# 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 March 31, 2023 -OR- $\Box$  transition report pursuant to section 13 or 15(d) of the securities exchange act of 1934 For the transition period from Commission file number 001-41058 Vaxxinity, Inc. (Exact name of registrant as specified in its charter) 86-2083865 Delaware (State or other jurisdiction of incorporation or organization) (I.R.S. Employe Identification No.) 505 Odyssey Way 32953 Merritt Island, FL (Address of principal executive offices) (Zip Code) (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: Trading Name of each exchange Symbol(s) on which registered Title of each class Class A Common Stock, par value \$0.0001 per share VAXX The Nasdaq Global Market Indicate by check mark whether the registrant (1) has filedall 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 registrantwas required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  $\boxtimes$  No  $\square$ Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (\$232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes 🗵 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," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange

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		Accelerated filer	
Non-accelerated filer	$\boxtimes$	Smaller reporting company	X
		Emerging growth company	X

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

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

As of May 5, 2023, the registrant had 112,665,699 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," "continue," "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 materially from those reflected in forward-looking statements include, among others, the following:

- the prospects of our product candidates, including the progress, number, scope, cost, results and timing of data from our development activities, preclinical trials and clinical trials for our product candidates or programs, such as the target indication(s) for development or approval, the size, design, population, conduct, cost, objective or endpoints of any clinical trial, or the timing for initiation or completion of or availability of results from any clinical trial, for submission, review or approval of any regulatory filing, or for meeting with regulatory authorities;
- the potential benefits that may be derived from any of our product candidates;
- the timing of and our ability to obtain and maintain regulatory approval for our existing product candidates, any product candidates that we may develop, and any related restrictions, limitations, or warnings in the label of any approved 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;
- · estimates of our addressable market and market growth, and expectations about market trends;
- our future operations, financial position, revenue, costs, expenses, uses of cash, capital requirements, our needs for additional financing or the period for which our existing cash resources will be sufficient to meet our operating requirements;
- our ability to comply with legal and regulatory requirements 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;
- · our ability to access capital on acceptable terms in a rising interest rate and tighter credit environment;
- · competitive companies and technologies within 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 and obtain alternative sources of raw materials;
- our ability and the potential to successfully manufacture our product candidates for pre-clinical use, for clinical trials and, if approved, on a larger scale for commercial use;

- the ability and willingness of our third-party collaborators, including UBI, to continue research and development activities relating to our product candidates and our ability to attract additional collaborators with development, regulatory and commercialization expertise;
- general economic, political, demographic and business conditions in the United States, Taiwan and other jurisdictions where we conduct business or clinical trials;
- the potential effects of government regulation, including regulatory developments in the United States and other jurisdictions;
- ability to obtain additional financing in future offerings or otherwise;
- the effects of the Russia-Ukraine conflict and the COVID-19 pandemic on business operations and the initiation, development and operation of our clinical trials, including patient enrollment of our clinical trials; and
- · our strategies, prospects, plans, expectations, forecasts or objectives.

We discuss many of these and other factors in greater detail under Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the Securities and Exchange Commission on March 27, 2023. These risk factors are not exhaustive. Other sections of this report may include additional factors which could adversely impact our business and financial performance. New risk factors emerge from time to time, and it is not possible to predict all such risk factors, nor can we assess the impact of all such risk factors on our business or the extent to which any factor or combination of factors may cause actual results to differ materially from those contained in any forward-looking statements. Forward-looking statements are not guarantees of performance. Given these uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as of the date hereof.

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 CONSOLIDATED BALANCE SHEETS (in thousands, except share and per share amounts)

	_	March 31, 2023 (Unaudited)	D	ecember 31, 2022
Assets				
Current assets:				
Cash and cash equivalents	\$	22,585	\$	33,475
Short-term investments		44,993		53,352
Restricted cash		100		1,095
Amounts due from related parties		518		414
Prepaid expenses and other current assets		5,237		5,551
Total current assets		73,433		93,887
Property and equipment, net		12,098		12,512
Total assets	\$	85,531	\$	106,399
Liabilities and stockholders' equity	_			
Current liabilities:				
Accounts payable	\$	3,029	\$	5,295
Amounts due to related parties		12,706		12,772
Accrued expenses and other current liabilities		9,439		11,370
Note payable, net of debt issuance cost		394		391
Note payable to related party		898		1,113
Total current liabilities	-	26,467		30,941
Other liabilities				
Note payable, net of debt issuance cost, net of current portion		9,832		9,933
Note payable to related party, net of current portion		2,862		3,112
Other long-term liabilities		236		236
Total liabilities		39,398		44,222
Commitments and contingencies (Note 14)				
Preferred stock: \$0.0001 par value, 50,000,000 shares authorized at March 31, 2023 and December 31,2022		_		
Stockholders' equity:				
Class A common stock, \$0.0001 par value; 1,000,000,000 shares authorized, 112,118,911 and 112,182,750 shares issued a	and			
outstanding at March 31, 2023 and December 31, 2022, respectively		278		278
Class B common stock, \$0.0001 par value; 100,000,000 shares authorized, 13,874,132 shares issued and outstanding at March 31, 2023 and December 31, 2022		1		1
Additional paid-in capital		369.026		366.798
Accumulated other comprehensive loss		(49)		(197)
Accumulated deficit		(323,124)		(304,703)
		46,133		62,177
Total stockholders' equity Total liabilities and stockholders' equity	¢	46,133	¢	106,399
rotal natifices and stockholders equity	\$	65,551	\$	100,399

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

# VAXXINITY, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (in thousands, except share and per share amounts) (Unaudited)

	Three Months I	Ended March 31,
	2023	2022
Operating expenses:		
Research and development	\$ 11,424	\$ 11,478
General and administrative	7,384	6,686
Total operating expenses	18,808	18,164
Loss from operations	(18,808)	(18,164)
Other (income) expense:		
Interest and other expense	192	105
Interest and other income	(567)	(5)
(Gain) loss on foreign currency transactions, net	(12)	(1)
Total other (income) expense, net	(387)	99
Net loss	(18,421)	(18,263)
Net loss per share, basic and diluted	(0.15)	(0.15)
Weighted average common shares outstanding, basic and diluted	126,061,273	125,709,613
Other comprehensive income:		
Unrealized gain on investments	148	
Other comprehensive income	\$ 148	\$

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

# VAXXINITY, INC. CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (in thousands, except share amounts) (Unaudited)

	Common Stoc	k-Class A	Common Sto	ck-Class B	-			
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive (Loss)	Accumulated Deficit	Stockholders' Equity
Balance at December 31, 2022	112,182,750 \$	278	13,874,132 \$		\$ 366,798 \$	(197) \$	(304,703) \$	62,177
Issuance of common stock upon exercise of stock options	6,161	_	_	_	- 4	_	_	4
Stock-based compensation expense	_	_	-	-	- 2,225	_	_	2,225
Unrealized gain on investments	_	_	-	_		148	_	148
Net loss	_	_					(18,421)	(18,421)
Balance at March 31, 2023	112,188,911 \$	278	13,874,132 \$		\$ 369,026 \$	(49) \$	(323,124) \$	46,133
	Common Stoc	k-Class A	Common Sto	ck-Class B	-			
						Accumulated Other		

