>				
Convertible notes payable	\$ —	\$ —	\$ 24,040	\$ 24,040
SAFES	—	—	24,335	24,335
Warrant liability	—	—	400	400
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 48,775</u>	<u>\$ 48,775</u>

<b>September 30, 2021</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Assets</b>				
Money market funds	\$ 84,000	\$ —	\$ —	\$ 84,000
	<u>\$ 84,000</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 84,000</u>

During the nine months ended September 30, 2020 and 2021, there were no transfers between Level 1, Level 2 and Level 3.

**Convertible Notes**

During the years ended December 31, 2019 and 2020, and the nine months ended September 30, 2021, the Company issued Convertible Notes. In accordance with ASC 480, a portion of the Convertible Notes were required to be measured and accounted for at fair value at each reporting date. The Company determined the Convertible Notes requiring a measurement to fair value represent a recurring measurement that is classified within Level 3 of the fair value hierarchy wherein fair value is estimated using significant unobservable inputs.

Convertible Notes requiring a measurement to fair value are as follows (in thousands):

	<b>September 30, 2021</b>
Beginning balance, December 31, 2020	\$ 24,680
Level 3 fair value of the principal amount of convertible notes	\$ 24,040
Change in fair value	2,667
Conversion to Series A preferred stock	(26,707)
Ending balance September 30, 2021	<u>\$ —</u>

The fair value of the Convertible Notes was estimated using a straight debt and conversion feature valuation model consisting of probability assumptions on multiple conversion scenarios, discount rates and interest rates.

In accordance with the Contribution and Exchange Agreement, on March 2, 2021, the Convertible Notes were converted into Series A preferred stock.

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**Simple Agreement for Future Equity**

During the year ended December 31, 2020, the Company executed SAFE arrangements. The fair value of the SAFEs on the date of issuance was determined to equal the proceeds received by the Company. The value of the SAFEs on the dates of conversion into preferred stock was determined to be equal to the fair value of the preferred stock issued, or \$15.6 million.

The following table sets forth a summary of the activities of the SAFE arrangements, which represents a recurring measurement that is classified within Level 3 of the fair value hierarchy wherein fair value is estimated using significant unobservable inputs (in thousands):

	<b>SAFE Liability</b>
Balance at December 31, 2020	\$ 24,335
Change in fair value	8,365
Issuance of SAFEs	2,900
Conversion to Series A preferred stock	(35,600)
Balance at September 30, 2021	<u>\$ —</u>

In accordance with the Contribution and Exchange Agreement, on March 2, 2021, the SAFEs were converted into Series A preferred stock.

**Warrants to Purchase Series A-1 Convertible Preferred Stock & Common Stock**

In connection with the 2020 Series A-1 convertible preferred stock ("Series A-1 preferred") financing transactions, the Company issued fully vested warrants to purchase 205,970 shares of Series A-1 preferred. The warrants were issued to advisors as consideration for assistance with the sale and issuance of the Series A-1 preferred. The warrants were determined to represent issuance costs and were recorded as a reduction in the proceeds received from the sale.

The warrants were issued to advisors of the company and represented non-variable contingently redeemable instruments. As such, the warrants were accounted for as liabilities and adjusted to fair value at each reporting period.

The warrants are exercisable on the date of issuance and have an exercise price of \$0.003 per share and a contractual term of ten years. In December 2020, 71,862 warrants were exercised at \$0.003 per share, resulting in cash proceeds of less than \$1,000. As of December 31, 2020, 134,106 warrants to purchase Series A-1 preferred were outstanding. The Company continued to re-measure the fair value of the liability associated with the warrant to purchase shares of Series A-1 preferred at the end of each reporting period until the Reorganization, when the warrant converted into Series A preferred stock and subsequently, in connection with the IPO, converted into Class A common stock.

The following table sets forth a summary of the activity of the warrant liability which represented a recurring measurement that is classified within Level 3 of the fair value hierarchy wherein fair value is estimated using significant unobservable inputs (in thousands):

	<b>Warrants Liability</b>
Balance at December 31, 2020	\$ 400
Change in fair value	214
Exchange of warrants for shares of Series A preferred stock	(614)
Balance at September 30, 2021	<u>\$ —</u>

On August 5, 2021, as partial consideration for the rights and licenses the company received pursuant to the Platform License Agreement, the company issued a warrant to United Biomedical, Inc., for the purchase of 1,928,020 shares of Class A common stock at an exercise price of \$12.45 per share. The fair value of this warrant as of September 30, 2021 was \$13.3 million. Due to its underlying characteristics, the warrant was classified as additional paid in capital with a corresponding recognition as an 'intangible asset - licensed intellectual property' to be amortized over its estimated useful life of twenty years.

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**4. Property, Equipment and Licensed Intellectual Property**

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

	<u>December 31,</u> <u>2020</u>	<u>September 30,</u> <u>2021</u>
Airplane	\$ 11,983	\$ 11,983
Laboratory and computer equipment	969	1,019
Furniture and fixtures	84	84
Total property and equipment	\$ 13,036	\$ 13,086
Less accumulated depreciation	(878)	(1,704)
Property and equipment, net	<u>\$ 12,158</u>	<u>\$ 11,382</u>

Depreciation and amortization expense for the three and nine months ended September 30, 2020 was less than \$0.1 million and less than \$0.1 million respectively. Depreciation and amortization expense for the three and nine months ended September 30, 2021 was \$0.4 million and \$0.9 million, respectively.

**Licensed intellectual property, net consisted of the following (in thousands):**

Licensed intellectual property is amortized over the estimated lifetime of the intangible asset (20 years).

As of September 30, 2021, the annual amortization schedule is as follows (in thousands):

	<u>September 30,</u> <u>2021</u>
Licensed intellectual property	\$ 13,320
Less accumulated amortization	(103)
Licensed intellectual property, net	<u>\$ 13,217</u>
	<b>Amount</b>
2021 (Q4 2021)	\$ 167
2022	666
2023	666
2024	668
2025 and thereafter	11,050
	<u>\$ 13,217</u>

**5. Accrued Expenses and Other Current Liabilities**

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

	<u>December 31,</u> <u>2020</u>	<u>September 30,</u> <u>2021</u>
Accrued professional fees and other	228	2,240
Accrued payroll and benefits	53	2,138
Accrued interest	33	31
Accrued external research and development	296	725
	<u>\$ 610</u>	<u>\$ 5,134</u>

**6. Convertible Notes Payable**

Beginning in April 2018, the Company issued several Convertible Notes, some of which were issued to related parties. The Convertible Notes bear simple interest at annual rates ranging from 4.8% to 6%. All unpaid principal, together with the accrued



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interest thereon, are payable upon an event of default or upon maturity, which ranges from one to three years. The Convertible Notes contain a number of provisions addressing automatic and optional conversion, events of default, and prepayment provisions.

The Company accounts for the Convertible Notes at fair value, in accordance with ASC 480, with any changes in fair value being recognized through the condensed combined consolidated statements of operations.

In accordance with the Contribution and Exchange Agreement, on March 2, 2021 each Reorg. Convertible Note (as defined below) that was outstanding was exchanged for shares of Series A preferred stock, as set forth in the applicable Convertible Note agreements and the Contribution and Exchange Agreement.

During the three and nine months ended September 30, 2021, the Company recognized interest expense of \$0.1 and \$0.2 million, respectively, related to the Convertible Notes. In addition, during the nine months ended September 30, 2021, the Company recognized a change in fair value of \$2.7 million in the accompanying condensed combined consolidated statements of operations related to the Convertible Notes.

The following table shows the activity of the Convertible Notes (in thousands):

	Convertible Notes									
	Principal Amount Payable		Change in Fair Value		Accrued Interest		Issuance	Conversion to Series A Preferred		Balance
	Standard	Related Party	Standard	Related Party	Standard	Related Party	Costs	Preferred		
December 31, 2019	\$ 11,170	\$ 510	\$ 33	\$ 26	\$ 378	\$ 4	\$ —	\$ —	\$ —	\$ 12,121
Additions	2,040	10,000	1,661	3,119	203	48	(300)	—	—	16,771
Settlements	(5,500)	—	—	—	—	—	—	—	—	(5,500)
September 30, 2020	\$ 7,710	\$ 10,510	\$ 1,694	\$ 3,145	\$ 581	\$ 52	\$ (300)	\$ —	\$ —	\$ 23,392

	Convertible Notes									
	Principal Amount Payable		Change in Fair Value		Accrued Interest		Issuance	Conversion to Series A Preferred		Balance
	Standard	Related Party	Standard	Related Party	Standard	Related Party	Costs	Preferred		
December 31, 2020	\$ 7,710	\$ 10,510	\$ 1,972	\$ 3,848	\$ 674	\$ 183	\$ (217)	\$ —	\$ —	\$ 24,680
Additions	—	2,000	812	1,855	48	121	—	—	—	4,836
Settlements	(2,000)	—	—	—	(187)	—	—	—	—	(2,187)
Amortization	—	—	—	—	—	—	50	—	—	50
Conversion of Convertible Notes to Series A preferred stock	—	—	—	—	—	—	167	(27,546)	—	(27,379)
September 30, 2021	\$ 5,710	\$ 12,510	\$ 2,784	\$ 5,703	\$ 535	\$ 304	\$ —	\$ (27,546)	\$ —	\$ —

## 7. Notes Payable

### Notes Payable with Related Parties

In December 2018, the Company entered into related party convertible notes payable (the “2018 Related Notes” and together with the Convertible Notes, the “Reorg. Convertible Notes”) for \$2.0 million in aggregate proceeds, received in three tranches. The 2018 Related Notes bore simple interest at an annual rate of 5% and contain a number of provisions addressing automatic and optional conversion, events of default and prepayment. In accordance with the Contribution and Exchange Agreement, on March 2, 2021, the 2018 Related Notes were converted into Series A preferred stock.

In November 2019, the Company borrowed \$0.1 million from its Chief Executive Officer (the “2019 Executive Note”). No formal loan agreement was executed. However, the Company has elected to accrue interest at an annual rate of 5%, consistent with the terms and conditions of the Convertible Notes and 2018 Related Notes, which was the closest benchmark the Company could evaluate. The 2019 Executive Note was repaid in August 2021.

### Note Payable—Airplane

In connection with the acquisition of an airplane, the Company entered into a note payable agreement (the “2025 Note”) in June 2020 for \$11.5 million, with an annual interest rate of 3.4% and a maturity date of June 9, 2025. Principal and interest payments are payable monthly in the amount of \$0.06 million with a final payment of \$9.4 million at maturity. The 2025 Note is guaranteed by the co-founders of the Company. In addition, the Company incurred debt issuance costs of \$0.3 million, which are being amortized over the term of the loan. There are no financial covenants associated with the 2025 Note.

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The carrying value of the 2025 Note is as follows (in thousands):

	<u>September 30,</u>
	<u>2021</u>
Principal	\$ 10,989
Unamortized debt issuance cost	(198)
Carrying amount	10,791
Less: current portion	(425)
Note payable, net of current portion and debt issuance cost	<u>\$ 10,366</u>

As of September 30, 2021, the remaining principal payments for the 2025 Note, are as follows (in thousands):

	<u>Amount</u>
2021	\$ 105
2022	429
2023	444
2024	458
2025 and thereafter	9,553
	<u>\$ 10,989</u>

Interest expense associated with the 2025 Note was less than \$ 0.1 million for each of the three and nine months ended September 30, 2020. Interest expense associated with the 2025 Note was \$0.1 million and \$0.3 million for the three and nine months ended September 30, 2021.

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**Note Payable—Paycheck Protection Program**

The Company applied for and received a loan, which is in the form of a note dated May 5, 2020, from HSBC Bank USA, National Association (“HSBC”) in the aggregate amount of approximately \$0.3 million (the “PPP Loan”), pursuant to the Paycheck Protection Program (“PPP”). The PPP, established as part of the Coronavirus Aid, Relief and Economic Security Act (“CARES Act”), provides for loans to qualifying businesses for amounts up to 2.5 times of the average monthly payroll expenses of the qualifying business. As of December 31, 2020, there were no events of default under the PPP Loan. The Company paid off the PPP Loan in full, including all accrued but unpaid interest to the repayment date, in August 2021.

**8. Convertible Preferred Stock**

As explained in Note 1, in accordance with the Contribution and Exchange Agreement, on March 2, 2021 each share of preferred stock of UNS and COVAXX, as well as each Reorg. Convertible Note, that was outstanding was exchanged for Vaxxinity’s preferred stock as set forth in the Contribution and Exchange Agreement. Each UNS convertible preferred share was exchanged for 0.2191 shares of Vaxxinity preferred stock and each share of COVAXX convertible preferred stock was exchanged for 3.4233 shares of Vaxxinity preferred stock.

As of September 30, 2021, Vaxxinity’s Amended and Restated Certificate of Incorporation (authorized 87,223,095 shares of convertible preferred stock with a par value of \$0.0001 per share, of which 62,223,095 shares have been designated as Series A preferred stock and 25,000,000 shares have been designated as Series B preferred stock.

The holders of Vaxxinity’s preferred stock have liquidation rights in the event of a deemed liquidation that, in certain situations, are not solely within the control of Vaxxinity. Therefore, the preferred stock is classified outside of stockholders’ deficit.

Preferred stock consisted of the following as of September 30, 2021:

<b>As of September 30, 2021</b>	<b>Issuance Dates</b>	<b>Shares issued and outstanding</b>	<b>Common Stock Issuable Upon Conversion</b>
Series A preferred stock	March 2021	62,223,095	39,989,083
Series B preferred stock	March 2021	5,441,863	3,497,337
Series B preferred stock	June 2021	9,923,711	6,377,700
		<u>77,588,669</u>	<u>49,864,120</u>

The common stock issuable upon conversion reflects the application of the stock split described in Note 1. All shares of preferred stock were automatically converted into shares of Vaxxinity’s Class A common stock concurrently with the closing of the Company’s IPO in November 2021.

**9. Simple Agreement for Future Equity**

During the year ended December 31, 2020, the Company executed SAFE arrangements. The SAFEs were not mandatorily redeemable, nor did they require the Company to repurchase a fixed number of shares. The Company determined that the SAFEs contained a liquidity event provision that embodied an obligation indexed to the fair value of the Company’s equity shares and could require the Company to settle the SAFE obligation by transferring assets or cash. For this reason, the Company recorded the SAFEs as a liability under ASC 480 and re-measured the fair value at the end of each reporting period, with changes in fair value reported in earnings.

In March 2020, the Company issued a SAFE (“SAFE 1”) for \$ 0.4 million, which converted into 463,162 shares of Series Seed-2 convertible preferred stock at \$0.7773 per share in April 2020. In June, July, and August 2020, the Company issued a series of SAFEs (“SAFE 2”) for \$14.7 million, which converted into 6,307,690 shares of Series A-2 convertible preferred stock (“Series A-2 preferred”) at \$2.3241 per share in August 2020.

The Company determined the fair value of SAFE 2 investment on the date of conversion and recognized the difference between the fair value on the date of conversion and the initial fair value of SAFE 2 investment in the consolidated statement of

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operations. A loss of \$0.6 million was recorded in the consolidated statement of operations for the nine months ended September 30, 2020.

In December 2020, the Company issued a series of SAFEs (collectively, "SAFE 3") for \$24.3 million. In January 2021, the Company issued additional SAFEs for \$ 2.9 million.

As explained in Note 1, in accordance with the Contribution and Exchange Agreement, on March 2, 2021, the shareholders of both UNS and COVAXX contributed their capital stock in exchange for Vaxxinity's capital stock. Prior to the Reorganization, all the holders of outstanding COVAXX SAFEs agreed to convert such SAFEs into shares of Series A-3 preferred stock of COVAXX, which shares were then exchanged for shares of the Company's Series A preferred stock.

#### **10. Common Stock**

As explained in Note 1, in accordance with the Contribution and Exchange Agreement, on March 2, 2021, all outstanding shares of common stock of UNS and COVAXX were contributed to Vaxxinity and exchanged for an aggregate of 57,702,458 shares of Vaxxinity's Class A common stock, 10,999,149 shares of Vaxxinity's Class B common stock and 37,388,014 shares of our Series A preferred was exchanged for Vaxxinity's common stock. Each UNS share of common stock was exchanged for 0.2191 shares of Vaxxinity common stock and each share of COVAXX common stock was exchanged for 3.4233 like shares of Vaxxinity common stock.

In September 2021, the Company converted 2,874,984 shares of Class A common stock held by the Company's Chief Executive Officer and Executive Chairman on a one-to-one basis for shares of Class B common stock.

As of September 30, 2021, Vaxxinity's Amended and Restated Certificate of Incorporation authorized 170,650,960 shares of common stock with a par value of \$0.0001 per share, of which 146,477,113 shares have been designated as Class A common stock and 24,173,847 shares have been designated as Class B common stock.

Holders of Class A common stock and Class B common stock have identical rights, except with respect to voting and conversion. Except as otherwise expressly provided in Vaxxinity's Amended and Restated Certificate of Incorporation or Bylaws, or required by applicable law, holders of Class A common stock will be entitled to one vote per share on all matters submitted to a vote of stockholders and holders of our Class B common stock will be entitled to ten votes per share on all matters submitted to a vote of stockholders.