	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Comprehensive (Loss)	Accumulated Deficit	Stockholders' Equity	
Balance at December 31, 2021	111,518,094 \$	278	13,874,132 \$	1	\$ 357,821 \$	- s	(229,481) \$	128,619	
Issuance of common stock upon exercise of stock options	448,998	_	_	_	121	_	_	121	
Stock-based compensation expense	-	_	_	_	2,178	_	_	2,178	
Net loss							(18,263)	(18,263)	
Balance at March 31, 2022	111,967,092 \$	278	13,874,132 \$	1	\$ 360,120 \$	<u> </u>	(247,744) \$	112,655	

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

# VAXXINITY, INC. CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (in thousands) (Unaudited)

		Three Months End		
		2023		2022
Cash flows from operating activities:				
Net loss	\$	(18,421)	\$	(18,263
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation expense		586		333
Amortization of debt issuance costs		13		14
Amortization of discount on short-term investments		(406)		
Stock-based compensation expense		2,225		2,178
Changes in operating assets and liabilities:				
Amounts due from related parties		(104)		(6
Prepaid expenses and other current assets		314		667
Long-term deposits		_		(1,351
Accounts payable		(2,260)		(1,733
Amounts due to related parties		(67)		(2,620
Accrued expenses and other current liabilities		(1,931)		1,268
Other long-term liabilities				(1
Net cash used in operating activities		(20,051)		(19,514
Cash flows from investing activities:				
Purchase of short-term investments		(18,588)		
Redemption of short-term investments		27,500		
Purchases of property and equipment		(172)		(713
Net cash provided by (used in) investing activities		8,740		(713
Cash flows from financing activities:				
Repayments of note payable		(111)		(107
Repayments of note payable with related party		(466)		_
Proceeds from exercise of stock options		4		121
Net cash provided by (used in) financing activities		(574)		14
Change in cash, cash equivalents and restricted cash		(11,885)		(20,213
Cash, cash equivalents and restricted cash at beginning of period		34,570		145,057
Cash, cash equivalents and restricted cash at end of period	\$	22,685	\$	124,844
Reconciliation of cash, cash equivalents and restricted cash:				
Cash, cash equivalents and restricted cash at end of period	S	22,685	\$	124,844
Less restricted cash		(100)		(78
Cash and cash equivalents end of period	\$	22,585	\$	124,766
Supplemental Disclosure				
Cash paid for interest	\$	192	\$	92
cash para for interest	φ.	172	Ψ	92

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

## 1. Nature of the Business

Vaxxinity, Inc., a Delaware corporation ("Vaxxinity," and together with its subsidiaries, the "Company"), was formed through the combination of two separate businesses that originated from United Biomedica1, Inc. ("UBI") in two separate transactions: a spin-out from UBI in 2014 of operations focused ondeveloping chronic disease product candidates that resulted in United Neuroscience ("UNS"), and a second spin-out from UBI in 2020 of operations focused on the development of a COVID-19 vaccine that resulted in C19 Corp. ("COVAXX"). On February 2, 2021, Vaxxinity was incorporated for the purpose of reorganizing and combining UNS and COVAXX and on March 2, 2021, did so by acquiring all of the outstanding equity interests of UNS and COVAXX pursuant to a contribution and exchange agreement (the "Contribution and Exchange Agreement") whereby the existing equity holders of UNS and COVAXX contributed their equity interests in each of UNS and COVAXX in exchange for equity in Vaxxinity (the "Reorganization"). On December 31, 2022, COVAXX merged with and into Vaxxinity.

The Company is a biotechnology company currently focused on developing product candidates for human use in the fields of neurology, pain, cardiovascular diseases and coronaviruses utilizing its "Vaxxine Platform"—a synthetic peptide vaccine technology first developed by UBI and subsequently refined over the last two decades. The Company is engaged in the development of rationally designed prophylactic and therapeutic vaccines to combat common chronic diseases with large global unmet medical need. The Company is also developing a heterologous booster vaccine for SARS-Cov-2. UBI is a significant shareholder of the Company and, therefore, considered a related party.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry including, but not limited to, uncertainty of product development and commercialization, lack of marketing and sales history, development by its competitors of new technological innovations, dependence on key personnel, market acceptance of products, product liability, protection of proprietary technology, ability to raise additional financing, and compliance with government regulations. If the Company does not successfully commercialize or out-license any of its product candidates, it will be unable to generate recurring product revenue or achieve profitability.

The Company's product candidates are in development and will require significant additional research and development efforts, including extensive pre-clinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance -reporting capabilities. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and is dependent upon the services of its employees and consultants.

## Liquidity

As of March 31, 2023, the Company had \$67.7 million of cash, cash equivalents and short term investments to fund operations, including \$22.6 million of cash and cash equivalents, \$45.0 million of short-term investments, and \$0.1 million of restricted cash. To date, the Company has primarily financed its operations through the sale of convertible preferred stock and common stock, borrowings under promissory notes (including Convertible Notes), a portion of which has been raised from related party entities, and grants from foundations such as the Coalition for Epidemic Preparedness Innovations (CEPI) and the Michael J. Fox Foundation (MJFF). The Company has experienced significant negative cash flows from operations since inception, and incurred a net loss of \$18.4 million for the three months ended March 31, 2023. Net cash used in operating activities for the three months ended March 31, 2023, the Company has an accumulated deficit of \$323.1 million. The Company expects to incur substantial operating losses and negative cash flows from operations for the foreseeable future. As of the date these unaudited condensed consolidated financial statements were available to be issued, the Company expects its existing cash and cash equivalents and short-term investments to be sufficient to fund its operating expenses and capital expenditure requirements for at least the next 12 months.

In order to continue to fund future research and development activities, the Company will need to seek additional capital. This may occur through strategic alliances, licensing arrangements, grants or future public or private debt or equity financings. Additional funding may not be available on terms the Company finds acceptable or at all. If the Company is unable to obtain sufficient capital to continue to advance its programs, the Company would be forced to delay, limit, reduce or terminate its product development or future prefer to develop and market itself.

The accompanying unaudited condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The unaudited condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

## 2. Summary of Significant Accounting Policies

## **Basis of presentation**

The accompanying interim unaudited condensed consolidated financial statements have been prepared using generally accepted accounting principles in the United States of America ("GAAP") and pursuant to the rules and regulations of the United States Securities and Exchange Commission ("SEC") for interim financial reporting.

These interim condensed consolidated financial statements are unaudited and, in the opinion of management, include all adjustments necessary to fairly present the results of the interim periods. The condensed consolidated balance sheet at December 31, 2022, has been derived from the audited financial statements at that date. Operating results for the three months ended March 31, 2023 and cash flows for the three months ended March 31, 2023 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2023 or any other future period. Certain information and footnote disclosures normally included in annual consolidated financial statements prepared in accordance with GAAP have been omitted in accordance with the rules and regulations for interim reporting of the SEC. These interim unaudited condensed financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on March 27, 2023 (the "Annual Report").

## Significant accounting policies

The significant accounting policies used in preparation of these unaudited condensed consolidated financial statements are disclosed in our annual consolidated financial statements for the year ended December 31, 2022 included in the Annual Report. There have been no changes to the Company's significant accounting policies during the three months ended March 31, 2023.

## Recently issued accounting pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies and are adopted by the Company as of the specified effective date.

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"). ASU 2016-13 significantly changes the impairment model for most financial assets and certain other instruments as it will require immediate recognition of estimated credit losses expected to occur over the remaining life of many financial assets, which will generally result in earlier recognition of allowances for credit losses on loans and other financial instruments. On January 1, 2023, the Company adopted ASU 2016-13. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

## 3. Fair Value Measurements

The Company's money market accounts and short-term investments are shown at fair value based on unadjusted quoted market prices in active markets for identical assets.

The following table presents information about the Company's financial instruments measured at fair value on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values (in thousands):

March 31, 2023	1	Level 1	1	Level 2		Level 3	Total
Assets:							
Short-term investments	\$	44,993	\$	_	\$	_	\$ 44,993
Money market accounts		8,976		_		—	8,976
Total assets	\$	53,969	\$	_	\$	_	\$ 53,969
10141 455015							
	÷	,		evel 2		Level 3	 Total
December 31, 2022		Level 1		Level 2	_	Level 3	 Total
	 	Level 1	\$	Level 2	\$	Level 3	\$ <b>Total</b> 53,352
December 31, 2022 Assets:		Level 1	_	Level 2 	\$	Level 3 	\$ 

During the three months ended March 31, 2023 and the year ended December 31, 2022, there were no transfers between Level 1, Level 2 and Level 3.

# 4. Short-Term Investments

The Company's short-term investments consist of the following (in thousands):

	As of March 31, 2023					
Amortized Cost	Unrealized Gains (Losses), Net	Recorded Basis				
\$ 45,042	\$ (49)	\$ 44,993				
\$ 45,042	\$ (49)	\$ 44,993				
As of December 31, 2022 Unrealized						
Amortized Cost		<b>Recorded Basis</b>				
\$ 53,549	\$ (197)	\$ 53,352				
\$ 53,549	\$ (197)	\$ 53,352				
	Amortized Cost           \$         45,042           \$         45,042           \$         45,042	Amortized Cost     Unrealized Gains (Losses), Net       \$ 45,042     \$ (49)       \$ 45,042     \$ (49)       • As of December 31, 2     Unrealized Gains (Losses), Net				

These securities mature in less than 1 year.

# 5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	March 31,		cember 31,
	2023	2022	
Clinical prepayments	\$ 2,878	\$	2,679
Prepaid insurance	1,257		1,870
Prepaid materials and supplies	237		248
Deposits	240		232
Other	 625		522
	\$ 5,237	\$	5,551

Clinical prepayments consist of amounts paid in advance to clinical research organizations ("CROs") for expenses related to our clinical trials, primarily UB-612, and included \$1.9 million on deposit as of March 31, 2023 that will be credited against final UB-612 trial expenses. The remaining clinical prepayment amounts are amortized to expense as earned by the CRO and clinical trial sites.

Prepaid insurance consists primarily of \$1.1 million and \$1.6 million for the unamortized portion of the Company's annual D&O insurance fee as of March 31, 2023 and December 31, 2022, respectively.

Prepaid materials and supplies consist of amounts paid in advance related to the procurement and/or production of materials for use in the Company's clinical trials, primarily UB-612. Amounts heldby related parties totaled \$0.2 million at March 31, 2023 and \$0.2 million at December 31, 2022.

# 6. Property and Equipment, Net

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

	N	March 31,		cember 31,
		2023		2022
Airplane	\$	11,983	\$	11,983
Laboratory and computer equipment		3,267		3,146
Leasehold improvements		403		403
Software		426		415
Facilities, furniture and fixtures		55		37
Vehicles		87		87
Construction in progress		87		65
Total property and equipment		16,307		16,136
Less: accumulated depreciation and amortization		(4,209)		(3,624)
Property and equipment, net	\$	12,098	\$	12,512

Depreciation expense for the three months ended March 31, 2023 and 2022 was \$0.6 million and \$0.3 million, respectively.

# 7. Accrued Expenses and Other Current Liabilities

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

	 March 31,		cember 31,
	 2023		2022
Accrued external research and development	\$ 6,491	\$	6,904
Accrued bonuses	1,527		2,568
Accrued professional fees and other	1,420		1,722
Accrued interest	1		176
	\$ 9,439	\$	11,370

# 8. Other Long-Term Liabilities

Other long-term liabilities consisted of the following (in thousands):

	March 31,	December 31,
	2023	2022
Accrued taxes	236	236
5	\$ 236	\$ 236

As of March 31, 2023 and December 31, 2022, approximately \$0.2 million of accrued taxes related to penalties and interest the Company may be subject to paying for late filing fees related to a foreign subsidiary. The Company expects these amounts to be forgiven but has accrued for them until the statute of limitations expires and it is appropriate to write them off.

# 9. Notes Payable

# 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 \$0.1 million with a final payment of \$9.4 million at maturity. The 2025 Note is guaranteed by the co-founders of the Company. In addition, the Company incurred debt issuance costs of \$0.3 million, which are being amortized over the term of the loan. There are no financial covenants associated with the 2025 Note.

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

	Ν	March 31,	De	cember 31,
		2023		2022
Principal	\$	10,344	\$	10,455
Unamortized debt issuance cost		(118)		(131)
Carrying amount		10,226		10,324
Less: current portion		(394)		(391)
Note payable, net of current portion and debt issuance cost	\$	9,832	\$	9,933

As of March 31, 2023, the remaining principal payments for the 2025 Note are as follows (in thousands):

	 Amount
2023 (remaining 9 months)	\$ 333
2024	458
2025	 9,553
	\$ 10,344

Interest expense associated with the 2025 Note was \$0.1 million and \$0.1 million for the three months ended March 31, 2023 and March 31, 2022, respectively. Accrued interest of less than \$0.1 million was included in accrued expenses and other current liabilities in the accompanying condensed consolidated balance sheets as of March 31, 2023 and December 31, 2022.

# Promissory Note with Related Party

In October 2022, the Company entered into a related party unsecured promissory note (the "2022 Promissory Note") with UBI for \$4.2 million. The 2022 Promissory Note accrues interest at 7.0% per annum and is due October 1, 2026. The 2022 Promissory Note was issued to satisfy accounts payable to UBI totaling \$4.2 million. As of March 31, 2023 and December 31, 2022, the outstanding principal amount under the 2022 Promissory Note was \$3.8 million and \$4.2 million, respectively. During the three months ended March 31, 2023, the Company incurred \$0.1 million in interest expense and \$0.1 million of interest was paid related to the Promissory Note.

The carrying value of the 2022 Promissory Note is as follows (in thousands):

	Ma	March 31, 2023		ember 31,
				2022
Principal	\$	3,759	\$	4,225
Less: current portion		(898)		(1,113)
Note payable with related party, net of current portion	\$	2,862	\$	3,112

As of March 31, 2023, the remaining principal payments for the 2022 Promissory Note are as follows (in thousands):

	Amount
2023 (remaining 9 months)	\$ 647
2024	1,029
2025	1,103
2026	980
	\$ 3,759

#### 10. Common Stock

The Company has reserved shares of Class A common stock for issuance for the following purposes:

	March 31,	December 31,
	2023	2022
Options and RSUs issued and outstanding	22,914,609	20,716,760
Options available for future grants	6,902,994	6,064,003
Warrants issued and outstanding	1,928,020	1,928,020
	31,745,623	28,708,783

# 11. Stock-Based Compensation

# 2021 Omnibus Incentive Compensation Plan

In November 2021, the Company established the 2021 Omnibus Incentive Compensation Plan (the "Plan"), which provides for the Company to grant nonqualified stock options, incentive (qualified) stock options, stock appreciation rights, restricted share awards, restricted stock units, performance awards, cash incentive awards and other equity-based awards (including fully vested shares).