Holders of Class A common stock and Class B common stock vote together as a single class on all matters submitted to a vote of stockholders, except (i) amendments to Vaxxinity's Amended and Restated

Certificate of Incorporation to increase or decrease the par value of a class of capital stock, in which case the applicable class would be required to vote separately to approve the proposed amendment and (ii) amendments to Vaxxinity's Amended and Restated Certificate of Incorporation that alter or change the powers, preferences or special rights of a class of capital stock in a manner that affects its holders adversely, in which case the applicable class would be required to vote separately to approve the proposed amendment.

Holders of common stock are entitled to receive, ratably, dividends as may be declared by Vaxxinity's board of directors out of funds legally available therefor if the board of directors, in its discretion, determines to issue dividends.

The voting, dividend, and liquidation rights of the holders of common stock are subject to and qualified by the rights, powers, and preferences of the holders of Vaxxinity's preferred stock.

The Company has reserved shares of common stock for issuance for the following purposes at September 30, 2021:

Series A preferred stock	39,989,083
Series B preferred stock	9,875,037
Options issued and outstanding	20,714,308
Options available for future grants	7,169,027
Warrants issued and outstanding to purchase shares of common	2,056,722
	<u>79,804,177</u>

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**11. Equity Incentive Plan****Stock Options**

In February 2021, the Company replaced the 2017 and 2020 Stock Option and Grant Plans with the newly-adopted 2021 Stock Option and Grant Plan (the "Plan"), which provides for the Company to grant qualified incentive options, nonqualified options, restricted stock awards, unrestricted stock awards, and restricted stock units to employees and non-employees to purchase the Company's common stock.

The maximum number of shares of common stock that can be issued under the Plan is 21,593,830 shares of Class A and 6,362,456 Class B shares. As of September 30, 2021, 7,169,027 shares were available for Class A common stock future grant. Shares that are forfeited, canceled, reacquired by the Company prior to vesting, satisfied without the issuance of stock, withheld to cover the exercise price or tax withholdings, or otherwise terminated, other than by exercise, shall be added back to the Shares available for issuance under the Plan.

The exercise price for grants made pursuant to the terms of the Plan is determined in the applicable grant by the board of directors. Any incentive options granted to persons possessing less than 10% of the total combined voting power of all classes of stock may not have an exercise price of less than 100% of the fair market value of the common stock on the grant date. Any incentive options granted to persons possessing more than 10% of the total combined voting power of all classes of stock may not have an exercise price of less than 110% of the fair market value of the common stock on the grant date.

The option term for incentive awards may not be greater than ten years from the date of the grant. Incentive options granted to persons possessing more than 10% of the total combined voting power of all classes of stock may not have an option term of greater than five years from the date of the grant. The vesting period for equity-based awards is determined at the discretion of the board of directors.

In August 2021, we canceled existing options to purchase, in aggregate, 6,342,456 shares of our Class A common stock held by Mei Mei Hu and Louis Reese in exchange for an equal number of options to purchase shares of our Class B common stock. The new options to purchase shares of our Class B common stock were issued with exercise prices equal to the fair value of our Class B common stock on the new grant date. The company concluded, due to an increased exercise price in the exchanged options, there will be no associated incremental value reflected in our stock compensation expense.

As of September 30, 2021 there were 14,351,853 options for Class A shares outstanding and 6,362,456 options for Class B shares outstanding, of which 7,092,282 Class A shares were exercisable.

Total stock-based compensation expense for stock options is as follows (in thousands):

	<b>Three Months Ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2020</b>	<b>2021</b>	<b>2020</b>	<b>2021</b>
Research and development	\$ 83	\$ 364	\$ 206	\$ 738
General and administrative	208	1,100	489	4,864
Total stock-based compensation expense	\$ 291	\$ 1,464	\$ 695	\$ 5,602

**Restricted Stock**

The following table summarizes the Company's restricted stock activity for the nine months ended September 30, 2021:

	<b>Number of Shares</b>	<b>Weighted average grant date fair value per share</b>
Unvested at December 31, 2020	15,405	\$ 0.32
Vested	(15,405)	\$ 0.32
Unvested at September 30, 2021	-	\$ -

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Stock-based compensation expense recognized on vested restricted stock was immaterial for the three and nine months ended September 30, 2020 and 2021, respectively.

## 12. Income Taxes

During the three and nine months ended September 30, 2020 and 2021, respectively, the Company recorded no income tax benefit for the net operating losses incurred in each year, due its uncertainty of realizing a benefit from those items. The Company's tax provision and the resulting effective tax rate for interim periods is determined based upon its estimated annual effective tax rate, adjusted for the effect of discrete items arising during the interim quarterly period. The impact of such inclusions could result in a higher or lower effective tax rate during a particular quarterly period, based upon the mix and timing of actual earnings or losses versus annual projections. In each quarterly period, the Company updates its estimate of the annual effective tax rate, and if the estimated annual tax rate changes, a cumulative adjustment is made in that quarter.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize its deferred tax assets, which primarily consist of net operating loss carryforwards. The Company has considered its history of cumulative net losses, estimated future taxable income and prudent and feasible tax planning strategies and has concluded that it is more likely than not that the company will not realize the benefits of its deferred tax

## 13. Net Loss Per Share

The Company's unvested restricted common shares have been excluded from the computation of basic net loss per share.

The Company's potentially dilutive securities, which include options, unvested restricted stock, convertible notes payable and convertible preferred stock, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share as of September 30, 2021 because including them would have had an anti-dilutive effect:

Series A preferred stock	39,989,083
Series B preferred stock	9,875,037
Options to purchase common stock	20,714,308
Warrants issued and outstanding to purchase shares of common stock	2,056,722
	<u>72,635,150</u>

## 14. Commitments and Contingencies

### *Contractual Obligations*

The Company enters into agreements with contract research organizations ("CROs") to conduct clinical trials and preclinical studies and contract manufacturing organizations ("CMOs") to produce vaccines and other potential product candidates. Contracts with CROs and CMOs are generally cancellable, with notice, at the Company's option.

As of September 30, 2021, the Company had remaining prepayments to CROs of \$1.0 million and remaining prepayments to CMOs of \$10.9 million for activities associated with the conduct of its clinical trials and for the production of the Company's anticipated vaccine product candidate.

### *Lease Agreements*

The Company has multiple operating lease agreements for office and laboratory space that extend through August 2022. The Company records total expense on a straight-line basis over the term of the lease agreement. One of the Company's leases requires the Company to provide a security deposit in the amount of \$0.02 million. The Company is also required to pay certain operating costs under its leases.

Rent expense for each of the three and nine months ended September 30, 2020 was less than \$0.1 million. Rent expense for each of the three and nine months ended September 30, 2021 was less than \$0.1 million. In August 2021, the Company entered into a lease for 5,248 square feet of lab space with Space Florida in Exploration Park, Florida commencing August 12, 2021. The lease has an initial one-year term with an annual lease obligation of \$0.2 million, after Lessee credits.

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***License Agreements***

In October 2014, the Company entered into a contribution agreement with UBI, whereby UBI contributed and assigned to the Company assets and granted a non-exclusive license to certain technologies deemed necessary or reasonably useful in the utilization of the licensed intellectual property. In consideration, the Company issued 32,505,306 shares of common stock to UBI. The agreement allowed for exploitation of all diagnostic, prophylactic, and therapeutic uses and indications in humans in the field of neurology. The agreement was amended in August 2019 to provide the Company with exclusivity (except as to UBI) in the field of neurology and the flexibility to pursue indications outside the initial field limitations. Details of amended agreement issued in exchange for warrants shown in Note 3.

In connection with the amendment, the Company agreed to execute an exclusive, worldwide license agreement for any product that is developed by the Company outside the original field. The terms and conditions are to be negotiated in good faith and mutually agreed upon. The Company anticipates that if it is required to enter into an exclusive license agreement, it will be able to negotiate financial terms for the license at prevailing market rates within the pharmaceutical industry. Accordingly, the Company may be required to pay UBI upfront fees, revenue royalties, development milestones, commercial milestones, sublicense fees, and other related fees.

Vaxxinity's COVAXX subsidiary was formed in March 2020 through a transfer of technology from UBI, UBI IP Holdings, and UBI US Holdings, LLC, all related parties of the Company, whereby the Company, pursuant to an April 2020 license agreement, obtained exclusive rights to intellectual property and technology related to the discovery of vaccines, diagnostic assays, and antigens for use against all coronaviruses including, without limitation, SARS, MERS, and COVID-19 in all strains in humans. The license is worldwide, perpetual, exclusive and fully paid-up. There are no future royalty or milestone payment obligations associated with the agreement. The Company has the right to grant sublicenses.

The Company considered ASC 805, "Business Combinations" and ASC 730, "Research and Development" in determining how to account for the issuance of common stock. The license agreement is considered to be a common control transfer; however, the related party did not have any basis in the assets licensed, so there was no accounting impact for the Company.

***Indemnification Agreements***

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to employees, consultants, vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any indemnification arrangements that could have a material effect on its financial position, results of operations, or cash flows, and it has not accrued any liabilities related to such obligations as of September 30, 2021.

***Legal Proceedings***

From time to time, the Company may become involved in legal proceedings arising in the ordinary course of business. As of September 30, 2021, the Company was not a party to any material legal matters or claims.

**15. Related Party Transactions**

Pursuant to a Master Services Agreement with UBI ("MSA"), UBI provides research, development and clinical functions to the Company. The Company pays for services provided by UBI based on the UBI costs incurred plus a markup of 7.5% and reimburses for certain pass-through costs. Total amounts due to UBI pursuant to this MSA were \$ 3.6 million and \$4.0 million, as of December 31, 2020 and September 30, 2021, respectively. Total service fees incurred were \$0.4 million and less than \$0.1 million for nine months ended September 30, 2020 and 2021, respectively.

The Company also maintains a purchase arrangement with UBI for the production and shipment of the Company's diagnostic test kits to its customers. The Company has prepaid for materials required in this arrangement and recognizes prepayments as cost of goods sold when UBI ships product containing the materials to the Company's customers. As of December 31, 2020 and

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September 30, 2021, \$2.9 million and \$1.0 million of diagnostic test kit materials prepaid to UBI are included in 'Prepaid expenses and other current assets' in the condensed combined consolidated balance sheets, respectively.

The Company is party to an MSA ("MSA Asia") with United Biomedical, Inc., Asia ("UBI-Asia") for manufacturing, quality control, testing, validation, and supply services. Payment terms are mutually agreed in connection with each work order relating to services rendered. Total amounts due to UBI-Asia UBI pursuant to this MSA were \$ 1.0 and \$1.1 million as of December 31, 2020 and September 30, 2021, respectively. Total service fees incurred were \$0.1 million and \$0.7 million for the nine months ended September 30, 2020 and 2021, respectively.

The Company is party to an MSA ("MSA Taiwan") with UBI Pharma, Inc. ("UBI-P"). Under the MSA Taiwan, UBI-P will provide the Company with manufacturing, quality control, testing, validation, and supply services. Payment terms are mutually agreed in connection with each work order relating to services rendered. No amounts were due to UBI-P as of December 31, 2020 or September 30, 2021, respectively.

The Company is party to an MSA ("MSA UBP") with United BioPharma, Inc. ("UBP"). Under the MSA UBP, UBP will provide the Company with manufacturing, testing and validation. Payment terms are within 45 days of the of invoice receipt. Total amounts due to UBP pursuant to this MSA were each \$0 million and \$5.9 million as of December 31, 2020 and September 30, 2021, respectively. Total service fees incurred were each \$0.0 million and \$14 million for the nine months ended September 30, 2020 and 2021, respectively.

The Company is party to an MSA ("COVID MSA") with UBI relating to the Company's COVID-19 program. The COVID MSA provides that UBI acts as COVAXX's agent with respect to matters relating the Company's COVID-19 program and provides research, development, manufacturing and back office administrative services to the Company. The Company pays for services based on the UBI costs incurred plus a markup of 10.0% and reimburses for certain pass-through costs.

The Company is party to a four-company MSA with UBI, UBI-Asia and United BioPharma, Inc ("UBP"). The Company is an exclusive licensee of technologies related to diagnostics, vaccines, and therapies for COVID-19 ("COVID-19 Relief MSA"). The MSA established the terms under which UBI-Asia provides research, development, testing and manufacturing services to the Company and UBP provides contract development and manufacturing services to the Company. The four companies party to the COVID-19 Relief MSA share common ownership through UBI.

In aggregate, total amounts due to related parties under the COVID MSA and the COVID-19 Relief MSA were \$ 2.9 million and \$10.3 million as of December 31, 2020 and September 30, 2021, respectively. Total service fees incurred under the COVID MSA and the COVID-19 Relief MSA were \$10.3 million and \$16.9 million during the nine months ended September 30, 2020 and 2021, respectively, with \$3.7 million representing a prepaid production deposit at September 30, 2021.

In August 2021, as partial consideration for the rights and licenses the company received pursuant to the Platform License Agreement, the company granted UBI a warrant to purchase 1,928,020 shares of our Class A common stock. As of September 30, 2021, all 1,928,020 shares of Class A common stock underlying the UBI Warrant are exercisable, and are not subject to vesting. The UBI Warrant has a term the earlier of five years from the date of issuance or acquisition of the Company.

***Taiwan Centers for Disease Control Grant ("Taiwan CDC")***

UBI-Asia, which is responsible for applying for and managing grants on our behalf under the COVID-19 program, was awarded a grant by the Taiwan CDC for COVID-19 vaccine development. The Company contracted with UBI-Asia to conduct a two-phase study of a COVID-19 vaccine clinical trial in Taiwan. The grant provides that costs incurred to complete the two phases of the clinical trial will be reimbursed based on the achievement of certain milestones as provided in the agreement. During the nine months ended September 30, 2021, the Company has provided for an estimate of \$7.2 million against Phase II study costs incurred during this time; this was recorded as contra research and development expenses in its condensed consolidated statement of operations.

***UBI IP Holdings***

The Company provides administrative services to UBI IP Holding ("UBI-IP"). Under the arrangement, the Company issues vendor payments and provides technical services mostly for legal services on behalf UBI-IP. The Company bills UBI-IP for services based on the costs incurred with no markup. Total amounts due to the Company from UBI-IP were each \$ 0.4 million as of December 31, 2020 and September 30, 2021, respectively.



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Total related party operating activity, including the activity described above, for the three and nine months ended September 30, 2020 and 2021 is as follows (in thousands):

	<b>For the Three Months</b>		<b>For the nine Months</b>	
	<b>Ended September 30,</b>		<b>Ended September 30,</b>	
	<b>2020</b>	<b>2021</b>	<b>2020</b>	<b>2021</b>
Operating expenses				
Research and development				
Services provided by related parties	\$ 7,425	\$ 13,515	\$ 8,898	\$ 38,667
Taiwan CDC grant reimbursement from related party	(474)	—	(474)	(7,199)
General and administrative	1,858	355	2,343	1,173
Services provided by related parties	\$ 8,809	\$ 13,870	\$ 10,767	\$ 32,641

#### **16. Subsequent Events**

The Company has evaluated subsequent events through December 17, 2021 and has concluded that no events or transactions have occurred that require disclosure in the accompanying consolidated financial statements, except as follows:

##### ***Issuance of Options***

In November 2021, the company issued 1,499,085 stock options to employees with a exercise price of \$ 13.00 per share in connection with the IPO.

##### ***Reverse Stock Split***

On October 29, 2021, the Company effectuated a reverse stock split of 1-for-1.556 (the "Stock Split") of the Company's Class A and Class B common stock pursuant to an amendment to the Company's Amended and Restated Certificate of Incorporation approved by the Company's board of directors and stockholders. As a result of the Stock Split, the Company also adjusted the share and per share amounts associated with its options and warrants to purchase shares of its common stock. These condensed combined consolidated financial statements have been retroactively adjusted to reflect the Stock Split for all periods presented. Any fractional shares that would have resulted from the Stock Split have been rounded down to the nearest whole share.

##### ***Initial Public Offering***

On November 15, 2021, the Company closed its IPO of 6,000,000 shares of Class A common stock at a public offering price of \$13.00 per share. On November 18, 2021 the Company held a subsequent closing for the issuance of an additional 537,711 shares of Class A common stock pursuant to a 30-day option granted to the underwriters to purchase up to an additional 900,000 shares of Class A common stock at the IPO price, less underwriting discounts and commissions. The aggregate net proceeds to the Company from the offering, after deducting underwriting discounts and commissions and other offering expenses payable by the Company, was approximately \$71.1 million. Upon the closing of the IPO, all previously outstanding shares of the Company's redeemable convertible preferred stock were automatically converted into shares of its Class A common stock.