At inception in November 2021, the maximum number of shares of Class A common stock that could be issued under the Plan was 8,700,000 shares of Class A common stock. This number increases automatically on January 1 of each year, commencing January 1, 2023, by the number of shares equal to the lesser of (i) 4% of the outstanding shares of our Class A common stock on the immediately preceding December 31, (ii) the number of shares determined by the compensation committee of the board of directors, if any such determination is made, and (iii) the number of shares underlying any awards granted during the preceding calendar year, net of the shares underlying awards canceled or forfeited under the Plan. On January 1, 2023, in accordance with the automatic "evergreen" provision of the Plan, the maximum number of shares that can be issued under the plan was increased to 11,886,306.

## Stock Options

As of March 31, 2023, there were options to purchase 16,252,154 shares of Class A stock outstanding and options to purchase 6,362,455 shares of Class B stock outstanding, of which options to purchase 10,449,895 shares of Class A common stock and options to purchase 4,992,111 shares of Class B common stock were exercisable, respectively. As of March 31, 2023, the maximum number of stock options awards available for future issuance under the Company's plans is 6,902,994.

The following table summarizes stock option activity during the three months ended March 31, 2023:

	Number of Stock Options Outstanding	Ex	Weighted xercise Price Per Share	Weighted Contractual Term (years)	-	Aggregate ntrinsic Value in thousands)
Balance at December 31, 2022	20,416,760	\$	5.07	6.8	\$	7,166
Granted	2,622,284		2.30			
Exercised	(6,161)		(0.57)			
Forfeited	(418,274)		(5.95)			
Balance at March 31, 2023	22,614,609	\$	4.74	6.0	\$	14,368
Options vested and exercisable at March 31, 2023	15,442,006	\$	4.59	5.3	\$	

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the options and the fair value of the common stock for those options that had exercise prices lower than the fair value of the common stock as of March 31, 2023.

The intrinsic value of options exercised during the three months ended March 31, 2023 was immaterial.

The weighted-average grant-date fair value per share of options granted during the three months ended March 31, 2023 was \$ 1.90.

## **Restricted Stock Units**

The following table summarizes the Company's restricted stock unit activity for the three months ended March 31, 2023:

	Number of Shares	Av Gra Fai	eighted verage ant Date ir Value r Share
Unvested at December 31, 2022	300,000	\$	3.76
Issued			
Unvested at March 31, 2023	300,000	\$	3.76

Stock-based compensation expense recognized on restricted stock was \$0.1 million for the three months ended March 31, 2023.

## Stock-Based Compensation Expense

The Company recorded stock-based compensation expense in the following expense categories in the accompanying unaudited condensed consolidated statements of operations (in thousands):

	Three Months	Three Months Ended March 31,			
	2023	2023			
General and administrative	\$ 1,403	\$	1,371		
Research and development	822		807		
Total stock-based compensation expense	\$ 2,225	\$	2,178		

As of March 31, 2023, total unrecognized compensation cost related to the unvested stock-based awards was \$ 17.3 million, which is expected to be recognized over a weighted average period of 3.0 years.

## 12. Income Taxes

The Company computes its expected annual effective income tax rate in accordance with FAB Accounting Standards Codification ("ASC") 740, "Income Taxes" and makes changes on a quarterly basis, as necessary, based on certain factors such as changes in forecasted annual pre-tax income; changes to actual or forecasted permanent book to tax differences; impacts from tax audits with state, federal or foreign tax authorities; impacts from tax law changes; or change in judgment as to the realizability of deferred tax assets. The Company identifies items which are unusual and non-recurring in nature and treats these as discrete events. The tax effect of discrete items is recorded in the quarter in which the discrete events occur.

The Company's effective tax rate for the three months ended March 31, 2023 and March 31, 2022 was 0%, due primarily to its uncertainty of realizing a benefit from net operating losses incurred during the period.

In assessing the realizability of deferred tax assets, management considers whether it is more-likely-than-not that some or all of the recorded deferred tax assets will be realized. The ultimate realization of deferred tax assets is dependent on the generation of future taxable income in the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Based on these items and the consecutive years of pretax losses (resulting from impairment), management determined that enough uncertainty exists relative to the realization of the deferred income tax asset balances to warrant the application of a full valuation allowance for all taxing jurisdictions.

The Company files income tax returns in the U.S. federal and various state and local jurisdictions. The Company also files returns in numerous foreign jurisdictions that have varied years remaining open for examination, but generally the statute of limitations is three to four years from when the return is filed. As of March 31, 2023, the Company has no ongoing audits.

The Company has US net operating loss ("NOL") carryforwards for federal and state income tax purposes. Use of the NOL carryforwards is limited under Section 382 of the Internal Revenue Code, as the Company had a change in ownership of more than 50% of its capital stock over athree-year period as measured under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"). These complex changes of ownership rules generally focus on ownership changes involving stockholders owning directly or



indirectly 5% or more of our stock, including certain public "groups" of stockholders as set forth under Section 382 of the Code, including those arising from new stock issuances and other equity transactions. Some of these NOL carryforwards will expire if they are not used within certain periods. At this time, the Company considers it more likely than not that it will not have sufficient taxable income in the future that will allow us to realize these NOL carryforwards.

# 13. Net Loss Per Share

The Company's potentially dilutive securities, which include options and restricted stock units have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share for the three months ended March 31, 2023 and 2022 because including them would have had an anti-dilutive effect:

	March	31,
	2023	2022
Restricted stock units issued and outstanding	300,000	300,000
Options issued and outstanding	22,614,609	20,274,077
Warrants issued and outstanding	1,928,020	1,928,020
	24,842,629	22,502,097

## 14. Commitments and Contingencies

# **Contractual Obligations**

The Company enters into agreements with CROs to conduct clinical trials and preclinical studies and 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 March 31, 2023, the Company had remaining prepayments to CROs of \$2.7 million and remaining prepayments to CMOs of \$0.2 million for activities associated with the conductof its clinical trials and for the production of the Company's anticipated vaccine product candidate.

## Michael J. Fox Foundation Grant

On November 3, 2021, the Company was awarded a grant from the Michael J. Fox Foundation for Parkinson's Research ("MJFF") in the amount of \$ 0.8 million to be used in a project for the exploration of markers for target engagement in individuals immunized with UB-312, an active **a** -Synuclein ("aSyn") immunotherapy. The Company will oversee sample management, sample preparation (IgG fractions) and distribution, aswell as characterize the binding properties of the antibodies against pathological forms of aSyn. As funding is expected to be received in tranches over a two-year period, and the amounts received in each tranche are expected to be utilized within 12 months, the funds received are recognized as a short-term accrued liability. The Company recognizes payments from MJFF as a reduction of research and development expenses, in the same period as the expenses that the grant is intended to reimburse are incurred. As of March 31, 2023, there was no balance remaining in theaccrued liability related to this grant. For the three months ended March 31, 2023 and 2022, the Company did not recognize any reduction of research and development expenses for amounts reimbursed through the grant.

## Coalition for Epidemic Preparedness Innovations ("CEPI") Grant

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

The Company will also be performing further manufacturing scale-up work to enable readiness for potential commercialization. Under the terms of the agreement with CEPI, if successful, a portion of the released doses of the commercial product will be delivered to the COVID-19 Vaccines Global Access ("COVAX") consortium for distribution to developing countries at low cost.