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion and analysis of our financial condition and results of operations should be read together with our combined consolidated financial statements and related notes and other financial information appearing elsewhere in this Quarterly Report on Form 10-Q ("Form 10-Q") and our audited consolidated financial statements and the related notes thereto and the discussion under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in the final prospectus for the Company's IPO dated November 11, 2021 and filed with the SEC on November 12, 2021 pursuant to Rule 424(b)(4) (the "Final Prospectus") under the Securities Act of 1933, as amended (the "Securities Act"). We intend for this discussion to provide you with information that will assist you in understanding our combined consolidated financial statements, the changes in key items in those combined consolidated financial statements from period to period and the primary factors that accounted for those changes. Some of the information contained in this discussion and analysis or set forth elsewhere in this Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks, uncertainties and assumptions. See the section of this Form 10-Q titled "Special Note Regarding Forward-Looking Statements" for a discussion of forward-looking statements. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Form 10-Q, our actual results could differ materially from management's expectations and the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

### Overview

Vaxxinity is engaged in the development and commercialization of rationally designed prophylactic and therapeutic vaccines to combat chronic disorders with large patient populations and unmet medical needs. While vaccines have traditionally been unable to effectively and safely combat such disorders, we believe our platform could overcome the traditional hurdles facing vaccines in this area. Our Vaxxine Platform relies on a synthetic peptide vaccine technology first developed by UBI and subsequently refined over the last two decades. We believe our vaccines have the potential to combat conditions that have not yet been successfully treated, or which have primarily been addressed with monoclonal antibodies (mAbs) which, while generally effective, are extremely costly and cumbersome, and thus have limited accessibility. Our pipeline primarily consists of five programs focused on chronic disease, particularly neurodegenerative disorders, in addition to other neurology and cardiovascular indications. In addition, our platform has the potential to combat infectious disease, and given the global COVID-19 pandemic and, we have been opportunistically advancing product candidates that address SARS-CoV-2.

We separated our business from UBI through two separate transactions: a spin-out from UBI in 2014 of operations focused on developing chronic disease product candidates that resulted in UNS, and a second spin-out from UBI in 2020 of operations focused on the development of a COVID-19 vaccine that resulted in COVAXX. On February 2, 2021, Vaxxinity was incorporated for the purpose of reorganizing and combining UNS and COVAXX and did so on March 2, 2021 through the Reorganization. In connection with the Reorganization, (i) all outstanding shares of UNS and COVAXX preferred stock and common stock were contributed to Vaxxinity and exchanged for an aggregate of 57,702,458 shares of our Class A common stock, 10,999,149 shares of our Class B common stock and 58,175,751 shares of our Series A preferred stock, (ii) the outstanding options to purchase shares of UNS and COVAXX common stock were terminated and substituted with options to purchase an aggregate of 19,712,504 shares of our Class A common stock, (iii) the outstanding warrant to purchase shares of COVAXX common stock was cancelled and exchanged for the Reorg. Warrant, which is exercisable for 128,702 shares of our Class A common stock, and (iv) the outstanding Convertible Notes and the Related Note were contributed to Vaxxinity and the former holders of such notes received an aggregate of 4,047,344 shares of our Series A preferred stock. As a result of the Reorganization, COVAXX and UNS became our wholly-owned subsidiaries. All shares of our Series A preferred stock converted into shares of our Class A common stock concurrently with the closing of our IPO. The Reorganization was determined to be a common control transaction, so the carrying values of all contributed assets and assumed liabilities remained unchanged and the financial information for all periods in this section of this Form 10-Q presented prior to the Reorganization are presented on a combined consolidated basis. COVAXX was incorporated on March 23, 2020, so periods prior to March 23, 2020 in this section of the Form 10-Q only reflect the historical financial information of UNS. Unless the context requires otherwise, in this section we use the terms "Vaxxinity," "we," "us" and "our" to refer to our operations (including through UNS and COVAXX) both prior to and after the Reorganization.

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

Our current pipeline consists of six programs from early to late-stage development, including five programs focused on chronic disease. Our neurodegenerative chronic disease program has three primary programs: UB-311, our leading neurology product candidate, which targets AD; UB-312, which targets PD; and an anti-tau product candidate which has the potential to address multiple neurodegenerative conditions, including AD. Additionally, we have two other primary programs focused on chronic disease: UB-313, which targets CGRP to prevent migraines; and our Anti-PCSK9 program, which targets hypercholesterolemia to reduce the risk of

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cardiac events. Through our Vaxxine Platform, we believe we may be able to address a wide range of other chronic diseases, including chronic diseases that are or could potentially be successfully treated by mAbs, which increasingly dominate the treatment paradigm for many chronic diseases.

Additionally, we have been developing a COVID-19 vaccine candidate. We have reported interim results and expect to report the complete results of our UB-612 Phase 2 clinical trial in Taiwan in the coming months. Following immunogenicity data from Phase 1 trial subjects who received two prime doses plus one booster dose of UB-612, we are exploring paths for its authorization as a heterologous boost (boosting the immunity of a subject who has already received a different vaccine) and as a three-dose regimen.

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

We have principally funded our operations through financing transactions. Through December 31, 2020, we received gross proceeds of \$99.3 million in connection with various financial instruments, including the sale of preferred stock, the issuance of promissory notes (including convertible promissory notes (“Convertible Notes”)), the entry into simple agreements for future equity (“SAFEs”) and a loan pursuant to the Paycheck Protection Program under the Coronavirus Aid, Relief, and Economic Security Act (“Paycheck Protection Program”). During the first half of 2021, we continued to finance our operations through the issuance of our Series B preferred stock, raising gross proceeds of \$43.5 million and \$79.4 million during the first and second quarter of 2021, respectively. In addition, during the three months ended March 31, 2021, we also financed our operations through the issuance of Convertible Notes and SAFEs, raising gross proceeds of \$2.0 million and \$2.9 million, respectively. In November we received gross proceeds of \$84.9 million as part of our initial public offering (“IPO”) on the Nasdaq. Due primarily to poor market conditions for biotech IPOs at this time, this represented a smaller capital raise than we had earlier anticipated.

Costs associated with research and development are the most significant component of our expenses. These costs can vary greatly from period to period depending on the timing of various trials for our product candidates. Our product candidates are in clinical stage or pre-clinical stage development, and we have generated limited revenue to date and have incurred significant operating losses since inception. Net losses were \$14.2 million and \$40.0 million for the years ended December 31, 2019 and 2020, respectively, and \$27.2 million and \$88.9 million for the nine months ended September 30, 2020 and 2021, respectively. As of September 30, 2021, we had an accumulated deficit of \$181.3 million.

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As of the date of this Form 10-Q, we expect our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements into 2023. Continued operations beyond 2023 will be dependent on our ability to raise additional capital to finance operations, to successfully commercialize our product candidates and/or to enter into collaborations with third parties for the development of our product candidates. Our estimates are based on a variety of assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than expected. See “Risk Factors— Risks Related to Our Financial Position and Need for Additional Capital.”

**Business Update Regarding COVID-19 Pandemic**

In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. The onset of the pandemic led to our institutional prioritization of COVID-19 vaccine development efforts, which correlated to a decline in research and development expenditures for our chronic disease product candidates. To date, our operations have not been negatively impacted by the COVID-19 pandemic in a material manner. However, at this time, we cannot predict the specific extent, duration or full impact that the COVID-19 pandemic will have on our financial condition and operations. The development of clinical supply materials has and continues to be delayed and enrollment of patients in our studies has and continues to be delayed or suspended, as hospitals and clinics in areas where we are conducting trials shift resources to cope with the COVID-19 pandemic and may limit access or close clinical facilities due to the COVID-19 pandemic. Additionally, if our trial participants are unable to travel to our clinical study sites as a result of quarantines or other restrictions resulting from the COVID-19 pandemic, we may experience higher drop-out rates or delays in our clinical studies. For example, the next clinical trial phase for UB-312 was scheduled to commence in late 2021 but was delayed due to the effects of emerging COVID-19 variants on hospitals and clinics. The impact of the COVID-19 pandemic on our financial performance will depend on future developments, including the duration and spread of the pandemic and related governmental advisories and restrictions. We continue to adjust our business plan to respond to the changes and opportunities caused by the COVID-19 pandemic, and as a result, the timing, extent and manner in which we pursue UB-612 continues to evolve. Currently, we are concentrating on the development of UB-612 and exploring paths for its authorization as a heterologous boost (boosting the immunity of a subject who has already received a different vaccine) and as a three-dose regimen. These developments and the impact of the COVID-19 pandemic on the financial markets and the overall economy are highly uncertain and cannot be predicted. If the financial markets and/or the overall economy are impacted for an extended period, our results may be materially adversely affected. See “Risk Factors—Risks Related to Our Business and Industry—The ongoing coronavirus pandemic has caused interruptions or delays of our business plan. Delays caused by the coronavirus pandemic may have a significant adverse effect on our business.”

## Recent Developments

In August 2021, we canceled existing options to purchase, in aggregate, 6,362,456 shares of our Class A common stock held by Mei Mei Hu and Louis Reese in exchange for an equal number of options to purchase shares of our Class B common stock. The new options to purchase shares of our Class B common stock were issued with exercise prices equal to the fair value of our Class B common stock on the new grant date. The company concluded, due to an increased exercise price in the exchanged options, there will be no associated incremental value reflected in our stock compensation expense.

In August 2021, we entered into a Platform License Agreement with UBI and certain of its affiliates that expanded intellectual property rights previously licensed under the original UBI licenses. The licenses granted under the original UBI licenses were terminated in connection with the Platform License Agreement. As partial consideration for the rights and licenses we received pursuant to the Platform License Agreement, we granted UBI a warrant to purchase 1,928,020 shares of our Class A common stock, at an exercise price of \$12.45 per share (subject to adjustment pursuant thereto).

On October 29, 2021, we effectuated the Stock Split, a reverse stock split of 1-for-1.556 of our Class A and Class B common stock, pursuant to an amendment to our Amended and Restated Certificate of Incorporation approved by our board of directors and stockholders. As a result of the Stock Split, the Company also adjusted the share and per share amounts associated with its options to purchase shares of its common stock. These share and per share amounts have been adjusted in this Form 10-Q to reflect the Stock Split for all periods presented. Any fractional shares that would have resulted from the Stock Split were rounded down to the nearest whole share.

On November 15, 2021, we closed our IPO of 6,000,000 shares of Class A common stock at a public offering price of \$13.00 per share. On November 18, 2021, the Company held a subsequent closing for the issuance of an additional 537,711 shares of Class A common stock, pursuant to a 30-day option granted to the underwriters to purchase up to an additional 900,000 shares of Class A common stock at the IPO price, less underwriting discounts and commissions. The aggregate net proceeds to us from the offering, after deducting underwriting discounts and commissions and other offering expenses payable by us, was approximately \$71.1 million. Upon the closing of the IPO, all previously outstanding shares of our redeemable convertible preferred stock were automatically converted into shares of Class A common stock.

## Components of Our Combined Consolidated Results of Operations

### **Revenue**

Revenue for the nine months ended September 30, 2021 and 2020 was less than \$0.1 million and \$0.6 million, respectively, and consisted of commercial sales of our ELISA tests. Our total revenue for the year ended December 31, 2020 was \$0.6 million and consisted of commercial sales of our ELISA tests. We had no revenue in 2019. While we continue to expect some revenue from sales of our ELISA tests, we do not expect to generate any meaningful revenue unless and until we obtain regulatory approval of and commercialize our product candidates, and we do not know when, or if, this will occur. If our development efforts for our product candidates are successful and result in commercialization, we may generate additional revenue in the future from a combination of product sales or payments from collaboration or license agreements that we have entered into or may enter into with third parties. See Risk Factors—Risks Related to the Discovery and Development of Product Candidates—We have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

### **Cost of Revenue**

Cost of revenue consists of kit production costs consisting of materials, labor and overhead expenses directly related to ELISA tests sold and the costs of expired ELISA tests, which are not available for commercial sale.

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

### **Research and Development Expenses**

The design, initiation and execution of candidate discovery and development programs of our future potential product candidates is key to our success and involves significant expenses. Prior to initiating these programs, project teams incorporating individuals from the essential disciplines within Vaxxinity scope out the activities, timing, requirements, inclusion and exclusion criteria and the primary and secondary endpoint. Once we have decided to proceed, our Vaxxine Platform enables the iteration of drug candidates in the discovery phase through rapid, rational design and formulation. After we have identified drug candidates, the costs of

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scaling the formulation from research grade to clinical grade, then to commercial grade, typically consumes significant resources. In addition, to internal research and development, we utilize service providers, including related parties, to complete activities we do not have the internal resources to handle.

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

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

We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by service providers. This process involves reviewing open contracts and purchase orders, communicating with personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. Any nonrefundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are expensed as the related goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered, at which point the net remainder is expensed.

We are heavily reliant on related parties for the advancement of our research and development programs, including for manufacturing, quality control, testing, validation, supply services, research support, development and clinical functions. During the years ended December 31, 2020 and December 31, 2019, related party expenses were approximately 56% and 29% of our operating expenses, respectively and during the nine months ended September 30, 2021 and September 30, 2020, related party expenses were approximately 43.3% and 49.8% of our operating expenses, respectively. We expect this reliance on related parties to diminish significantly in the future.

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

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. Additionally, greater research and development overhead is required to support broader and more rapid development of our Vaxxine Platform and new product candidates. As a result, we expect that our research and development expenses will ultimately increase. We are currently expecting to initiate a Phase 2b early AD efficacy trial in the second half of 2022, which would significantly increase our research and development expenses. If we decide to advance UB-311 through the clinic without a strategic partner, our costs would increase more significantly than if we engage a partner to fund the development of UB-311.

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

***General and Administrative Expenses***

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

We also anticipate that our general and administrative expenses will increase in the future as a result of increased costs associated with being a public company. In each case these increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, personnel-related stock-based compensation costs, lawyers and accountants, among other expenses, and, in the case of public company-related expenses, services associated with maintaining compliance with Nasdaq listing and SEC requirements, director and officer liability insurance costs and investor and public relations costs.

**Other Expense (Income)**

*Interest Expense, Net*

Net interest expense (income) consists of (i) interest income earned on our cash and cash equivalents, (ii) interest expense recognized on the note payable entered into during June 2020 for the acquisition of an airplane (the "2025 Note"), (iii) interest expense recognized on the Convertible Notes and (iv) interest expense recognized on other promissory notes, including \$0.1 million borrowed from our Chief Executive Officer (the "Executive Note") and a related party Convertible Note payable for \$2.0 million in aggregate proceeds that was received in three tranches (the "2018 Related Notes"). The Executive Note was repaid in full in August 2021.

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

We issued a series of Convertible Notes during the years ended December 31, 2018, 2019 and 2020, a series of SAFEs during the year ended December 31, 2020, and warrants to purchase shares of our Series A-1 preferred stock ("Series A-1 Warrants") during the year ended December 31, 2020, each of which were measured and accounted for at fair value. We remeasured the fair value of each of the Convertible Notes, SAFEs and Series A-1 Warrants at each reporting date and recognize changes in the fair value in our combined consolidated statements of operations. Inputs to the calculation of fair value generally include market and acquisition comparable(s) as well as other variables. In connection with the Reorganization, all outstanding Convertible Notes and SAFEs were exchanged for Series A preferred stock and all outstanding Series A-1 Warrants were exchanged for shares of Series A preferred stock, which were subsequently exchanged into shares of Class A common stock upon closing of the IPO in November 2021.

*Foreign Currency Losses*

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

*Provision for Income Taxes*

We have not recorded any significant amounts related to income tax but have reserved \$0.2 million of unrecognized tax benefits against NOLs. We have not recorded any income tax benefits for the majority of our net losses we incurred to date.

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

Deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax bases of existing assets and liabilities and for loss and credit carryforwards, which are measured using the enacted tax rates and laws in effect in the years in which the differences are expected to reverse. The realization of our deferred tax assets is dependent upon the generation of future taxable income, the amount and timing of which are uncertain. Valuation allowances are provided, if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. As of December 31, 2020, we continue to maintain a full valuation allowance against all of our deferred tax assets based on evaluation of all available evidence. We file income tax returns in the U.S. federal and state jurisdictions and may become subject to income tax audit and adjustments by related tax authorities. Our tax return periods (for entities then in existence) for U.S. federal income taxes for the tax years since 2015 remain open to examination under the statute of limitations by the Internal Revenue Service and state jurisdictions. We record reserves for potential tax payments to various tax authorities related to uncertain tax positions, if any. The nature of uncertain tax positions is subject to significant judgment by management and subject to change, which may be substantial. These reserves are based on a determination of whether and how much a tax benefit taken by us in our tax filings or positions is more likely than not to be realized following the resolution of any potential contingencies related to the tax benefit. We develop our assessment of uncertain tax positions, and the associated cumulative probabilities, using internal expertise and assistance from third-party experts. As additional information becomes available, estimates are revised and refined. Differences between estimates and final settlement may occur resulting in additional tax expense. Potential interest and penalties associated with such uncertain tax positions is recorded as a component of our provision for income taxes.



**Factors Affecting the Comparability of Our Combined Consolidated Results of Operations**

On March 2, 2021, Vaxxinity entered into the Contribution and Exchange Agreement, pursuant to which the outstanding equity interests of UNS and COVAXX were contributed to Vaxxinity in return for equity interests in Vaxxinity, resulting in UNS and COVAXX becoming wholly owned subsidiaries of Vaxxinity. Accordingly, all share and per share amounts prior to the Reorganization have been adjusted to reflect the Reorganization. In addition, we formed COVAXX, and commenced our COVAXX business, on March 23, 2020. As a result, the historical financial information between March 23, 2020 and March 2, 2021 described in this Form 10-Q refers to the combined historical financial information of UNS and COVAXX and the historical financial information prior to March 23, 2020 described in this Form 10-Q refers only to the historical financial information of UNS. As such, our business operations for the three months ended September 30, 2021 reflect the operations of our UNS and COVAXX businesses on a combined consolidated basis for that period, while our operations for the nine months ended September 30, 2021 reflect the operations of Vaxxinity and its subsidiaries. Our business operations for nine months ended September 30, 2020 reflect the operations of our UNS business from January 1, 2020 to March 22, 2020 and our UNS and COVAXX businesses on a combined consolidated basis for the remainder of that nine-month period, while our operations for the nine months ended September 30, 2021 reflect the operations of our UNS and COVAXX businesses on a combined consolidated basis for the period from January 1, 2021 to March 1, 2021 and of Vaxxinity and its subsidiaries for the remainder of that nine-month period. See Note 1 to our combined consolidated financial statements included elsewhere in this Form 10-Q filing.