Cash payments received in advance under the CEPI Funding Agreement are restricted as to their use until expenditures contemplated in the funding agreement are incurred. As funding is expected to be received in tranches over an 18-month period, and the amounts received in each tranche are expected to the utilized within 12 months, the funds received are reflected within restricted cash with a corresponding

short-term accrued liability. As of March 31, 2023, the Company had no remaining restricted cash or accrued liability related to CEPI funding. The Company recognizes payments from CEPI as a reduction of research and development expenses, in the same period as the expenses that the grant is intended to reimburse are incurred. For the three months ended March 31, 2023, the Company recognized a reduction of \$1.0 million of research and development expenses.

## Lease Agreements

The Company has two operating lease agreements for office and laboratory space. The Company is also required to pay certain operating costs under its leases.

In August 2022, the Company entered into a lease for 9,839 square feet of lab and office space with Space Florida in Exploration Park, Florida commencing August 12, 2022. The lease has an initial one-year term with an annual lease obligation of \$0.5 million, after lessee credits. Additionally, the lease requires the Company to provide a security deposit in the amount of less than \$0.1 million.

In April 2022, the Company entered into a facility lease agreement for 4,419 square feet of office space in New York, New York. The lease commenced in April 2022 and will expire in March 2029 with no option to renew. This lease and its terms were reviewed using the guidance found in ASC 842, "Leases". Since the lease has a non-cancellable period of one year, and after the first year both the Company and the landlord have the option to early terminate the lease for any or no reason, the Company has elected to apply the short-term expedient, which does not subject the New York lease to capitalization.

Rent expense for the three months ended March 31, 2023 and 2022 was \$0.1 million and \$0.1 million, respectively.

# License Agreements

In August 2021, the Company entered into a license agreement (the "Platform License Agreement") with UBI and certain of its affiliates that expanded intellectual property rights held under previously issued license agreements with UBI. As part of the agreement, the Company obtained a worldwide, sublicensable (subject to certain conditions), perpetual, fully paid-up, royalty-free license to research, develop, make, have made, utilize, import, export, market, distribute, offer for sale, sell, have sold, commercialize or otherwise exploit peptide-based vaccines in the field of all human prophylactic and therapeutic uses, except for such vaccines related to human immunodeficiency virus (HIV), herpes simplex virus (HSE) and Immunoglobulin E (IgE). The patents and patent applications licensed under the Platform License Agreement include claims directed to a CpG delivery system, artificial T helper cell epitopes and certain designer peptides and proteins utilized in UB-612. In consideration for the Platform License Agreement, the Company issued to UBI a warrant to purchase Class A common stock (the "UBI Warrant").

The Company considered ASC 805, "Business Combinations" ("ASC 805") and ASC 730, "Research and Development" ("ASC 730") in determining how to account for the issuance of the UBI Warrant. The UBI Warrant was issued to a related party in exchange for a license agreement. The majority of the voting interests in the related party and in the Company were held by a group of immediate family members, at the time of the transaction, and as such the transaction constitutes a common control transaction, which requires the license to be accounted for at the carrying value in the books of the transferor. As the related party did not have any basis in the assets licensed, there was no accounting impact for the Company.

## Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to employees, consultants, vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and executive officers that will require the Company to, among other things, indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnification obligations. The Company is not aware of any indemnification arrangements that could have a material effect on its financial position, results of operations, or cash flows, and it has not accrued any liabilities related to such obligations as of March 31, 2023 and December 31, 2022.

## Legal Proceedings

From time to time, the Company may become involved in legal proceedings arising in the ordinary course of business. As of March 31, 2023 and December 31, 2022, the Company was not a party to any material legal matters or claims.

## Loss Contingency

In April 2021, the Company engaged United Biopharma, Inc. ("UBP") to begin acquiring raw materials for use in the production of GMP grade recombinant protein for UB-612, the Company's COVID-19 vaccine candidate under an Authorization to Proceed ("ATP") agreement. Through August 2021, \$7.2 million of materials were ordered, \$3.0 million of materials were received by UBP and paid for with an advance payment from the Company, and the Company expensed \$1.2 million as these raw materials were used to produce proteins. During 2022, the Company recognized an additional \$1.8 million in expense related to the materials UBP had taken possession of but had not yet used in production.

When the Company asked to pause further manufacture of protein upon rejection of the Emergency Use Authorization application by Taiwan in August 2021, UBP requested that its suppliers cancel the remaining \$4.2 million in orders for which it had not taken possession of the materials. In the fourth quarter of 2022, the Company learned that most of the suppliers refused to cancel the orders, although some agreed to seek other buyers for the materials. For these orders, management has not yet concluded that a loss for the Company for this entire amount is probable, since they were not originally authorized by the ATP, and UBP's suppliers may be able to dispose of some amount to other buyers. Hence, an expense has not been recognized for them.

## 15. Benefit Plans

In March 2018, the Company established a defined contribution savings plan under Section 401(k) of the Code. This plan covers substantially all U.S. employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. The Company matches employee contributions to the Plan at 100% up to 4% of the employee's base salary.

The Company offers its Ireland-based employees a Personal Retirement Savings Account ("PRSA") that allows participants to defer a portion of their annual compensation. The Company provides contributions equal to 5% of each participant's annual salary. During three months ended March 31, 2023 and 2022, the Company contributed less than \$ 0.1 million to PRSA accounts.

#### 16. Related Party Transactions

The Company has related party arrangements with UBI and a number of its affiliated companies listed namely, United Biomedical, Inc., Asia ("UBIA"), UBI Pharma, Inc. ("UBI-P"), United BioPharma, Inc ("UBP") and UBI IP Holding ("UBI-IP").

As of March 31, 2023, UBI owned 44% of the Company's stock. The majority of the voting interests in both UBI and the Company were held by a group of immediate family members, and as such the entities are under common control.

These related parties are governed by various Master Services Agreements ("MSA") detailed below.

UBI MSA - UBI provides research, development and clinical functions to the Company. There is also a purchase arrangement with UBI for the production and shipment of the Company's diagnostic test kits.

UBIA MSA - UBI-Asia for manufacturing, quality control, testing, validation, and supply services.

UBP MSA - UBP provides the Company with manufacturing, testing and validation services.

COVID MSA ("COVID MSA") - COVID MSA provides that UBI acts as COVAXX's agent with respect to matters relating the Company's COVID-19 program and provides research, development, manufacturing and back office administrative services to the Company.

COVID-19 Relief MSA - A four-company MSA with UBI, UBI-Asia and UBP. The Company is an exclusive licensee of technologies related to diagnostics, vaccines, and therapies for COVID-19. The MSA established the terms under which UBI-Asia provides research, development, testing and manufacturing services to the Company and UBP provides contract development and manufacturing services to the Company.

Total amounts due to related parties were \$12.7 million and \$12.8 million as of March 31, 2023 and December 31, 2022, respectively. Total amounts due from related parties were \$0.5 million and \$0.4 million as of March 31, 2023 and December 31, 2022, respectively. Total expenses incurred, including interest expense, were \$1.2 million and \$0.8 million for the three months ended March 31, 2023 and 2022, respectively.