**Combined Consolidated Results of Operations****Comparison of the three and nine months ended September 30, 2020 and 2021**

The following table summarizes our combined consolidated results of operations for the three and nine months ended September 30, 2020 and 2021, together with the dollar change in those items from period to period:

(amounts in thousands)	Three months ended September 30,			Nine months ended September 30,		
	2020	2021	Change	2020	2021	Change
Revenue:	\$ 117	\$ 50	\$ (67)	\$ 557	\$ 67	\$ (490)
Costs of revenue	(178)	9	187	52	1,937	1,885
Gross profit	295	41	(254)	505	(1,870)	(2,375)
Operating expenses:						
Research and development	7,867	23,616	15,749	12,109	54,221	42,112
General and administrative	5,122	6,700	1,578	9,453	21,130	11,677
Total operating expenses	12,989	30,316	17,327	21,562	75,351	53,789
Loss from operations	(12,694)	(30,275)	(17,581)	(21,057)	(77,221)	(56,164)
Other expense:						
Interest expense, net	331	109	(222)	737	493	(244)
Change in fair value of convertible notes	2,786	—	(2,786)	4,781	2,667	(2,114)
Change in fair value of simple agreements for future equity	615	—	(615)	615	8,365	7,750
Change in fair value of warrant liability	—	—	—	—	214	214
Foreign currency loss	39	5	(34)	48	24	(24)
Other expense, net	3,771	114	(3,657)	6,181	11,763	5,582
Net loss	\$ (16,465)	\$ (30,389)	\$ (13,924)	\$ (27,238)	\$ (88,984)	\$ (61,746)

**Revenue**

Total revenue was less than \$0.1 million and \$0.6 million for the nine months ended September 30, 2021 and 2020, respectively. Total revenue was less than \$0.1 million and \$0.2 million for the three months ended September 30, 2021 and 2020, respectively. All revenue and comparable increases were due to sales of our ELISA tests.

**Gross Profit**

The gross profit percentage for the three months ended September 30, 2021 was 82% however the sales volume was de minimis. During the nine months ended September 30, 2021, we wrote off \$1.9 million in expired ELISA tests that had no commercial value, creating a cost of revenue and resulting negative gross profit percentage presentation. In September 2020, the company revised its estimate for Cost of Goods Sold creating a negative value in the third quarter of 2020 and normalized year to date presentation.

**Research and Development Expenses**

*Comparison of three months ended September 30, 2021 to three months ended September 30, 2020*

Research and development expenses were \$23.6 million and \$7.8 million for the three months ended September 30, 2021 and 2020, respectively. The \$15.8 million increase was primarily due to an increase in allocated costs of \$13.5 million and unallocated costs of \$2.3 million. Of the allocated increase, \$12.7 million was related to our UB-612 clinical trial in Taiwan (primarily consisting of materials and manufacturing costs as well as increases in CRO costs), \$0.9 million of which was related to UB-311 (primarily production related) with \$0.1 million reduction across our other programs. The unallocated increase was primarily driven by an increase of \$1.8 million in personnel costs as well as \$0.4 million investment in a new laboratory setup in our Florida facility and less than \$0.1 million in consulting costs.

*Comparison of nine months ended September 30, 2021 to nine months ended September 30, 2020*

Research and development expenses were \$54.2 million and \$12.1 million for nine months ended September 30, 2021 and nine months ended September 30, 2020, respectively. The \$42.1 million increase was primarily due to an increase in allocated costs of \$38.8 million and unallocated costs of \$3.3 million. Of the allocated increase, \$38.9 million in costs related to our UB-612 clinical trial in Taiwan (primarily consisting of materials and manufacturing costs as well as increases in CRO costs). This increase was partially offset by a decline of \$0.8 million in mostly trial-related CRO and material costs associated with UB-312 along with increase in costs of \$0.7 million across our other programs. Unallocated costs increased by \$3.3 million, driven primarily by increased personnel costs of \$4.0 million in connection with the ramp-up of our UB-612 development efforts as well as \$0.6 million primarily in new laboratory setup, and partially offset by the reversal of a \$1.3 million payroll tax liability.

**General and Administrative Expenses**

*Comparison of three months ended September 30, 2021 to three months ended September 30, 2020*

General and administrative expenses were \$6.7 million and \$5.1 million for the three months ended September 30, 2021 and 2020, respectively. The \$1.6 million increase was related to our continued organizational growth to support our ramp-up in research and development efforts, as well as increased costs for preparations for being a public company.

*Comparison of nine months ended September 30, 2021 to nine months ended September 30, 2020*

General and administrative expenses were \$21.1 million and \$9.5 million for the nine months ended September 30, 2021 and 2020, respectively. The \$11.6 million increase was primarily due to increased salaries and personnel-related costs and professional services costs related to our continued organizational growth to support our ramp-up in research and development efforts, as well as increased costs for preparations for being a public company.

**Interest Expense, Net**

*Comparison of three months ended September 30, 2021 to three months ended September 30, 2020*

Interest expense was \$0.1 million and \$0.3 million for the three months ended September 30, 2021 and 2020, respectively. The \$0.2 million decrease was primarily due to interest expense related to a lower principal balance on the Convertible Notes as a result of being exchanged for Series A preferred stock in connection with the Reorganization. Interest income on cash was negligible for each of the three months ended September 30, 2021 and 2020.

*Comparison of nine months ended September 30, 2021 to nine months ended September 30, 2020*

Interest expense was \$0.5 million and \$0.7 million for the nine months ended September 30, 2021 and 2020, respectively. The \$0.2 million decrease was primarily due to interest expense related to a lower principal balance on the Convertible Notes which were exchanged into Series A preferred stock in connection with the Reorganization. Interest income on cash was negligible for each of the nine months ended September 30, 2021 and 2020.

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

*Comparison of three months ended September 30, 2021 to three months ended September 30, 2020*

The \$2.7 million decrease in the Convertible Notes for the three months ended September 30, 2021 was a result of the conversion of the Convertible Notes occurring prior to the third quarter of 2021. In connection with the Reorganization, all

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outstanding Convertible Notes, SAFEs and Series A-1 Warrants were exchanged into shares of Series A preferred stock, which were subsequently exchanged into shares of Class A common stock upon closing of the IPO in November 2021 as described in Note 8.

*Comparison of nine months ended September 30, 2021 to nine months ended September 30, 2020*

The decrease in the fair value of the Convertible Notes of \$2.1 million for the nine months ended September 30, 2021 was primarily related to the change in probability that the Convertible Notes will be converted to equity and have a higher rate of return. The increase in the change in fair value of SAFEs of \$7.7 million for the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020 (when there were no outstanding SAFEs) was primarily related to insight into the pricing of Vaxxinity's next stock issuance at a higher valuation. The increase in the change in fair value of Series A-1 Warrants of \$0.2 million for the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020 was primarily related to an increase in value of the Series A-1 preferred stock. In connection with the Reorganization, all outstanding Convertible Notes, SAFEs and Series A-1 Warrants were exchanged into shares of Series A preferred stock, which were subsequently exchanged into shares of Class A common stock upon the closing of the IPO in November 2021 as described in Note 8.

**Foreign Currency Loss (Gain)**

*Comparison of three months ended September 30, 2021 to three months ended September 30, 2020*

The change in foreign currency loss reflected a de minimis decrease in the foreign exchange rate for the three months ended September 30, 2021 compared to the three months ended September 30, 2020.

*Comparison of nine months ended September 30, 2021 to nine months ended September 30, 2020*

The change in foreign currency loss reflected a de minimis increase in the foreign exchange rate for the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020.

**Liquidity and Capital Resources**

**Sources of Liquidity**

We have generated, and expect to continue to generate, limited revenue from sales of our ELISA tests and have not yet commercialized any of our product candidates, which are in various phases of pre-clinical and clinical development. We have financed operations primarily through the issuance of convertible preferred stock, borrowings under promissory notes (including Convertible Notes) and the execution of SAFEs. Through December 31, 2020, we received gross proceeds of \$99.3 million in connection with the issuance of various financial instruments, including the sale of preferred stock, the issuance of promissory notes (including Convertible Notes), the execution of SAFEs and a loan pursuant to the Paycheck Protection Program. In addition, we also generated revenue from the sale of an option to negotiate a license with UNS (which option has expired) and the sales of ELISA tests in 2020 and 2021. During the nine months ended September 30, 2021, we raised a total of \$127.8 million, which consisted of \$122.9 million in gross proceeds from the issuance of our Series B preferred stock and \$2.0 million and \$2.9 million in net proceeds from the issuance of Convertible Notes and SAFEs, respectively. At September 30, 2021, we had \$89.4 million in cash and cash equivalents, compared to \$31.1 million as of December 31, 2020 and \$0.5 million as of December 31, 2019. The increase in cash and cash equivalents balances for the periods reported are primarily due to the factors described under "—Cash Flows" below

**Cash Flows**

The following table provides information regarding our cash flows for the nine months ended September 30, 2020 and 2021:

(amounts in thousands)	Nine months ended September 30,	
	2020	2021
Net cash provided by (used in):		
Operating activities	\$ (22,669)	\$ (67,026)
Investing activities	(1,026)	(50)
Financing activities	41,378	125,308
Net increase (decrease) in cash:	\$ 17,683	\$ 58,232

**Operating Activities**

Net cash used in operating activities for the nine months ended September 30, 2021 was \$67 million, primarily due to a \$88.9 million net loss and an increase of \$3.9 million in net operating assets and liabilities and an increase in total non-cash items of \$18.0 million. The cash flow impact from changes in net operating assets and liabilities were primarily due to \$13.2 million in

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amounts due to related party as well as \$4.8 million related to accrued expense, accounts payable and other liabilities. These increases were offset by \$10.1 million in prepaid expenses for UB-612 production as well as \$4.0 million related to deferred offering costs. The primary non-cash adjustments to net loss included an \$11.2 million change in the fair market value of financial instruments as well as \$5.6 million of stock-based compensation and \$0.9 million in depreciation.

Net cash used in operating activities for the nine months ended September 30, 2020 was \$22.7 million, primarily due to a \$27.2 million net loss and a decrease of \$2.3 million in net operating assets and liabilities and an increase in total non-cash items of \$6.8 million. The cash flow impact from changes in net operating assets and liabilities were primarily due to \$5.3 million in prepaid expenses for UB-612 production as well as \$0.5 million increase in deferred offering costs. These increases were offset by \$2.2 million increase in amounts due to related party as well as \$1.3 million related to accrued expenses, accounts payable and other liabilities. The primary non-cash adjustments to net loss included an \$4.8 million change in the fair market value of financial instruments as well as \$0.6 million change in fair value of simple agreement for future equity, \$0.7 million of stock-based compensation and \$0.4 million in depreciation.

**Investing Activities**

Net cash used in investing activities totaled \$0.05 million for the nine months ended nine months ended September 30, 2021. The cash used in investing activities consisting primarily of the acquisition of equipment.

Net cash used in investing activities totaled \$1.0 million for the nine months ended nine months ended September 30, 2020. The cash used in investing activities consisting primarily of the acquisition of equipment.

**Financing Activities**

Net cash provided by financing activities totaled \$125.3 million for the nine months ended September 30, 2021. We raised capital to support our operations through the issuance of Series B preferred stock, with net proceeds of \$122.7 million, and the issuance prior to the Reorganization of SAFEs and Convertible Notes, with net proceeds of \$2.9 million and \$2.0 million, respectively. We also repaid \$2.0 million in relation to a Convertible Note and \$0.2 million in relation to a Paycheck Protection Program.

Net cash provided by financing activities totaled \$41.3 million for the nine months ended September 30, 2020. We raised capital to support our operations through the issuance of \$19.8 million of convertible preferred stock, \$15.0 million of simple agreement for future equity and \$12.0 million of convertible notes. We also repaid \$5.5 million in relation to Convertible Notes.

**Funding Requirements**

We have generated approximately \$3.6 million in revenue since inception and have incurred net losses in each reporting period since inception. We expect to generate only modest revenue from sales of our ELISA tests, and do not expect to generate any meaningful revenue unless and until we obtain regulatory approval of and commercialize our product candidates. We do not know when, or if, this will occur. If we do not receive regulatory approval for any of our product candidates, or if we receive approval but our commercialization results fall short of our expectations, we will continue to incur significant losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates and begin to commercialize any approved products.

As of the date of this Form 10-Q, we expect our existing cash and cash equivalents will be sufficient to fund our operating expenses into 2023. As of nine months ended September 30, 2021, other than our 2025 Note, we have no material debt obligations.

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

- the pre-clinical development of our early-stage programs;
- necessary regulatory approvals for any product candidates that successfully complete clinical trials;
- the manufacture of our pre-clinical and clinical drug material and development of processes for late stage and commercial manufacturing;
- the establishment of a sales, marketing, medical affairs and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval and intend to commercialize on our own;

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- the expansion of operational, financial and management systems and infrastructure, our facilities and the increase of personnel to support operations, including as necessary to operate as a public company; and
- the maintenance, expansion and protection of our intellectual property portfolio, and the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims.

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

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

***Contract Research and Manufacturing Organizations***

We recorded accrued expenses of \$0.3 million and \$0.7 million in our balance sheet for expenditures incurred by CROs and contract manufacturers as of December 31, 2020 and September 30, 2021, respectively.

***Tax-Related Obligations***

We have reserved \$0.6 million of unrecognized tax benefits against NOLs. Additionally, as of December 31, 2020, we accrued \$0.2 million in interest and penalties related to prior year tax filings.

***Off-Balance Sheet Arrangements***

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

**Critical Accounting Policies and Estimates**

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

The Company has not experienced any changes to our accounting policies during the three months ended September 30, 2021. Please refer to the Final Prospectus where these policies are described in detail.

***Taiwan Centers for Disease Control Grant***

UBIA, which is responsible for applying for and managing grants on our behalf, was awarded a grant by the Taiwan Centers for Disease Control ("TCDC") for COVID-19 vaccine development. The grant provides that costs incurred to complete the two phases of the clinical trial will be reimbursed based on the achievement of certain milestones as defined in the agreement. We are entitled to reimbursement under the TCDC grant. At each reporting date, we assess the status of all of the activities involved in completing the clinical study in relation to the milestones. We account for the amounts that have been received from the TCDC to reimburse costs

incurred on the clinical study and not expected to be refunded back to the TCDC as contra research and development expenses in the accompanying combined consolidated statement of operations.

#### **Recently Issued Accounting Pronouncements**

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our combined consolidated financial statements included elsewhere in this Form 10-Q filing.

#### **The JOBS Act**

The JOBS Act permits an emerging growth company such as ours to take advantage of specified exemptions from various requirements that are otherwise applicable generally to public companies in the United States. We have elected to take advantage of certain of the reduced disclosure obligations in this quarterly filing. 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. We have elected to avail ourselves of this exemption and, therefore, while we are an emerging growth company, we will not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not emerging growth companies. The Company also intends 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 the Sarbanes-Oxley Act. See “Risk Factors—Risks Related to Our Class A Common Stock—We are an “emerging growth company” and a “smaller reporting company” and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies, which could make our Class A common stock less attractive to investors and adversely affect the market price of our Class A common stock.”

#### **Item 3. Quantitative and Qualitative Disclosures about Market Risks**

We are exposed to market risk in the ordinary course of our business. These risks primarily relate to foreign currency and changes in interest rates.

##### *Foreign Currency Exchange Risk*

We have limited exposure to foreign currency exchange risk as most of our operating activities are primarily denominated in U.S. dollars. We believe actual foreign exchange gains and losses did not have a significant impact on our results of operations for any periods presented herein. The results of the analysis based on our financial position as of September 30, 2021, indicated that a hypothetical 10% increase or decrease in applicable foreign currency exchange rates would not have a material effect on our financial results.

##### *Interest Rate Risk*

We are exposed to market risk related to changes in interest rates. As of December 31, 2019 and 2020 and September 30, 2021, our cash equivalents consisted of interest-bearing checking accounts. We issued Convertible Notes, which Convertible Notes were exchanged for Series A preferred stock in connection with the Reorganization. The Convertible Notes bore simple interest at the annual rates ranging from 5% to 6%, with redemption terms payable at the earlier of one year, or upon the event of default. In addition, the Convertible Notes contained provisions addressing automatic and optional conversion. Given the redemption of the Convertible Notes, and the short-term nature and fixed interest rate, we believe there is no material exposure to interest rate risk. Additionally, the 2025 Note we entered into for the year ended December 31, 2020 bears an annual interest rate of 3.4% and matures in June 2025. Given the fixed interest rate of the 2025 Note, we believe there is no material exposure to interest rate risk. The results of the analysis based on our financial position as of September 30, 2021, indicated that a hypothetical 100 basis point increase or decrease in risk-free rates would not have a material effect on our financial results.

Our measurement of interest rate risk involves assumptions that are inherently uncertain and, as a result, cannot precisely estimate the impact of changes in interest rates on net interest revenues. Actual results may differ from simulated results due to balance growth or decline and the timing, magnitude, and frequency of interest rate changes, as well as changes in market conditions and management strategies, including changes in asset and liability mix.

#### **Item 4. Controls and Procedures**

##### **Limitations on effectiveness of controls and procedures**

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control

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objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

**Evaluation of disclosure controls and procedures**

Our management, with the participation of our principal executive officer and principal accounting officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, 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 and as a result of the material weaknesses described below, our principal executive officer and principal accounting officer concluded that, as of September 30, 2021, our disclosure controls and procedures were not effective at the reasonable assurance level.

**Material Weaknesses in Internal Control over Financial Reporting**

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual and interim financial statements will not be detected or prevented on a timely basis.

As previously reported and disclosed in the "Risk factors" section of this Form 10-Q, in connection with the audits performed for UNS for the fiscal years ended December 31, 2017, 2018 and 2019 and for COVAXX for the period ended June 30, 2020, we concluded that there were material weaknesses in the design of our internal control over financial reporting relating to (i) documenting and performing the monthly financial close, account reconciliation and analysis processes on a timely basis; (ii) ensuring that formal processes for identifying and analyzing complex transactions exist; (iii) ensuring proper segregation of duties and responsibilities within our finance department; (iv) ensuring that a process exists for determining whether key contracts, documents and agreements are considered for accounting and disclosure and accurately supported by accounting records; and (v) ensuring that a process existing to document accurate accruals for all internal related-party resources across our affiliated entities.

As previously reported and disclosed in the "Risk factors" section of this Form 10-Q, in connection with the preparation of our unaudited combined consolidated financial statements for the three and six months ended June 30, 2021 and 2020, we identified material weaknesses in the design of our internal controls related to the recording of stock-based compensation expenses and the aggregating and mapping of amounts from trial balances to financial statements. We are in the process of implementing measures designed to improve internal control over financial reporting to remediate the control deficiencies that led to these material weaknesses.

In connection with the preparation of our unaudited combined consolidated financial statements for the three and nine months ended September 30, 2021, we continued to identify material weaknesses in the design of our internal controls over financial reporting.

**Remediation Measures**

We are investing resources to remediate the material weaknesses identified in the audits performed for UNS and COVAXX described above through a combination of hiring and training additional qualified accounting and financial reporting personnel and further evolving and refining our accounting processes and policies.

During the quarterly period ended June 30, 2021, we also implemented a new process and system to improve the recording of stock-based compensation expenses.

As mentioned above, we are in the process of implementing measures designed to remediate the material weaknesses identified in connection with the preparation of our unaudited combined consolidated financial statements for the three and six months ended June 30, 2021 and 2020. These remediation activities involve designing and implementing improved processes and internal controls, including by implementing improved processes related to the aggregating and mapping of amounts from trial balances to financial statements and engaging third-party experts to assist with the valuation and review of stock options and complex transactions.

While we are working to remediate the identified material weaknesses as timely and efficiently as possible, at this time we cannot provide an estimate of costs expected to be incurred in connection with our remediation efforts, we cannot provide an estimate of the time it will take to complete remediation, nor can we provide assurance that our efforts will successfully prevent any errors or omissions that may result because of these material weaknesses.

## Changes in Internal Control over Financial Reporting

Other than the measures described in “Remediation Measures” above, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 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

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

### Item 1A. Risk Factors

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

#### Summary Risk Factors

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

- clinical drug development involves a lengthy and expensive process, and if our pre-clinical development or clinical trials are prolonged or delayed or do not achieve expected results, we may be unable to commercialize our product candidates;
- we depend on intellectual property licensed from UBI and its affiliates, the termination of which could result in the loss of significant rights;
- even if we obtain regulatory approval of any of our product candidates in Taiwan or other jurisdictions, we may never obtain approval for or commercialize our product candidates in other jurisdictions;
- after receipt of regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny and post-marketing requirements, which may include burdensome post-approval study or risk management requirements;
- if we are able to commercialize any product candidate, the successful commercialization of such product candidate will depend on the extent governmental authorities, private health insurers and other third-party payors provide coverage, adequate reimbursement levels and favorable pricing policies;
- the manufacture of peptide-based medicines is complex and manufacturers often encounter difficulties in production;
- we have no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability;
- the regulatory landscape that will govern our product candidates is uncertain, and changes in regulatory requirements could result in delays or discontinuation of development of our product candidates or unexpected costs;
- developments by competitors may render our products or technologies obsolete or non-competitive or may reduce the size of our markets;
- our capital resources may not be sufficient to successfully complete the development and commercialization of our product candidates, which could delay, limit, reduce or terminate our development or commercialization efforts;



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- we have incurred significant losses since inception, and we expect to incur losses for the foreseeable future and may never achieve or maintain profitability;
- conflicts of interest and disputes exist and may further arise between us and UBI and its affiliates, and these conflicts and disputes might ultimately be resolved in a manner unfavorable to us;
- we will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations;
- the dual-class structure of our common stock and the Voting Agreement (as defined below) will have the effect of concentrating voting power, which will significantly limit your ability to influence significant corporate decisions;
- we rely on contract manufacturers for the manufacture of raw materials for our research programs, pre-clinical studies and clinical trials and we do not have long-term contracts with many of these parties, which could impact our ability to commercialize our products;
- undetected errors or defects in our production could harm our reputation or expose us to product liability claims;
- we rely on in-licensed intellectual property and technology, and the loss of such rights, our licensors' inability or refusal to enforce or defend such rights, and the requirement to pay royalties, milestones and other amounts could harm our business;
- the degree of protection afforded by our intellectual property rights is uncertain because such rights offer only limited protection and may not adequately protect our rights or permit us to gain or keep a competitive advantage;
- we have identified significant deficiencies and material weaknesses, and have previously identified material weaknesses, in our internal control over financial reporting and if we are unable to remediate our existing deficiencies and material weaknesses and otherwise develop and maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud, and as a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our Class A common stock;
- cyberattacks or other failures in our or our third-party vendors', contractors' or consultants' telecommunications or information technology systems could result in information theft, compromise, or other unauthorized access, data corruption and significant disruption of our business operations, and could harm our reputation and subject us to liability, lawsuits and actions from governmental authorities; and
- we are subject to privacy, tax, anti-corruption and other stringent laws, regulations, policies and contractual obligations across multiple jurisdictions and changes in, or our failure to comply with, such laws, regulations, policies and contractual obligations could adversely affect our business, financial condition, results of operations and prospects.

### **Risks Related to the Discovery and Development of Product Candidates**

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

Our business is dependent on the successful development, regulatory approval and commercialization of product candidates based on our Vaxxine Platform. If we and our collaborators are unable to obtain approval for and effectively commercialize our product candidates, our business would be significantly harmed. Even if we complete the necessary pre-clinical studies and clinical trials, the regulatory approval process is expensive, time-consuming and uncertain, and we may not be able to obtain approvals for the commercialization of any product candidates we may develop. Changes in regulatory approval policies, changes in or the enactment of additional statutes or regulations, or changes in regulatory review processes, may cause delays in the approval of a particular product candidate or rejection of an application for a particular product candidate. We have not obtained regulatory approval for any product candidate to date, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. Any regulatory approval we ultimately obtain may be limited or subject to restrictions, including labeling requirements, or post-approval commitments that render the approved product not commercially viable. While our enzyme-linked immunosorbent assay ("ELISA") test has received an EUA from the FDA, there can be no assurance that any of our product candidates will receive an EUA or regulatory approval or that there will not be changes in formulation, whether required by any regulatory authority or at our determination for operational or scientific reasons, affecting the use of our products. Further, some countries may not rely on an EUA or regulatory approval issued by another jurisdiction, and we may be required to seek separate

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EUAs or regulatory approval from different regulatory authorities in different jurisdictions. See “Risk Factors—Even if we obtain approval of any of our product candidates in one jurisdiction, we may never obtain approval for or commercialize any of our products in other jurisdictions, which would limit our ability to realize their full market potential.”

To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate through extensive pre-clinical studies and clinical trials that our products are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of pre-clinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials and results from post-hoc data analysis may not be predictive of final results and may not support product approval. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through pre-clinical studies and initial clinical trials. For example, an EUA for UB-612 was denied by the TFDA in August 2021 because the neutralizing antibody response generated by UB-612, as compared to a designated adenovirus vectored vaccine, did not meet the TFDA’s specified evaluation criteria, but, in collaboration with UBIA, we appealed the decision and have asked the TFDA to update their criteria to include a comparison of geometric mean neutralizing titers against the Delta variant. The outcome of that appeal remains highly uncertain. If results from our clinical trials differ from previous reports or market expectations, such as a potential development of market expectations that COVID-19 boosters or vaccines be developed specifically to address certain variants which we fail to satisfy, or if we fail to obtain a required regulatory approval, the price of our Class A common stock could decrease substantially. Several companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our ongoing and future clinical trials may not be successful.

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

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

To the extent our CROs fail to enroll participants for our clinical trials, fail to conduct the trial in accordance with the trial protocol GCP or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business and delay our ability to seek approval for our product candidates. For example, due to an error by the CRO responsible for administering blinded placebo and active doses to trial subjects, which reduced the confidence of subsequently collected data, we decided to discontinue a Phase 2a LTE trial for UB-311. In that case, however, we determined that we had collected sufficient data on UB-311’s tolerability and immunogenicity. To date, we have not completed clinical trials sufficient for obtaining marketing approvals for any of our product candidates. Our most advanced candidates are UB-612 and UB-311, each of which is in Phase 2 of clinical development. Our product candidate UB-312 is in Phase 1 of clinical development and UB-313 has entered IND-enabling studies. All of our other research programs are in the pre-clinical development stage.

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

- the delay or refusal of regulators or IRBs to authorize us to commence a clinical trial at a prospective trial site;
- changes in regulatory requirements, policies and guidelines;
- delays or failure to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

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- delays in patient enrollment and variability in the number and types of patients available for clinical trials;
- negative or inconclusive results, which may require us to conduct additional pre-clinical or clinical trials or to abandon product candidates that we expect to be promising;
- delays in manufacturing and control of clinical trial materials;
- shortages of materials required for the production of our product candidates;
- disruptions from events surrounding the COVID-19 pandemic;
- safety or tolerability concerns causing us to suspend or terminate a trial if it is determined that the participants are being exposed to unacceptable health risks;
- lower than anticipated retention rates of patients and volunteers in clinical trials and difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- failure of us, our CROs or clinical trial sites to comply with regulatory requirements;
- failure of our CROs or clinical trial sites to meet their contractual obligations to us in a timely manner, or at all, deviating from the clinical trial protocol or dropping out of a trial;
- delays relating to adding new clinical trial sites;
- delays in establishing necessary pre-clinical or clinical data;
- the occurrence of unexpected severe or serious product-related adverse events in a clinical trial;
- the quality or stability of the product candidate falling below acceptable standards;
- the inability to produce or obtain sufficient quantities of the product candidate to complete clinical trials on time, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- the lack of adequate funding to continue the clinical trial;
- developments observed in trials conducted by competitors for related technology that raises general concerns from regulatory authorities about risk to patients of similar vaccine technology;
- the determination that a product candidate will not be producible in relevant quantities at the manufacturing stage;
- the failure of regulatory authorities such as the FDA or the TFDA to approve our manufacturing processes or facilities or those of contract manufacturers with which we contract for clinical and commercial supplies; and
- the transfer of manufacturing processes to larger-scale facilities operated by contract manufacturers or by us, and delays or failure by our contract manufacturers or us to make any necessary changes to such manufacturing process.

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

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen and other trial procedures and the rate of dropout among clinical trial participants. Further, none of our trials to date of UB-311 and UB-312 have been large enough to determine whether their assessments of efficacy were statistically significant. Therefore, we are able to report potential trends on such measures, but we will not be able to

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make more definitive statements about the efficacy of our product candidates until we complete clinical trials that are adequately powered to demonstrate statistical significance of clinically meaningful results.

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

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

To market any products, we must establish and comply with numerous and varying regulatory requirements in different countries regarding safety and efficacy and obtain relevant approvals to market our product candidates. While we have not obtained any regulatory approvals for our product candidates to date, we have reported the interim results and are expecting to report the complete results of our UB-612 Phase 2 clinical trial in Taiwan in the coming months. As discussed above under “—Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes, and results of earlier studies and trials may not be predictive of future results. If our pre-clinical development or clinical trials are prolonged or delayed, or if we do not or cannot achieve the results we expect, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our product candidates on a timely basis or at all,” an EUA for UB-612 was denied by the TFDA in August 2021, which decision we have appealed in collaboration with UBIA. Approval by the TFDA or by another foreign regulatory authority in any other jurisdiction does not ensure approval by comparable regulatory authorities in other countries or jurisdictions, including approval by the FDA in the United States. The failure to obtain approval in one jurisdiction may delay or otherwise negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Approval procedures vary among countries and even if we have obtained approval in one country, approval in other countries can involve additional product testing and validation and additional administrative review periods.

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

***Interim, “top-line” and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are also subject to audit and verification procedures that could result in material changes in the final data.***

From time to time, we may publicly disclose preliminary or top-line data from our pre-clinical studies and clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also may make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our pre-clinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our Class A common stock.

Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and the Company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically

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extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

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

We will be required to identify and enroll a sufficient number of patients for our planned clinical trials. Trial participant enrollment could be limited in future trials given that many potential participants may be ineligible because of pre-existing conditions, medical treatments or other reasons. For example, trial participant enrollment for our COVID-19 product candidates could be negatively impacted as COVID-19 vaccination rates increase and the number of potential unvaccinated participants decreases. We may not be able to initiate or continue clinical trials required by applicable regulatory authorities or any of our other product candidates that we pursue if we are unable to locate and enroll enough eligible patients or volunteers to participate in these clinical trials. Patient enrollment is affected by other factors, as well, including the incidence and severity of the disease under investigation; the design of the clinical trial protocol; the size and nature of the patient population; the eligibility criteria for the trial in question; the perceived risks and benefits of the product candidate under trial; the perceived safety and tolerability of the product candidate; the proximity and availability of clinical trial sites for prospective patients; the availability of competing therapies and clinical trials; effects of the COVID-19 pandemic on our clinical trial sites; our ability to monitor patients adequately during and after treatment; patient referral practices of physicians; clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including standard-of-care and any new drugs that may be approved for the indications we are investigating; and efforts to facilitate timely enrollment in clinical trials.

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

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

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

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

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, our business will be seriously harmed. Further, if a regulatory authority identifies previously unknown problems with our platform, any or all of our product candidates may also be affected.

Moreover, the policies of regulatory authorities may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or

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abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

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

We commenced operations through UNS and COVAXX in 2014 and 2020, respectively. Our operations to date have been limited to organizing and staffing Vaxxinity, business planning, raising capital, developing our Vaxxine Platform, identifying and testing potential product candidates and conducting clinical trials. We have a limited track record of successfully conducting late-stage clinical trials, obtaining marketing approvals, manufacturing a commercial-scale product, or arranging for a third-party to do so on our behalf, or conducting sales and marketing activities necessary for successful product commercialization. Accordingly, you should consider our prospects considering the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, especially clinical-stage biopharmaceutical companies such as ours. Any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

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

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

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

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

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

- regulatory authorities may withdraw or limit their approval of such product candidates and require us to take our approved product(s) off the market;
- regulatory authorities may require the addition of labeling statements, such as a “boxed” warning or a contraindication, or submission of field alerts to physicians and pharmacies;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the product candidates;
- actual or potential drug-related side effects could negatively affect patient recruitment or the ability of enrolled patients to complete a trial for our products or product candidates;
- market acceptance of our products by patients and physicians may be reduced and sales of the product may decrease significantly;
- regulatory authorities may require a REMS plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;

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- we may be subject to regulatory investigations and government enforcement actions;
- we may decide or be required to remove such product candidates from the marketplace;
- we could be sued and potentially held liable for injury caused to individuals exposed to or taking our product candidates;
- sales of the product(s) may decrease substantially; and
- our reputation may suffer.

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

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

The regulatory requirements to which our product candidates will be subject are complex and uncertainties exist. Even with respect to more established vaccine products, the regulatory landscape is still developing, especially as it relates to novel adjuvants in vaccines, such as CpG1, which we use at low concentration in our COVID-19 product candidates. Although regulatory authorities decide whether individual clinical trial protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if another regulatory authority has reviewed the trial and authorizes its initiation. The FDA, for example, can place an IND on clinical hold even if other regulatory agencies have provided a favorable review. In addition, adverse developments in clinical trials involving novel adjuvants in vaccines, such as CpG1, conducted by others may cause regulatory authorities to change the requirements for approval of any of our product candidates.