Total related party operating activity, including the activity described above, are as follows (in thousands):

	<u>March 31,</u> 2023	December 31, 2022	
Consolidated balance sheet			
Assets			
Prepaid expenses and other current assets	\$ 237	\$ 237	
Amounts due from related parties	518	414	
Liabilities			
Amounts due to related parties	12,706	12,772	
Current portion of note payable	898	1,113	
Note payable	2,862	3,112	
Accrued interest payable	_	73	
	Three Months Ended March 31		
	2023	2022	

Operating expenses		
Research and development		
Services provided by related parties	\$ 381	\$ 784
General and administrative		
Services provided by related parties	\$ 754	\$ _
Other income/expense		
Related party interest expense	\$ 69	\$ 

# 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 unaudited condensed consolidated financial statements and related notes and other financial information appearing elsewhere in this Quarterly Report on Form 10-Q. We intend for this discussion to provide you with information that will assist you in understanding our unaudited condensed consolidated financial statements, the changes in key items in those unaudited condensed 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 Quarterly Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks, uncertainties and assumptions. See the section of this Quarterly Report titled "Special Note Regarding Forward-Looking Statements" for a discussion of forward-looking statements. As a result of many factors, including those factors set forth under "Risk Factors" in Item 1A of Part I of our Annual Report on Form 10-K for the year ended December 31, 2022, in Item 1A of Part II of this Quarterly Report on Form 10-Q, or in other filings that we make with the SEC, 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. Investors and others should note that we routinely use the Investors section of our website to announce material information to investors and the marketplace. While not all of the information that we post on the Investors section of our website is of a material nature, some information could be deemed to be material. Accordingly, we encourage investors, the media, and others interested in us to review the information that we share on the Investors section of our website, https://vaxxinity.com/.

## Overview

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

Our current pipeline consists of six programs from early to late-stage development, including five programs focused on chronic disease: UB-311, our leading neurology product candidate, which targets Alzheimer's disease ("AD"); UB-312, which targets Parkinson's disease ("PD") and other synucleinopathies; VXX-301, an anti-tau product candidate which has the potential to address multiple neurodegenerative conditions, including AD; UB-313, which targets Calcitonin Gene-Related Peptide ("CGRP") to prevent migraines; and VXX-401, which targets proprotein convertase subtilisin/kexin type 9 serine protease ("PCSK9") to reduce reduce low-density lipoprotein ("LDL") cholesterol, a risk factor for atherosclerotic heart disease. Through our Vaxxine Platform, we believe we may be able to address a wide range of other chronic diseases, including diseases that are or could potentially be successfully treated by mAbs, which increasingly dominate the treatment paradigm but remain accessible only to a small proportion of patients who could potentially benefit from them.

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

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 March 31, 2023, we received gross proceeds of \$306.4 million in connection with various financing transactions, including the sale of preferred and common stock, the issuance of promissory notes (including convertible promissory notes ("Convertible Notes")), and the entry into simple agreements for future equity ("SAFEs").

Costs associated with research and development are the most significant component of our expenses. These costs can vary greatly from period to period depending on the timing of various trials for our product candidates. We expect our allocated research and development costs and general and administrative expenses could increase over time if we expand the number of product candidates that we are advancing, advance any of the current pipeline candidates to later stage clinical trials which typically have more subjects and higher

costs, or incur increased costs as a result of operating as a public company. Further, we anticipate incurring greater selling and marketing expenses if we commercialize any of our product candidates in the future and prepare for such commercialization. Our product candidates are in clinical stage or pre-clinical stage development. We have generated limited revenue to date and have incurred significant operating losses since inception. Net losses were \$18.4 million and \$18.3 million for the three months ended March 31, 2023 and 2022, respectively. As of March 31, 2023, we had an accumulated deficit of \$323.1 million. We expect our expenses and capital requirements may increase over time in connection with our planned operations, which include:

- continuing pre-clinical studies, existing clinical trials, or initiating new clinical trials for product candidates UB-312, UB-313, VXX-401, UB-612, and other product candidates;
- hiring additional clinical, quality control, medical, scientific and other technical personnel to support additional clinical and research and development programs;
- expanding operational, financial and management systems and infrastructure, expanding our facilities and increasing personnel to support operations;
- · undertaking actions to meet the requirements and demands of being a public company;
- · maintaining, expanding and protecting our intellectual property portfolio;
- · seeking regulatory approvals for any product candidates that successfully complete clinical trials; and
- undertaking pre-commercialization and commercialization activities to establish sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we elect to commercialize products on our own or jointly with third parties.

As of the date of this report, we expect our existing cash and cash equivalents and our short-term investments will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 12 months and into mid-2024. Thereafter, our viability will depend on our ability to raise additional capital to finance operations, to successfully commercialize our product candidates, if approved, or to enter into collaborations with third parties for the development of our product candidates. If we are unable to do any of the foregoing, we would be forced to delay, limit, reduce or terminate our product candidate development or future commercialization efforts. Our estimates are based on a variety of assumptions that may prove to be wrong, and we could exhaust our available capital resources."

# **Business Update Regarding COVID-19 Pandemic**

In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. The onset of the pandemic led to our institutional prioritization of COVID-19 vaccine development efforts, which correlated with a relative decline in research and development expenditures for our chronic disease product candidates. To date, our operations have not been negatively impacted by the COVID-19 pandemic in a material manner. While the pandemic hassubsided around the world since 2020, we cannot predict the specific extent, duration or full impact that future outbreaks associated with new variants of the COVID-19 virus may have on our financial condition and operations. Potential impacts could include delays of the development of clinical supply materials, and enrollment of patients in our studies may be delayed or suspended, as hospitals and clinics in areas where we are conducting trials may need to shift resources to cope with COVID-19 and may limit access or close clinical facilities. Additionally, if our trial participants are unable to travel to our clinical study sites as a result of quarantines or other restrictions resulting from COVID-19 outbreaks, we may experience higher drop-out rates or delays in our clinical studies. The impact of the COVID-19 pandemic on our financial performance will depend on future outbreaks 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 coronavirus pandemic has caused interruptions or delays of our business" in our Annual Report on Form 10-K for the year ended December 31, 2022.

# **Components of Our Unaudited Condensed Consolidated Results of Operations**

## Revenue

We recorded no revenue for the three months ended March 31, 2023 and 2022. We do not expect to generate any meaningful revenue unless and until we obtain regulatory approval of and commercialize or out-license at least one of 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. We have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

#### Cost of Revenue

We recorded no cost of revenue for the three months ended March 31, 2023 and 2022. 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 the cost of revenue will increase in absolute dollars as and if our revenue grows and will vary from period to period as a percentage of revenue.

#### **Research and Development Expenses**

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

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

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

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

We continue to work with related parties for the advancement of our research and development programs, including for manufacturing, quality control, testing, validation, and supply services. While this related party work has significantly diminished over the last year, and we expect this trend to continue, we are still reliant on UBIA to provide certain manufacturing-related and prior-conducted clinical data that will be needed for inclusion in our regulatory applications for UB-612. During the three months ended March 31, 2023 and 2022, related party expenses were approximately 3.3% and 6.8% of our research and development expenses, respectively.

Where appropriate, we allocate our third-party research and development expenses on a program-by-program basis. These expenses primarily relate to outside consultants, CROs, contract manufacturers and research laboratories in connection with pre-clinical development, process development, manufacturing and clinical development activities. We do not allocate our internal costs, such as employee costs, costs associated with our discovery efforts, laboratory supplies and facilities, including depreciation or other indirect costs, to specific programs because these costs often relate to platform development, to multiple programs simultaneously or to discovery



of new programs, and any such allocation would necessarily involve significant estimates and judgments and, accordingly, would be imprecise. When we refer to the research and development expenses associated with a specific program, these refer exclusively to the allocated third-party expenses associated with that product candidate. All other research and development costs are referred to as unallocated costs.

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

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

#### General and Administrative Expenses

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

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

# Other Expense (Income)

# Interest Expense

Interest expense consists of interest incurred on (i) the note entered into during June 2020 for the acquisition of an airplane (the "2025 Note") and (ii) the related party promissory note (the "2022 Promissory Note") entered into during 2022.