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

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

Even if we receive regulatory approval to market any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may materially adversely affect our business, financial condition, results of operations and prospects. We have not previously submitted a biologics license application (“BLA”) to the FDA, or similar regulatory approval filings to comparable foreign authorities, for any product candidate and never received regulatory approval for any of our product candidates. Further, other jurisdictions may consider our product candidates to be new drugs, not biologics or medicinal products, and require different marketing applications. Even if a regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, product sampling, adverse event reporting, storage, advertising, marketing, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports and registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such products. There also are continuing, annual program user fees for any marketed products. In the United States, biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our contract manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any contract manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

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

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

In addition, regulatory policies may change or additional government regulations or legislation may be enacted that could prevent, limit or delay regulatory approval of our product candidates, particularly in countries where elections may result in changes in government administration. If we fail to comply with existing requirements, are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained or face regulatory or enforcement actions, which may materially adversely affect our business, financial condition, results of operations and prospects.

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

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize our product candidates.

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

We may in the future seek a breakthrough therapy designation for one or more product candidates eligible for such designation. A breakthrough therapy is defined as a product candidate that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Product candidates designated as



breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the BLA.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to product candidates considered for approval under conventional FDA procedures and it would not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidate no longer meets the conditions for qualification or it may decide that the time period for FDA review or approval will not be shortened. Further, certain of our product candidates, including our COVID-19 product candidates, are not eligible for breakthrough therapy designation, and we will be unable to take advantage of such designation for such product candidates.

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

We are developing certain product candidates for the treatment of serious or life-threatening conditions, including UB-311, and therefore may decide to seek approval of such product candidates under the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it is designed to treat a serious or life-threatening disease or condition and generally provides a meaningful advantage over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit.

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

If we decide to submit a new drug application ("NDA") seeking accelerated approval or receive an expedited regulatory designation for our product candidates, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. Failure to obtain accelerated approval or any other form of expedited development, review or approval for a product candidate would result in a longer time period to commercialization of such product candidate, if any, and could increase the cost of development of such product candidate, which could harm our competitive position in the marketplace. An EUA for UB-612 was denied by the TFDA in August 2021. If we do not receive an EUA from regulatory authorities for product candidates for which we request such approval, we may be required to conduct further clinical trials which could increase the expense of obtaining, and delay the receipt of, marketing approvals in any jurisdiction where we do not receive an EUA. Regulatory authorities may also cease granting EUAs for product candidates targeting COVID-19 or otherwise, which would delay our ability to commercialize product candidates for which we might seek an EUA in the future.

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

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

During the regulatory review process, we will need to identify success criteria and endpoints such that regulatory authorities will be able to determine the clinical efficacy and safety profile of any product candidates we may develop. Because our initial focus

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is to identify and develop product candidates to treat or prevent diseases in which there is little clinical experience using new technologies, there is heightened risk that regulatory authorities may not consider the clinical trial endpoints that we propose to provide clinically meaningful results. In addition, the resulting clinical data and results may be difficult to analyze.

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

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

We and our collaboration partners have conducted, currently are conducting and intend in the future to conduct, clinical trials outside the United States, particularly in Taiwan where we have reported interim results and expect to report the complete results of our UB-612 Phase 2 clinical trial in the coming months.

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

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

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

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

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

- limitations or warnings contained in the approved labeling for a product candidate and any other product insert requirements of regulatory authorities;
- changes in the standard of care for the targeted indications for any of our product candidates;
- limitations in the approved clinical indications for our product candidates;
- demonstrated clinical safety and efficacy compared to other products;
- the impact of disease variants, such as the Delta variant of SARS-CoV-2, on the efficacy and marketability of our product candidates targeting such diseases;

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- lack of significant adverse side effects, and the prevalence and severity of any side effects;
- sales, marketing and distribution support;
- availability of coverage and extent of reimbursement from managed care plans and other third-party payors;
- timing of market introduction and perceived effectiveness of our products as well as competitive products;
- continued projected growth of the markets in which our products compete;
- the degree of cost-effectiveness of our product candidates;
- the impact of past product price increases and limitations on future price increases for our products;
- availability of alternative therapies;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second or third-line therapy for particular diseases;
- whether the product can be used effectively with other therapies to achieve higher response rates;
- adverse publicity about our product candidates or favorable publicity about competitive products;
- if and when we are able to obtain regulatory approvals for indications for our products;
- our ability to establish and maintain a continuous supply of our products for commercial sale;
- potential or perceived advantages or disadvantages of our products over alternative treatments;
- convenience and ease of administration of our products; and
- the effect of current and future healthcare laws.

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

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

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

## Risks Related to Our Financial Position and Need for Additional Capital

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

As of September 30, 2021, we had cash and cash equivalents amounting to \$89.4 million. We believe that we will continue to expend substantial resources for the foreseeable future developing our proprietary product candidates. These expenditures will include costs associated with research and development, conducting pre-clinical studies and clinical trials, seeking regulatory approvals, as well as launching and commercializing products approved for sale and costs associated with manufacturing products. In addition, other unanticipated costs may arise. Because the outcomes of our anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our proprietary product candidates.

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

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

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

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

We have incurred significant losses since our inception. Our combined consolidated net loss for the year ended December 31, 2020 was approximately \$40.0 million. As of September 30, 2021, our combined accumulated deficit was \$181.3 million. Our expectation is that we will continue to incur losses as we continue our research and development of, and seek regulatory approvals for, our product candidates and maintain and develop new platforms, prepare for and begin to commercialize any approved product candidates and add infrastructure and personnel to support our product development efforts and operations as a public company. We have devoted substantially all of our financial resources and efforts to research and development, including pre-clinical studies and clinical trials and we anticipate that our expenses will continue to increase over the next several years as we continue these activities. The net losses and negative cash flows incurred to date, together with expected future losses, have had, and may continue to have, an adverse effect on our working capital. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

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

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

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

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

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

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. Our current or future license agreements may also be terminated if we are unable to meet the payment or other obligations under the agreements.

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

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

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

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

As of December 31, 2020, we had U.S. federal net operating loss carryforwards (“NOLs”) of \$44.5 million, which may be available to offset future taxable income, if any, and have no expiration date but are limited in their usage (for taxable years beginning after December 31, 2020) to an annual deduction equal to 80% of annual taxable income. In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the “Code”), a corporation that undergoes an “ownership change,” generally defined as a greater than 50% change by value in its equity ownership over a three-year period, is subject to limitations on its ability to utilize its pre-change NOLs and its research and development credit carryforwards to offset future taxable income. Our existing NOLs and research and development credit carryforwards may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change, our ability to utilize NOLs and research and development credit carryforwards could be further limited by Sections 382 and 383 of the Code. In addition, future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Sections 382 and 383 of the Code. For these reasons, we may not be able to utilize a material portion of the NOLs or research and development credit carryforwards even if we attain profitability.

**Risks Related to the Manufacturing of Our Product Candidates**

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

The formulation of peptide-based medicines is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and analytics. We are currently dependent on contract manufacturers, including UBI, its affiliates and C S Bio Co. (“CSBio”), to conduct the manufacturing and supply activities for our product candidates and the underlying component parts, but may choose to conduct these manufacturing activities ourselves in the future. If our contract manufacturers are unable to manufacture our product candidates in clinical quantities or, when necessary, in commercial quantities and at sufficient yields, then we will need to identify and reach supply arrangements with additional third parties. Further, our product candidates may be in competition with other products for access to these facilities and may be subject to delays in manufacture if our contract manufacturers give other products higher priority. We and our contract manufacturers must comply with cGMP, regulations and guidelines for the manufacturing of our product candidates used in pre-clinical studies and clinical trials and, if approved, marketed products. If we or our contract manufacturers do not receive any regulatory approvals required to manufacture our product candidates, production and fulfillment of orders will be delayed, which may materially adversely affect our business. Manufacturers of biotechnology products often encounter difficulties in production, particularly in scaling up and validating initial production. Furthermore, if microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities where our product candidates are made, such manufacturing facilities may be closed for an extended period of time to investigate and remedy the contamination. Shortages of raw materials may also extend the period of time required to develop our product candidates.

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

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

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

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

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

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

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

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

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

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

UBI is our largest stockholder, the licensor of certain of our intellectual property and is a commercial partner for the Company. In addition, Dr. Wang, UBI's founder, a member of its board of directors and a member of our scientific advisory board, holds shares of our common stock. Our co-founders (Mei Mei Hu and Louis Reese), one of their affiliates and UBI (collectively, our "principal stockholders"), are party to a voting agreement (the "Voting Agreement,"), which provides Mei Mei Hu with the authority (and irrevocable proxies) to vote the shares of capital stock held by the stockholders party to the Voting Agreement at her discretion

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on all matters to be voted upon by stockholders. Our CEO, Mei Mei Hu, and two of our other directors, Louis Reese and James Chui, also serve on and constitute a majority of the board of directors of UBI. UBI's equity interests in the Company, and the overlapping directorships, could give rise to conflicts of interest, in particular when a decision could favor the interests of UBI (or its affiliates) or us over the other. Further, we have historically depended heavily on UBI and its affiliates for our business operations, including the provision of research, development and manufacturing services. While we have taken steps to separate our operations from those of UBI and currently anticipate taking additional steps to lessen our dependence, we still have ongoing commercial relationships with UBI and its affiliates. With respect to our UB-612 program, we have partnered with UBIA for the development of UB-612 in Taiwan, UBIP for the formulation-fill-finish services, and United BioPharma, Inc. ("UBP") as the sole manufacturer of protein. Relating to our chronic disease pipeline, we continue to work with UBI on certain early stage research activities, and UBIP and UBIA for the production and testing of clinical material for our UB-312 program.

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

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

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

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

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

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



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

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

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

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

We have established and intend to continue to establish strategic partnerships, collaborations, licensing agreements, or other arrangements with third parties. For our research, development and commercialization activities, we have depended, and will continue to depend, on our partners to design and conduct their own clinical studies. As a result, these activities may not be able to be conducted in the manner or on the time schedule we currently contemplate, which may negatively impact our business operations. While we have certain contractual rights to information about pre-clinical and clinical developments and results under certain of our collaboration and license agreements, including our agreements with UBIA and Aurobindo, we cannot be certain that clinical trials conducted in connection with such collaboration programs will be conducted in a manner consistent with the best interests of our business. In addition, if any of our partners, collaborators or licensees withdraw support for these programs or proposed products or otherwise impair their development, our business could be negatively affected. Also, our inability to find a partner for any of our product candidates may result in our termination of that specific product candidate program or evaluation of a product candidate in a particular indication. Because of contractual restraints and the limited number of contract manufacturers with the expertise, required

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regulatory approvals and facilities to manufacture our product candidates on a commercial scale, replacement of a contract manufacturer may be expensive and time-consuming and may cause interruptions in the production of our product candidates, which could delay our clinical trials or interrupt our potential future commercial sales. Even if we find or establish a strategic partner, collaborator or licensee for one or more of our product candidates, there is no assurance that upon the approval of one or more of such product candidates that such product candidates will be successfully commercialized.

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

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

- collaborators or licensees may have significant discretion in determining the efforts and resources that they will apply to developing or commercializing our product candidates, and they may not sufficiently fund the development or commercialization of a product candidate;
- collaborators and licensees may not perform their obligations as expected by us or by health authorities, such as the FDA, the TFDA or comparable foreign regulatory authorities;
- collaborators and licensees may dissolve, merge, be bought or may otherwise become unwilling to fulfill the initial terms of the collaboration with us, or we may be unwilling to continue our arrangement following such an occurrence;
- collaborators and licensees may fail to perform their obligations under their agreements or may be slow in performing their obligations;
- collaborations and licensees may be terminated for the convenience of the collaborator or licensee and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates;
- collaborators and licensees may not pursue commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' or licensees' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities, or due to the actual or perceived competitive situation in a specific indication;
- collaborators and licensees may delay clinical trials, stop a clinical trial or abandon a product candidate, repeat or conduct additional clinical trials or may require a new formulation of a product candidate for clinical testing;
- collaborators and licensees could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- disagreements with collaborators or licensees, including disagreements over proprietary rights, contract interpretation and breach of contract claims, payment obligations or the preferred course of development, might cause delays or termination of the research, development or commercialization of products or product candidates, might lead to additional responsibilities, including financial obligations for us with respect to products or product candidates, or delays or withholding of payments due to us or might result in litigation or arbitration, any of which would be time-consuming and expensive, and could limit our ability to execute on our strategies and delay or prevent our ability to devote resources to other product candidates;
- collaborators or licensees may not properly obtain, maintain, enforce or defend our intellectual property or may use our proprietary information in such a way that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation; and

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

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

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

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

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

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

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

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

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

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

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

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

#### **Risks Related to Our Intellectual Property Rights**

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

We are dependent on technology, patents, know-how and proprietary information, both our own and those licensed from UBI and its affiliates. We entered into the Platform License Agreement in August 2021 pursuant to which we obtained a worldwide, sublicensable (subject to certain conditions), perpetual, fully paid-up, royalty-free (i) exclusive license (even as to the Licensors) under all patents owned or otherwise controlled by the Licensors or their affiliates existing as of the effective date of the Platform License Agreement, (ii) exclusive license (except as to the Licensors) under all patents owned or otherwise controlled by the Licensors or their affiliates arising after the effective date during the term of the Platform License Agreement, and (iii) non-exclusive license under all know-how owned or otherwise controlled by the Licensors or their affiliates existing as of the effective date or arising during the term of the Platform License Agreement, in each of the foregoing cases, to research, develop, make, have made, utilize, import, export, market, distribute, offer for sale, sell, have sold, commercialize or otherwise exploit peptide-based vaccines in the field of all human prophylactic and therapeutic uses, except for such vaccines related to human immunodeficiency virus, herpes simplex virus and Immunoglobulin E. The patents licensed to us under the Platform License Agreement include patents directed to a CpG delivery system, artificial T helper cell epitopes and certain designer peptides and proteins, each of which is utilized in our COVID-19 product candidates. Any termination of these licenses will result in the loss of significant rights and will restrict our ability to develop and commercialize our product candidates.

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

Agreements under which we license intellectual property or technology to or from UBI, its affiliates and from other third parties may be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant

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

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

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

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

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

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our compliance with reporting, financial or other obligations under the license agreement;
- the amount and timing of payments owed under license agreements; and
- the allocation of ownership of inventions and know-how resulting from the creation or use of intellectual property by our licensors and by us and our partners.

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

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marketplace, limit our ability to commercialize our products and product candidates and delay or render impossible our achievement of profitability.

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

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

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

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

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

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

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

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The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we may fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

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

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

In addition, patents have a limited lifespan. In the United States, for example, the natural expiration of a patent is generally 20 years after its effective filing date. Various extensions may be available, however, the life of a patent and the protection it affords is limited. Given the amount of time required for the development, testing, regulatory review and approval of new product candidates, our patents protecting such candidates might expire before or shortly after such candidates are commercialized. If we encounter delays in obtaining regulatory approvals, the period of time during which we could market a product under patent protection could be further reduced. Even if patents covering our product candidates are obtained, once such patents expire, or if such patents are waived or suspended, we may be vulnerable to competition from similar or biosimilar products. For example, the Biden administration recently indicated its support for a proposal at the World Trade Organization to waive patent rights with respect to COVID-19 vaccines. The current proposal is for a temporary waiver of intellectual property rights that cover COVID-19 vaccines, however, the ultimate timing and scope of the waiver, if approved, is unknown. The scope and timing of such waiver will likely be subject to extensive negotiations given the complexity of the matter, which may result in prolonged uncertainty and therefore could adversely affect our business. Any expiration, waiver or suspension of our patent or other intellectual property protection by the U.S. or other foreign governments could lead to the launch of a similar or biosimilar version of one of our products and would likely result in an immediate and substantial reduction in the demand for our product, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

The patent position of pharmaceutical companies is generally uncertain because it involves complex legal, scientific and factual considerations for which legal principles remain unsolved. The standards applied by the United States Patent and Trademark Office (“USPTO”) and foreign patent offices in granting patents are not always applied uniformly or predictably, and can change. Additionally, the laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant challenges in protecting and defending such rights in foreign jurisdictions. We may face similar challenges. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property rights, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement, misappropriation or other violation of our patents or other intellectual property, including the unauthorized reproduction of our manufacturing or other know-how or the marketing of competing products in violation of our intellectual property rights generally. Any of these outcomes could impair our ability to prevent competition from third parties, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

Further, the existence of issued patents does not guarantee our right to practice the patented technology or commercialize a patented product candidate. Third parties may design around our patents, or have or obtain rights to patents which they may use to

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

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

Many countries, including certain countries in Asia, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. Our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. For example, the research resulting in certain of our licensors' patents and technology, including patents and technology relating to our COVID-19 product candidates, was funded in part by the Taiwanese government. As a result, the Taiwanese government may have certain rights to such patent rights and technology.

Furthermore, certain of our patents and technology, including patents and technology relating to UB-312, were funded in part by grants from nonprofit third parties, including the Michael J. Fox Foundation. We are required to fulfill certain contractual obligations with respect to products created using such grant funding, including certain reporting requirements. We also have submitted grant proposals relating to our UB-612 product candidate. If these grant proposals are awarded, or if we receive funding from other nonprofit third parties in the future, we may be required to fulfill other contractual obligations, such as publishing the results of our scientific studies, making certain products available at an affordable price in a list of clearly defined low and lower-middle income countries and ensuring that certain products are available in geographic regions where there has been an outbreak of an infectious disease at certain reduced economic rates.

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

Many of our current and former employees, consultants and independent contractors including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including some which may be competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees, consultants or independent contractors have used or disclosed intellectual property, including trade secrets or other proprietary information, of such individual's current or former employers, or that patents and applications we have filed to protect inventions of these individuals, even those related to one or more of our current or future product candidates, are rightfully owned by their former or concurrent employer. In addition, while we typically require our employees, consultants and independent contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, or such agreements may be breached or alleged to be ineffective, and the assignment may not be self-executing, which may result in



claims by or against us related to the ownership of such intellectual property or may result in such intellectual property becoming assigned to third parties.

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

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

Uncertainties resulting from our participation in patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Furthermore, because of the substantial amount of discovery required in certain jurisdictions in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, the perceived value of our product candidates or intellectual property could be diminished. Accordingly, the market price of our Class A common stock could decline. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States or abroad could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. For example, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. Specifically, these decisions stand for the proposition that patent claims that recite laws of nature are not themselves patentable unless those patent claims have sufficient additional features that provide practical assurance that the processes are genuine inventive applications of those laws. What constitutes a "sufficient" additional feature is uncertain. Furthermore, in view of these decisions, since December 2014, the USPTO has published and continues to publish revised guidelines for patent examiners to apply when examining process claims for patent eligibility. This combination of events has created uncertainty with respect to the validity and enforceability of patents, even once they are obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways. In addition, the complexity and uncertainty of European and Asian patent laws have also increased in recent years. For example, in October 2020, China adopted amendments to its patent law (the "Amended PRC Patent Law"), which became effective on June 1, 2021. The Amended PRC Patent Law contains both patent term extension and a mechanism for early resolution of patent disputes. However, the provisions for patent term extension and an early resolution mechanism are unclear and remain subject to the approval of implementing regulations that have yet to be finalized, leading to uncertainty about their scope and implementation. Complying with these laws and regulations could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

***Obtaining and maintaining our patent protection, including patents licensed from third parties, depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.***

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications will be due to be paid to the USPTO and various government patent agencies outside the United States over the lifetime of our patents and patent applications and any patent rights we may own or license in the future. Additionally, the USPTO and various government patent agencies outside the United States require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain cases, an inadvertent lapse can be cured by payment of a late fee or

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by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. For example, certain of our patents which include claims utilized in our UB-311 anti-A $\beta$  vaccine product candidate recently lapsed in certain European and Asian countries due to non-payment of fees. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official communications within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering or otherwise protecting our technologies or our product candidates, our competitors may be able to enter the market with similar or identical products or technology without infringing our patents, which could have a material adverse effect on our business. In addition, to the extent that we have responsibility for taking any action related to the prosecution or maintenance of patents or patent applications in-licensed from a third party, any failure on our part to maintain the in-licensed intellectual property could jeopardize our rights under the relevant license and may have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

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

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

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

We may not have adequate remedies in the event of unauthorized use or disclosure of our proprietary information in the case of a breach of any such agreements and our trade secrets and other proprietary information could be disclosed to third parties, including our competitors. Many of our partners also collaborate with our competitors and other third parties. The disclosure of our trade secrets to our competitors, or more broadly, would impair our competitive position and may materially harm our business, financial condition, results of operations and prospects. Costly and time-consuming litigation could be necessary to enforce and

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determine the scope of our proprietary rights, and failure to maintain trade secret protection could adversely affect our competitive business position. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. Courts outside the United States are sometimes less willing to protect proprietary information, technology and know-how. In addition, others may independently discover or develop substantially equivalent or superior proprietary information and techniques, and the existence of our own trade secrets affords no protection against such independent discovery.

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

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

***Intellectual property rights do not necessarily address all potential threats.***

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

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

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

## Risks Related to Our Business and Industry

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

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

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the Centers for Medicare and Medicaid Services (“CMS”), the federal agency responsible for administering the Medicare program, makes the principal decisions about coverage and reimbursement for new treatments under Medicare. Private payors may follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for novel products such as ours. In addition, certain Affordable Care Act marketplace and other private payor plans are required to include coverage for certain preventative services, including vaccinations recommended by the U.S. Centers for Disease Control’s (“CDC’s”), Advisory Committee on Immunization Practices (“ACIP”) without cost share obligations (*i.e.*, co-payments, deductibles or co-insurance) for plan members. For Medicare beneficiaries, our product candidates, apart from our COVID-19 product candidates, 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 product candidates, once approved, are reimbursed only under the Part D program, physicians may be less willing to use our products because of the claims adjudication costs and time related to the claims adjudication process and collection of co-payment associated with the Part D program. If our product candidates, once approved, are reimbursed only under the Part B program, certain potential drawbacks associated with the Part B program, such as the time and effort required to seek reimbursement after purchase, may make our product candidates less attractive to clinics or other potential customers. Outside of Medicare, private insurance is likely to raise similar claims adjudication and co-payment considerations, which may also make our product candidates less attractive to potential customers using private insurance.

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

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

party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries.

If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, financial condition, results of operations or prospects could be materially adversely affected. Cost-control initiatives could cause us, or any collaborators, to decrease the price we, or they, might establish for products, which could result in lower than anticipated product revenues. Further, our competitors have more experience dealing with and contracting with payors for preferred coverage, which could potentially put us at a competitive disadvantage. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for any of our product candidates for which we, or any future collaborator, obtain marketing approval could significantly harm our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

***Our business and current and future relationships with third-party payors, healthcare professionals and customers in the United States and elsewhere will be subject to applicable healthcare laws and regulations, which could expose us to significant penalties.***

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

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, some of whom may recommend, purchase or prescribe our product candidate, if approved, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations.

If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business.

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

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

Cyber threats are persistent and constantly evolving. Such threats, which may include ransomware or other malware, phishing attacks, denial of services attacks, man-in-the-middle attacks and others, have increased in frequency, scope and potential impact in recent years, which increase the difficulty of detecting and successfully defending against them. We may not be able to anticipate all types of security threats, and, despite our efforts, we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. There can be no assurance that we or our third-party service providers, contractors or consultants will be successful in preventing cyberattacks or successfully mitigating their effects. Our IT

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systems and those of our third-party service providers, contractors or consultants are additionally vulnerable to security breaches from inadvertent or intentional actions by our employees, third-party vendors, contractors, consultants, business partners and/or other third parties. These threats pose a risk to the security of our systems and networks, the confidentiality and the availability, security and integrity of our data, and these risks apply both to us and to third parties on whose systems we rely for the conduct of our business. If the IT systems of our third-party vendors and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of a similar nature from occurring. Any cyberattack or destruction or loss of, unauthorized access to, processing of, or exfiltration of data could have a material adverse effect on our business, financial condition, results of operations and prospects. For example, if such an event were to occur and cause interruptions in our operations, or those of our third-party vendors and other contractors and consultants, it could result in a material disruption or delay of the development of our product candidates. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyberattacks or other data security breaches, particularly those involving personal information or protected health information, and may incur significant additional expense to implement further data protection measures. As cyber threats continue to evolve, we may be required to incur material additional expenses in order to enhance our protective measures or to remediate any information security vulnerability.

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

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

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

Internationally, laws, regulations and standards in many jurisdictions apply broadly to the collection, transmission, storage, use, processing, destruction, retention and security of personal information. For example, in the European Union, the collection, transmission, storage, use, processing, destruction, retention and security of personal data is governed by the provisions of the General

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Data Protection Regulation (the “GDPR”) in addition to other applicable laws and regulations. The GDPR came into effect in May 2018, repealing and replacing the European Union Data Protection Directive, and imposing revised data privacy and security requirements on companies in relation to the processing of personal data of European Union data subjects. The GDPR, together with national legislation, regulations and guidelines of the European Union Member States governing the collection, transmission, storage, use, processing, destruction, retention and security of personal data, impose strict obligations with respect to, and restrictions on, the collection, use, retention, protection, disclosure, transfer and processing of personal data. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union that are not deemed to have protections for personal information, including the United States. The GDPR authorizes fines for certain violations of up to 4% of the total global annual turnover of the preceding financial year or €20 million, whichever is greater. Such fines are in addition to any civil litigation claims by data subjects. Separately, Brexit has led and could also lead to legislative and regulatory changes and may increase our compliance costs. As of January 1, 2021, and the expiry of transitional arrangements agreed to between the United Kingdom and the European Union, data processing in the United Kingdom is governed by a United Kingdom version of the GDPR (combining the GDPR and the Data Protection Act 2018), exposing us to two parallel regimes, each of which authorizes similar fines and other potentially divergent enforcement actions for certain violations. On June 28, 2021, the European Commission adopted an adequacy decision for the United Kingdom, allowing for the relatively free exchange of personal information between the European Union and the United Kingdom. Other jurisdictions outside the European Union are similarly introducing or enhancing privacy and data security laws, rules and regulations, which could increase our compliance costs and the risks associated with noncompliance. We cannot guarantee that we are, or will be, in compliance with all applicable international regulations as they are enforced now or as they evolve.

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

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

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

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

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

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

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

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face and will continue to face competition from third parties that use similar platforms and from third parties focused on developing and commercializing other peptide and peptide-based product candidates. The competition is likely to come from multiple sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions, government agencies and public and private research institutions.

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

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

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

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

If these competitors access the marketplace with safer, more effective, or less expensive therapeutics, our product candidates, if approved for commercialization, may not be profitable to sell or worthwhile to continue to develop. Technology in the pharmaceutical industry has undergone rapid and significant change, and we expect that it will continue to do so. Any compounds, products or processes that we develop may become obsolete or uneconomical before we recover any expenses incurred in connection with their development. The success of our product candidates will depend upon factors such as product efficacy, safety, reliability,



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availability, timing, scope of regulatory approval, acceptance and price, among other things. Other important factors to our success include speed in developing product candidates, completing clinical development and laboratory testing, obtaining regulatory approvals and manufacturing and selling commercial quantities of potential products.

Our product candidates are intended to compete directly or indirectly with existing products and products currently in development. Even if approved and commercialized, our product candidates may fail to achieve market acceptance with hospitals, physicians, patients or third-party payors. Hospitals, physicians or patients may conclude that our products are less safe or effective or otherwise less attractive than existing drugs. If our product candidates do not receive market acceptance for any reason, our revenue potential would be diminished, which would materially adversely affect our ability to become profitable.

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

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

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

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

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

conduct business could also have an adverse impact on our reputation, business, financial condition, results of operations and prospects.

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

We have offices in two different countries and additional operations in two different countries. We have also used, and plan to use, a network of agents in countries around the world to conduct our sales and marketing operations. If we are unable to manage the risks of our global operations, including fluctuations in foreign exchange and inflation rates, international hostilities, natural disasters, security breaches, our ability to supply our product candidates on a timely and large scale basis in local markets, lead times for shipping, accounts receivable collection times, import or export licensing requirements, language barriers, failure to maintain compliance with our clients' control requirements and multiple legal and regulatory systems, our results of operations and ability to grow could be materially adversely affected. In particular, our business and stock price may be affected by fluctuations in foreign exchange rates between currencies in different jurisdictions in which operate or in which we may have sales in the future.

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

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

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

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

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

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

- decreased demand for our future product candidates;
- adverse publicity and injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- compensation in response to a liability claim;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources; and
- the inability to commercialize our products or product candidates.

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

***We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.***

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

- the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors;

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

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

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

As of September 30, 2021, we had 75 full-time employees. Our focus on the development of UB-311, our COVID-19 product candidates and other product candidates requires us to manage and operate our business in a highly efficient manner. We have a limited number of employees upon which we rely to effectively manage and operate our business and we cannot assure you that operational issues will not arise.

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

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

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

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

Many of our employees have become or will soon become vested in a substantial amount of our Class A common stock or a number of common stock options. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of Class A our common stock, particularly after the expiration of the lock-up agreements in connection with

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our initial public offering. Our future success also depends on our ability to continue to attract and retain additional executive officers and other key employees.

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

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

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or investigational medicines and regulatory approvals; and
- our inability to generate revenue from acquired technology or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

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

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

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

Natural disasters or pandemics, other than or in addition to COVID-19 and including any potential future waves of COVID-19, could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage, pandemic, such as the COVID-19 pandemic, or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities on which we rely, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business.

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

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

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

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

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

We also expect that operating as a public company will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash and cash equivalents position and results of operations.

***The ongoing coronavirus pandemic has caused interruptions or delays of our business plan. Delays caused by the coronavirus pandemic may have a significant adverse effect on our business.***

In December 2019, a strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China, and on March 12, 2020, the World Health Organization declared COVID-19 to be a pandemic. In an effort to contain and mitigate the spread of COVID-19, many countries, including the United States, Canada and China, have imposed unprecedented restrictions on travel, quarantines and other public health safety measures. The extent to which the pandemic may impact our business will depend on future developments, which are highly uncertain and cannot be predicted, but the development of clinical supply materials could be delayed and enrollment of patients in our studies may be delayed or suspended, as hospitals and clinics in areas where we are conducting trials shift resources to cope with the COVID-19 pandemic and may limit access or close clinical facilities due to the COVID-19 pandemic. Additionally, if our trial participants are unable to travel to our clinical study sites as a result of quarantines or other restrictions resulting from the COVID-19 pandemic, we may experience higher drop-out rates or delays in our clinical studies. We have manufacturers and collaboration partners located in foreign jurisdictions, and travel restrictions have limited, and may continue to limit, our ability to visit their locations in person and conduct on-site inspections.

Government-imposed quarantines and restrictions may also require us to temporarily suspend or terminate activity at our clinical sites. Furthermore, if we determine that our trial participants may suffer from exposure to COVID-19 as a result of their participation in our clinical trials, we may voluntarily terminate certain clinical sites as a safety measure until we reasonably believe that the likelihood of exposure has subsided. As a result, we may encounter difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials, and our expected development timelines for our product candidates may be negatively impacted. We cannot predict the ultimate impact of the COVID-19 pandemic as consequences of such an event are highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical studies or as a whole; however, the COVID-19 pandemic may materially disrupt or delay our business operations, further divert the attention and efforts of the medical community to coping with COVID-19, disrupt the marketplace in which we operate, and/or have a material adverse effect on our operations.

Moreover, the various precautionary measures taken by many governmental authorities around the world in order to limit the spread of COVID-19 has had and may continue to have an adverse effect on the global markets and global economy generally, including on the availability and pricing of employees, resources, materials, manufacturing and delivery efforts and other aspects of the global economy. There have been business closures and a substantial reduction in economic activity in countries that have had significant outbreaks of COVID-19. Significant uncertainty remains as to the potential impact of the COVID-19 pandemic on the global economy as a whole. It is currently not possible to predict how long the pandemic will last or the time that it will take for economic activity to return to prior levels. The COVID-19 pandemic could materially disrupt our business and operations, interrupt our sources of supply, hamper our ability to raise additional funds or sell securities, continue to slow down the overall economy or curtail consumer spending.

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

An EUA for UB-612 was denied by the FDA in August 2021. In addition to appealing that decision, we are exploring paths to approval of UB-612 as a three-dose regimen and as a heterologous boost (boosting the immunity of a subject who has already received a different vaccine). Other companies have also responded to the pandemic at a faster pace, and to date more than twenty vaccines have been approved for use in one or more countries around the world, including three in the United States. As of December 17, 2021, approximately 47% of the global population has been fully vaccinated, up from approximately 27% on August 31, 2021. As our competitors continue to develop, receive regulatory approval for and commercialize their own COVID-19 vaccines and boosters, vaccination rates will continue to increase, which will result in a material decrease in demand for our COVID-19 product candidates and a corresponding decrease in our revenues. Further, the existence and significance of the opportunity to provide COVID-19 boosters in the future is highly uncertain, and there can be no assurance that we will commercially benefit from the development of a COVID-19 booster market.

**Risks Related to Our Class A Common Stock**

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

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

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

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

- our operating and financial performance and prospects;
- our announcements or our competitors' announcements regarding new products or services, enhancements, significant contracts, acquisitions or strategic investments;
- any delay in our development or regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings;
- if any of our product candidates receives an EUA or regulatory approval, the terms of such approval and market acceptance and demand for such product candidates;
- the success of any efforts to acquire or in-license additional technologies, products or product candidates;
- changes in earnings estimates or recommendations by securities analysts who cover our Class A common stock;
- fluctuations in our financial results or, in the event we provide it from time to time, earnings guidance, or the financial results or earnings guidance of companies perceived by investors to be similar to us;
- changes in our capital structure, such as future issuances of securities, sales of large blocks of common stock by our stockholders, including our principal stockholders, or the incurrence of additional debt;
- additions and departure of key personnel;

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- any disputes relating to our intellectual property, including any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- reputational issues, including reputational issues involving our competitors and their products;
- actions by institutional stockholders;
- changes in general economic and market conditions, including related to the COVID-19 pandemic;
- changes in industry conditions or perceptions or changes in the market outlook for the industry in which we compete, including changes in the structure of healthcare payment systems; and
- changes in applicable laws, rules or regulations or regulatory actions affecting us or our clients and other dynamics.