#### Interest Income

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

# (Gain) Loss on Foreign Currency Translation, Net

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

## Provision for Income Taxes

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

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

Deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax basis of existing assets and liabilities and for loss and credit carryforwards, which are measured using the enacted tax rates and laws in effect in the years in which the differences are expected to reverse. The realization of our deferred tax assets is dependent upon the generation of future taxable income, the amount and timing of which are uncertain. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. As of March 31, 2023, we continue to maintain a full valuation allowance against all of our deferred tax assets based on evaluation of all available evidence.

file income tax returns in the U.S. federal and state jurisdictions and may become subject to income tax audit and adjustments by related tax authorities. Our tax return periods (for entities then in existence) for U.S. federal income taxes for the tax years since 2017 remain open to examination under the statute of limitations by the Internal Revenue Service and state jurisdictions. We record reserves for potential tax payments to various tax authorities related to uncertain tax positions, if any. The nature of uncertain tax positions is subject to significant judgment by management and subject to change, which may be substantial. These reserves are based on a determination of whether and how much a tax benefit taken by us in our tax filings or positions is more likely than not to be realized following the resolution of any potential contingencies related to the tax benefit. We develop our assessment of uncertain tax positions, and the associated cumulative probabilities, using internal expertise and assistance from third-party experts. As additional information becomes available, estimates are revised and refined. Differences between estimates and final settlement may occur resulting in additional tax expense. Potential interest and penalties associated with such uncertain tax positions are recorded as a component of our provision for income taxes.

## **Condensed Consolidated Results of Operations**

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

Three Months Ended March 31,				
(In thousands)	2023	2022	Change \$	Change %
Operating expenses:				
Research and development	11,424	11,478	(54)	(0)%
General and administrative	7,384	6,686	698	10 %
Total operating expenses	18,808	18,164	644	4 %
Loss from operations	(18,808)	(18,164)	(644)	4 %
Other (income) expense:				
Interest expense	192	105	87	83 %
Interest income	(567)	(5)	(562)	11,240 %
(Gain) loss on foreign currency translation, net	(12)	(1)	(11)	1,081 %
Total other (income) expense, net	(387)	99	(486)	(491)%
Net loss	\$ (18,421)	\$ (18,263)	\$ (158)	\$ 1%

## Comparison of the Three Months Ended March 31, 2023 and 2022

## **Research and Development Expenses**

Research and development expenses were \$11.4 million and \$11.5 million for the three months ended March 31, 2023 and 2022, respectively.

The \$0.1 million decrease was comprised of a \$0.1 million increase in allocated costs (i.e., costs that can be directly attributed to a specific clinical program) and a \$0.2 million decrease in unallocated costs. The increase in allocated cost was due to increases in costs for our VXX-401 hypercholesteremia program, platform development and activities supporting multiple programs totaling \$1.2 million, partially offset by decreases in costs related to our UB-612 COVID-19 vaccine program, UB-312 PD program and UB-313 CGRP program totaling \$1.1 million. The \$0.2 million decrease in unallocated costs was driven by a decrease in salaries and personnel costs, and consulting and external contractor services supporting research and development activities across the pipeline, partially offset by an increase in travel expenses.

#### General and Administrative Expenses

General and administrative expenses were \$7.4 million and \$6.7 million for the three months ended March 31, 2023 and 2022, respectively.

The \$0.7 million increase was primarily due to increases in professional and consulting services, travel expenses, salaries and personnel costs, and depreciation related to assets placed in service primarily at our Florida lab, partially offset by a decrease in director and officer insurance expense of \$0.4 million.

# Interest Expense

Interest expense was \$0.2 million and \$0.1 million for the three months ended March 31, 2023 and 2022, respectively.



#### Interest Income

Interest income on cash and short-term investments was \$0.6 million and less than \$0.1 million for the three months ended March 31, 2023 and 2022, respectively.

# (Gain) Loss on Foreign Currency Translation, Net

The net (gain) loss on foreign currency translation reflects de minimis fluctuations in the foreign exchange rate.

# Liquidity and Capital Resources

## Sources of Liquidity

We have not yet obtained regulatory approval for or commercialized any of our product candidates, which are in various phases of preclinical and clinical development. We have financed operations primarily through the issuance of common stock, convertible preferred stock, borrowings under promissory notes (including the Convertible Notes) and the execution of SAFEs. Through March 31, 2023, we received gross proceeds of \$306.4 million in connection with various financing transactions, including the sale of preferred and common stock, the issuance of promissory notes (including Convertible Notes), and the execution of SAFEs. As of March 31, 2023, we had \$67.7 million of cash, cash equivalents and short-term securities to fund operations, including \$22.6 million of cash and cash equivalents, \$45.0 million of short-term investments, and a \$0.1 million restricted cash balance, compared to \$87.9 million as of December 31, 2022. The decrease in cash, cash equivalents and short-term securities 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 three months ended March 31, 2023 and 2022 (in thousands):

	March 31, 2023		December 31, 2022	
Balance Sheet Data:				
Cash and cash equivalents	\$	22,585	\$	33,475
Short-term investments, net		44,993		53,352
Restricted cash		100		1,095
Total assets		85,531		106,399
Total liabilities		39,398		44,222
Total stockholders' equity	\$	46,133	\$	62,177

	Tł	Three Months Ended March 31,	
		2023	2022
Statement of Cash Flow Data:			
Net cash (used in) provided by operating activities	\$	(20,051) \$	(19,514)
Net cash (used in) provided by investing activities		8,740	(713)
Net cash (used in) provided by financing activities		(574)	14
Net (decrease) in cash, cash equivalents and restricted cash	\$	(11,885) \$	(20,213)

#### **Operating** Activities

Net cash used in operating activities for the three months ended March 31, 2023 was \$20.1 million, primarily resulting from an \$18.4 million net loss, an unfavorable \$4.0 million change in operating assets and liabilities and total non-cash items of \$2.4 million. The changes in net operating assets and liabilities were primarily due to a decrease of \$0.1 million in amounts due to related party, a \$1.9 million decrease in accrued expenses and other current liabilities, and a \$0.3 million decrease in prepaid expenses. The non-cash adjustments to net loss primarily consisted of \$2.2 million of stock-based compensation and \$0.6 million in depreciation.

Net cash used in operating activities for the three months ended March 31, 2022 was \$19.5 million, primarily resulting from a \$18.3 million net loss, an unfavorable \$3.8 million change in operating assets and liabilities and total non-cash items of \$2.5 million. The changes in net operating assets and liabilities were primarily due to a decrease of \$2.6 million in amounts due to related party, a \$1.3 million increase in accounts payable and other liabilities, a \$0.7 million decrease in prepaid expenses, and a \$1.4 million decrease in long-term deposits. The primary non-cash adjustments to net loss consisted of \$2.2 million of stock-based compensation and \$0.3 million in depreciation.

#### **Investing** Activities

Net cash provided by investing activities totaled \$8.7 million for the three months ended March 31, 2023. The cash provided by investing activities consisted primarily of the acquisition and redemption of short-term investments, and the acquisition of laboratory and computer equipment.

Net cash used in investing activities totaled \$0.7 million for the three months ended March 31, 2022. The cash used in investing activities consisted primarily of the acquisition of equipment.

## **Financing** Activities

Net cash used by financing activities was less than \$0.6 million for the three months ended March 31, 2023.

Net cash used by financing activities was less than \$0.1 million for the three months ended March 31, 2022.

## Funding Requirements

We have incurred net losses in each reporting period since inception. We do not expect to generate any revenue unless and until we obtain regulatory approval of and commercialize our product candidates, or enter into collaboration or licensing arrangements with one or more third-party strategic partners. We do not know when, or if, this will occur. We will continue to incur significant losses for the foreseeable future even if we ultimately receive regulatory approval for one or more of our product candidates and commercialize any approved products, 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.

As of the date of this Quarterly Report, we expect our existing cash, cash equivalents and short-term investments will be sufficient to fund our operating expenses for at least the next 12 months and into mid-2024. As of March 31, 2023, other than our 2025 Note and the 2022 Promissory Note, we have no material debt obligations.

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

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

- the current and potential impacts of the Russia-Ukraine conflict, the COVID-19 pandemic, inflation and rising interest rates on our business;
- the costs of acquiring, licensing or investing in businesses, product candidates and technologies;
- · market acceptance of our product candidates, to the extent any are approved for commercial sale; and
- · the effect of competing technological and market developments.

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

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

## **Contract Research and Manufacturing Organizations**

We recorded accrued expenses of \$4.8 million in our balance sheet for expenditures incurred by CROs and contract manufacturers as of March 31, 2023 and \$4.3 million as of December 31, 2022.

## Tax-Related Obligations

We have reserved \$0.7 million of unrecognized tax benefits against NOLs. Additionally, as of March 31, 2023, we accrued \$0.2 million in interest and penalties related to prior year tax filings.

## **Off-Balance Sheet Arrangements**

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

## **Critical Accounting Policies and Estimates**

The preparation of financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the amounts reported in our unaudited condensed 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, or take other corrective actions, either of which may also have a material effect on our unaudited condensed consolidated financial statements. Significant estimates contained within these unaudited condensed consolidated financial statements. Significant estimates for unaudited condensed consolidated financial statements, include, but are not limited to, the estimated fair value of our common stock, stock-based compensation, 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 infacts and circumstances. If market and affected.

While our significant accounting policies are described in detail in our annual consolidated financial statements for the year ended December 31, 2022 included in our Annual Report on Form 10-K for the year ended December 31, 2022, we believe that the following critical accounting policies and estimates have a higher degree of inherent uncertainty and require our most significant judgments.

## Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate accrued research and development expenses. As we advance our programs, we anticipate more complex clinical studies resulting in greater research and development



expenses, which will place even greater emphasis on the accrual. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. In the past years, UBI and its affiliated companies performed and administered a significant amount of research and development work on our behalf. Having UBI and its affiliated company act as intermediaries added to the complexity of determining appropriate accruals, and we have largely moved away from this model. Certain accruals and amounts owed to the UBI entities are still under review, and these amounts may change as a result of this review.

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

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

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

# Stock-Based Compensation

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

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

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

## Coalition for Epidemic Preparedness ("CEPI") Grant

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



We will also be performing further manufacturing scale-up work to enable readiness for potential commercialization. Under the terms of the agreement with CEPI, if successful, a portion of the released doses of the commercial product will be allocated for delivery to the COVID-19 Vaccines Global Access ("COVAX") consortium for distribution to developing countries at low cost.

Cash payments received in advance under the CEPI Funding Agreement are restricted as to their use until expenditures contemplated in the funding agreement are incurred. As funds are received, they are included within restricted cash offset by a corresponding short-term accrued liability. We recognize payments from CEPI as a reduction of research and development expenses, in the same period as the expenses that the grant is intended to reimburse are incurred.

## Item 3. <u>Ouantitative and Oualitative Disclosures About Market Risk.</u>

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 nothave 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 March 31, 2023, 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 March 31, 2023 and December 31, 2022, our cash equivalents consisted of interest-bearing checking accounts and money market accounts. The 2025 Note we entered into for the year ended December 31, 2020 bears a fixed annual interest rate of 3.4% and matures in June 2025. Additionally, the 2022 Promissory Note we entered into for the year ended December 31, 2022 bears a fixed annual interest rate of 7.0% and matures in October 2026. Given that the 2025 Note and the 2022 Promissory Note bear fixed rates of interest, we believe there is no material exposure to interest rate risk. The results of the analysis based on our financial position as of March 31, 2023, 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, we cannot precisely estimate the impact of changes in interest rates on net interest revenues. Actual results may differ from simulated results due to changes in the amount of ourcash equivalents and the timing, magnitude, and frequency of interestrate changes, as well as changes in market conditions and management strategies, including changes in asset and liability mix.

# Item 4. Controls and Procedures.

## **Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our principal executive officer and principal financial officer, evaluated, as of 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). In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs. Based on management's evaluation, our principal executive officer and principal financial officer concluded that, as of March 31, 2023, our disclosure controls and procedures were effective at the reasonable assurance level.

#### **Changes in Internal Control over Financial Reporting**

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 March 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## Inherent Limitations on Effectiveness of Controls

Our management, including the principal executive officer and principal financial officer, does not expect that our disclosure controls or our internal control over financial reporting will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to



their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of the effectiveness of controls to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

# PART II – OTHER INFORMATION

# Item 1A. <u>Risk Factors.</u>

There have been no material changes to the risk factors described in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission on March 27, 2023.

# Item 6. <u>Exhibits</u>.

The following exhibits required by Item 601 of Regulation S-K are filed herewith or have been filed previously with the SEC as indicated below:

Exhibit	
No.	Index to Exhibits
3.1	Amended and Restated Certificate of Incorporation of Vaxxinity, Inc. (incorporated by reference to Exhibit 3.1 of our Current Report on Form 8-K (File No. 001-41058) filed on November 17, 2021).
3.2	Amended and Restated Bylaws of Vaxxinity, Inc. (incorporated by reference to Exhibit 3.2 of our Current Report on Form 8-K (File No. 001-41058) filed on November 17, 2021).
4.1	Warrant to Purchase Shares of Class A Common Stock of Vaxxinity, Inc. (incorporated by reference to Exhibit 4.1 of our Registration Statement on Form S-1/A (File No. 333-260163) filed on November 5, 2021).
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*
32.1	Certifications of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes- Oxley Act of 2002**
101.INS	Inline XBRL Instance Document*
101.SCH	Inline XBRL Taxonomy Extension Schema Document*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document*
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL document).*
* File	d herewith.
** Fur	nished herewith.

# 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 on May 9, 2023.

VAXXINITY, INC.

By:

/s/ Mei Mei Hu Mei Mei Hu,

President and Chief Executive Officer (Principal executive officer)

By:

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/s/ Jason Pesile Jason Pesile Senior Vice President, Finance & Accounting (Principal financial officer and principal accounting officer)

# CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mei Mei Hu, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Vaxxinity, Inc.;

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: May 9, 2023

<u>/s/ Mei Mei Hu</u> Mei Mei Hu President and Chief Executive Officer (Principal Executive Officer)

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By:

# CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jason Pesile, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Vaxxinity, Inc.;

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

By:

(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.

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Date: May 9, 2023

/s/ Jason Pesile Jason Pesile Senior Vice President, Finance and Accounting (Principal Financial and Accounting Officer)

# CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL 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 Annual Report of Vaxxinity, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby 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 their knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; 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: May 9, 2023

By: <u>/s/ Mei Mei Hu</u> Mei Mei Hu President and Chief Executive Officer (Principal Executive Officer)

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Date: May 9, 2023

By: <u>/s/ Jason Pesile</u> Jason Pesile Senior Vice President, Finance and Accounting (Principal Financial and Accounting Officer)