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

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

Our Class A common stock has one vote per share, and our Class B common stock has ten votes per share. Our principal stockholders have entered into the Voting Agreement. Ms. Hu, as proxyholder under the Voting Agreement, controls approximately 58.60% of the total voting power of our outstanding capital stock. The Voting Agreement provides Ms. Hu with the authority (and irrevocable proxies) to direct the vote and vote the shares of capital stock held by the parties to the voting agreement at her discretion on all matters to be voted upon by stockholders. The voting power covered by the Voting Agreement may increase over time as the UBI Warrant is exercised and as our principal stockholders exercise or vest equity awards outstanding at the time of the completion of our initial public offering. If all such equity awards held by our principal stockholders had been exercised or vested and exchanged for shares of common stock and the UBI Warrant had been exercised in full for shares of Class A common stock as of the date of the completion of our initial public offering, assuming no other equity awards had been exercised or vested, the Voting Agreement would cover, in the aggregate as of the completion of our initial public offering, approximately 67.60% of the total voting power of our outstanding capital stock. As a result, if our principal stockholders retain all or a large portion their common stock, including the common stock issuable upon the exercise or vesting of such principal stockholders' outstanding equity awards or upon the exercise of the UBI Warrant, our principal stockholders will be able to significantly influence (if not control) any action requiring the approval of our stockholders, including the election of our board of directors, the adoption of amendments to our Charter and Bylaws and the approval of any merger, consolidation, sale of all or substantially all of our assets or other major corporate transaction. Assuming our principal stockholders retain their equity interests and the Voting Agreement remains in effect, our principal stockholders will effectively control all such matters submitted to the stockholders for the foreseeable future. Our principal stockholders will also have the voting power to determine the composition of our board of directors, which in turn will be able to determine matters affecting us, including, among others:

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

Our principal stockholders may have interests that differ from yours and may vote in a way with which you disagree and which may be adverse to your interests. This concentrated control may have the effect of delaying, preventing or deterring a change in control of the Company, could deprive our stockholders of an opportunity to receive a premium for their capital stock as part of a sale in the Company and might ultimately affect the market price of our Class A common stock. In addition, each share of Class B



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common stock will automatically convert into one share of Class A common stock upon any transfer, whether or not for value and whether voluntary or involuntary or by operation of law, except for certain transfers described in our Charter, including, without limitation, certain transfers for tax and estate planning purposes. Such issuances will be dilutive to holders of our Class A common stock.

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

We are an “emerging growth company,” as defined in the JOBS Act. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which we have annual gross revenues of \$1.07 billion or more; (ii) the date on which we have issued more than \$1.0 billion in non-convertible debt in the previous three years; (iii) the date we qualify as a “large accelerated filer” under the Exchange Act, which would occur at the end of a given fiscal year if the market value of our common stock that is held by non-affiliates is \$700 million or more as of the last business day of the second fiscal quarter of such year (and we have been a public company for at least 12 months and have filed one annual report on Form 10-K); and (iv) the last day of the fiscal year ending after the fifth anniversary of our initial public offering. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to these provisions. These provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits

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against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our Charter inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business or financial condition.

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

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

- our dual-class common stock structure and the Voting Agreement, which provide our principal stockholders with a majority of the voting power of our capital stock will enable our principal stockholders to influence the outcome of matters submitted to our stockholders for approval even if they own significantly less than a majority of the number of shares of our outstanding common stock;
- our Charter does not provide for cumulative voting in the election of directors;
- vacancies on our board of directors may be filled only by our board of directors and not by stockholders;
- our stockholders may act by written consent only so long as the Voting Agreement is in effect and our principal stockholders hold a majority of the voting power of then-outstanding shares of our capital stock;
- a special meeting of our stockholders may only be called by the chairperson of our board of directors, our Chief Executive Officer, our President, a majority of our board of directors or, so long as the Voting Agreement is in effect and our principal stockholders hold a majority of the voting power of then-outstanding shares of our capital stock, our stockholders;
- amendments to certain provisions of our Charter and stockholder-proposed amendments to our Bylaws require the affirmative vote of the holders of at least 66 2/3% in voting power of all the then outstanding shares of our capital stock entitled to vote thereon at any time the Voting Agreement is not in effect or our principal stockholders do not hold, in the aggregate, a majority of the voting power of then-outstanding shares of our capital stock;
- our Charter authorizes our board of directors, subject to the limitations imposed by Delaware law or the Nasdaq's listing rules, without any further vote or action by our stockholders, to issue preferred stock in one or more series and to fix the designations, powers, preferences, limitations and rights of the shares of each series; and
- advance notice procedures apply for stockholders to nominate candidates for election as directors or to bring matters before an annual meeting of stockholders.

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

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

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

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

The trading market for our Class A common stock will depend in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. If no or few securities or industry analysts cover us, the price

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and trading volume of our Class A common stock likely would be negatively impacted. If one or more of the securities or industry analysts who cover us downgrade our Class A common stock or publish inaccurate or unfavorable research about us, the trading price of our Class A common stock would likely decline. If analysts publish target prices for our Class A common stock that are below our then-current public price of our Class A common stock, it could cause the trading price of our Class A common stock to decline significantly. Further, if one or more of these analysts cease coverage of the Company or fail to publish reports on us regularly, demand for our Class A common stock could decrease, which might cause our Class A common stock trading price and trading volume to decline.

#### **General Risk Factors**

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

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

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

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

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

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

Further, we believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These

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inherent limitations include the facts that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

***We have identified material weaknesses, and have previously identified material weaknesses, in our internal control over financial reporting. If we are unable to remediate our existing material weaknesses and otherwise develop and maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud, and as a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our Class A common stock.***

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. A material weakness is a deficiency or a combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. In connection with the audits performed for UNS for the fiscal years ended December 31, 2017, 2018 and 2019 and for COVAXX for the period ended June 30, 2020, we concluded that there were material weaknesses in the design of our internal control over financial reporting relating to (i) documenting and performing the monthly financial close, account reconciliation and analysis processes on a timely basis; (ii) ensuring that formal processes for identifying and analyzing complex transactions exist; (iii) ensuring proper segregation of duties and responsibilities within our finance department; (iv) ensuring that a process exists for determining whether key contracts, documents and agreements are considered for accounting and disclosure and accurately supported by accounting records; and (v) ensuring that a process existing to document accurate accruals for all internal related-party resources across our affiliated entities.

We subsequently remediated these material weaknesses described above through a combination of hiring and training additional qualified accounting and financial reporting personnel and further evolving and refining our accounting processes and policies. In connection with our preparation of our unaudited combined consolidated financial statements for the six months ended June 30, 2021, we identified material weaknesses in the design of our internal controls over financial reporting. In connection with the preparation of our unaudited combined consolidated financial statements for the three and nine months ended September 30, 2021, we continued to identify significant deficiencies in the design of our internal controls over financial reporting. We are in the process of implementing measures designed to improve internal control over financial reporting to remediate the control deficiencies that led to these material weaknesses by designing and implementing improved processes and internal controls, including evaluating the adequacy of our enterprise resource planning system, further segregating duties among accounting and finance personnel and establishing further processes to identify and analyze complex transactions. We cannot assure you that we will be able to successfully remediate these material weaknesses or other material weaknesses that may be discovered in the future. If we are unable to successfully remediate these issues or future issues or if we fail to design and operate effective internal controls, it could result in material misstatements or omissions in our financial statements and potentially require us to restate our financial statements, which may result in the trading value of our Class A common stock being materially adversely affected.

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

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

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

During the three months ended September 30, 2021, we have engaged in the following transactions that were not registered under the Securities Act. The share amounts and per share prices set forth below have not been adjusted to give effect to the Stock Split.

- In July 2021, we granted 2,389,469 stock options to purchase shares of our Class A common stock to our officers, employees, directors, consultants and other key persons at a weighted average price of \$4.33 per share under our Existing 2021 Plan.

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- In August 2021, as partial consideration for the rights and licenses we received pursuant to the Platform License Agreement, we granted UBI the UBI Warrant, which entitles UBI to purchase 3,000,000 shares of our Class A common stock at an exercise price of \$8.00 per share (subject to adjustment for the Stock Split and other adjustments pursuant thereto).
- In August 2021, we canceled existing options to purchase, in aggregate, 9,899,982 shares of our Class A common stock held by Ms. Hu and Mr. Reese in exchange for an equal number of options to purchase shares of our Class B common stock.

None of the foregoing transactions involved any underwriters, underwriters' discounts or commissions or any public offering. Unless otherwise stated, the sales of the above securities were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(a)(2) of the Securities Act (or Regulation D or Regulation S promulgated thereunder) or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or pursuant to benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to, or for sale in connection with, any distribution thereof and appropriate legends were placed upon the stock certificates issued in these transactions.

**Use of Proceeds**

On November 15, 2021, the Company closed its IPO of our common stock of 6,000,000 shares of Class A common stock at a public offering price of \$13.00 per share. On November 18, 2021, the Company held a subsequent closing for the issuance of an additional 537,711 shares of Class A common stock, pursuant to a 30-day option granted to the underwriters to purchase up to an additional 900,000 shares of Class A common stock at the IPO price, less underwriting discounts and commissions. The aggregate net proceeds to us from the offering, after deducting underwriting discounts and commissions and other offering expenses payable by us, was approximately \$71.1 million. Upon the closing of the IPO, all previously outstanding shares of our redeemable convertible preferred stock were automatically converted into shares of Class A common stock. We registered the shares offered in the IPO under the Securities Act pursuant to a Registration Statement on Form S-1 (File No.333-260163), as amended (the "Registration Statement"), declared effective by the SEC on November 10, 2021. The proceeds from our IPO have been invested primarily in money market accounts. There has been no material change in the expected use of the net proceeds from our IPO as described in our prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on November 12, 2021.

**Item 6. Exhibits.**

<u>Exhibit No.</u>	<u>Description</u>
3.1	<a href="#">Amended and Restated Certificate of Incorporation (Incorporated by reference to Exhibit 3.1 of Form 8-K, filed by Vaxxinity, Inc. on November 17, 2021 (File No. 001-41058))</a> .
3.2	<a href="#">Amended and Restated Bylaws (Incorporated by reference to Exhibit 3.2 of Form 8-K, filed by Vaxxinity, Inc. on November 17, 2021 (File No. 001-41058))</a> .
4.1	<a href="#">Warrant to Purchase Shares of Class A Common Stock of Vaxxinity, Inc. (Incorporated by reference to Exhibit 4.1 of Form S-1/A, filed by Vaxxinity, Inc. on November 5, 2021 (File No. 333-260163))</a> .
10.1	<a href="#">Form of Indemnification Agreement between Vaxxinity, Inc. and each of its directors and executive officers (Incorporated by reference to Exhibit 10.1 of Form S-1/A, filed by Vaxxinity, Inc. on November 5, 2021 (File No. 333-260163))</a> .
10.2	<a href="#">Registration Rights Agreement, dated November 15, 2021, by and among Vaxxinity, Inc. and the "Investors," as defined therein (Incorporated by reference to Exhibit 10.1 of Form 8-K, filed by Vaxxinity, Inc. on November 17, 2021 (File No. 001-41058))</a> .
10.3	<a href="#">Voting Agreement, dated as of October 1, 2021, among Louis Reese, Blackfoot Healthcare Ventures, LLC and United Biomedical, Inc. (Incorporated by reference to Exhibit 10.3 of Form S-1/A, filed by Vaxxinity, Inc. on November 5, 2021 (File No. 333-260163))</a> .
10.4	<a href="#">Platform License Agreement, dated as of August 5, 2021, among Vaxxinity, Inc., United Biomedical, Inc., UBI IP Holdings and UBI US Holdings, LLC (Incorporated by reference to Exhibit 10.4 of Form S-1/A, filed by Vaxxinity, Inc. on November 5, 2021 (File No. 333-260163))</a> .
10.5	<a href="#">United Neuroscience 2017 Share Option and Grant Plan† (Incorporated by reference to Exhibit 10.5 of Form S-1/A, filed by Vaxxinity, Inc. on November 5, 2021 (File No. 333-260163))</a> .
10.6	<a href="#">C19 Corp. 2020 Stock Option and Grant Plan† (Incorporated by reference to Exhibit 10.6 of Form S-1/A, filed by Vaxxinity, Inc. on November 5, 2021 (File No. 333-260163))</a> .
10.7	<a href="#">Vaxxinity, Inc. 2021 Stock Option and Grant Plan† (Incorporated by reference to Exhibit 10.7 of Form S-1/A, filed by Vaxxinity, Inc. on November 5, 2021 (File No. 333-260163))</a> .
10.8	<a href="#">Letter agreement by and between United Neuroscience, LLC and Dr. Farshad Guirakhoo, dated May 4, 2020† (Incorporated by reference to Exhibit 10.8 of Form S-1/A, filed by Vaxxinity, Inc. on November 5, 2021 (File No. 333-260163))</a> .
10.9	<a href="#">Vaxxinity, Inc. 2021 Omnibus Incentive Compensation Plan† (Incorporated by reference to Exhibit 10.9 of Form S-1/A, filed by Vaxxinity, Inc. on November 5, 2021 (File No. 333-260163))</a> .
10.10	<a href="#">Vaxxinity, Inc. 2021 Employee Stock Purchase Plan† (Incorporated by reference to Exhibit 10.10 of Form S-1/A, filed by Vaxxinity, Inc. on November 5, 2021 (File No. 333-260163))</a> .
10.11	<a href="#">Form of Incentive Stock Option Grant Notice under the 2021 Stock Option and Grant Plan† (Incorporated by reference to Exhibit 10.11 of Form S-1/A, filed by Vaxxinity, Inc. on November 5, 2021 (File No. 333-260163))</a> .
10.12	<a href="#">Form of Non-Qualified Stock Option Grant Notice under the 2021 Stock Option and Grant Plan† (Incorporated by reference to Exhibit 10.12 of Form S-1/A, filed by Vaxxinity, Inc. on November 5, 2021 (File No. 333-260163))</a> .
10.13	<a href="#">Form of Restricted Stock Award Notice under the 2021 Stock Option and Grant Plan† (Incorporated by reference to Exhibit 10.13 of Form S-1/A, filed by Vaxxinity, Inc. on November 5, 2021 (File No. 333-260163))</a> .
10.14	<a href="#">Form of Notice of Stock Option Award 2021 Omnibus Incentive Compensation Plan† (Incorporated by reference to Exhibit 10.14 of Form S-1/A, filed by Vaxxinity, Inc. on November 5, 2021 (File No. 333-260163))</a> .
10.15	<a href="#">Form of Notice of Restricted Stock Unit Award 2021 Omnibus Incentive Compensation Plan† (Incorporated by reference to Exhibit 10.15 of Form S-1/A, filed by Vaxxinity, Inc. on November 5, 2021 (File No. 333-260163))</a> .
31.1	<a href="#">Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*</a>
31.2	<a href="#">Certification of Principal Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*</a>
32.1	<a href="#">Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002* ‡</a>
32.2	<a href="#">Certification of Principal Accounting Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002* ‡</a>

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101	The following financial information from the quarterly report on Form 10-Q for the quarter ended September 30, 2021, formatted in Inline Extensible Business Reporting Language (iXBRL): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Income (Loss), (iii) Consolidated Statements of Comprehensive Income (Loss), (iv) Consolidated Statements of Stockholders' Equity, (v) Consolidated Statements of Cash Flows, and (vi) related Condensed Notes to the Unaudited Consolidated Financial Statements, tagged in detail.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL document).

\* These exhibits are incorporated herein by reference.

† Indicates management contract or compensatory plan or arrangement.

‡ The certifications attached as Exhibits 32.1 and 32.2 that accompany this Form 10-Q are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Vaxxinity, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing.





**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.

**VAXXINITY, INC.**

Date: December 23, 2021

By: /s/ Mei Mei Hu  
Mei Mei Hu  
Chief Executive Officer

Date: December 23, 2021

By: /s/ Martin Doran  
Martin Doran  
Treasurer and Principal Accounting Officer

## CERTIFICATION

I, Mei Mei Hu, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2021 (the "Report") of Vaxxinity, Inc. (the "Registrant");
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 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)):
  - 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) [Paragraph intentionally omitted in accordance with SEC Release Nos. 34-47986 and 34-54942];
  - 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 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 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: December 23, 2021

/s/ Mei Mei Hu  
Mei Mei Hu  
Chief Executive Officer  
(principal executive officer)

## CERTIFICATION

I, Martin Doran, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2021 (the "Report") of Vaxxinity, Inc. (the "Registrant");
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 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) [Paragraph intentionally omitted in accordance with SEC Release Nos. 34-47986 and 34-54942];
  - 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 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 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: December 23, 2021

/s/ Martin Doran  
Martin Doran  
Treasurer and Principal Accounting Officer  
(principal financial officer)

**Certification of Principal Executive Officer  
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 Vaxxinity, Inc. (the "Company") for the quarter ended September 30, 2021, as filed with the Securities and Exchange Commission (the "Report"), I, Mei Mei Hu, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 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: December 23, 2021

/s/ Mei Mei Hu  
Mei Mei Hu  
Chief Executive Officer  
(principal executive officer)

This certification accompanies the foregoing Report pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. A signed original of this certification has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

**Certification of Principal Executive Officer  
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 Vaxxinity, Inc. (the "Company") for the quarter ended September 30, 2021, as filed with the Securities and Exchange Commission (the "Report"), I, Martin Doran, Treasurer and Chief Accounting Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 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: December 23, 2021

/s/ Martin Doran  
Martin Doran  
Treasurer and Principal Accounting Officer  
(principal financial officer)

This certification accompanies the foregoing Report pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. A signed original of this certification has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

