UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

☒

For the quarterly period ended September 30, 2024

OR

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

☐

For the transition period from _____ to _____

Commission File Number: 001-40928

Ventyx Biosciences, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**83-2996852**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
12790 El Camino Real , Suite 200	
San Diego , CA	**92130**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (760) 593-4832

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

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

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

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

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

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

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

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

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

As of November 4, 2024, the registrant had

70,710,667
shares of common stock, $0.0001 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or Quarterly Report, contains forward-looking statements that are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than statements of historical facts included in this Quarterly Report are forward-looking statements. In some cases, you can identify forward-looking statements by the following words: "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "ongoing," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words.

These forward-looking statements involve risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. Forward-looking statements in this Quarterly Report include, but are not limited to, statements about:

- our expectations regarding our product candidates and their related benefits;
- our beliefs regarding the perceived benefits and limitations of competing products, and the future of competing products and our industry;
- details regarding our strategic vision and product candidate pipeline;
- our beliefs regarding the success, cost and timing of our development activities and current and future clinical trials, including study design;
- the anticipated timing of releasing data for any current or future clinical trials;
- the anticipated timing of commencement, enrollment, and completion of any current or future clinical trials for our product candidates;
- the timing or likelihood of regulatory filings or other actions and related regulatory authority responses;
- disruptions in the supply chain, including raw materials needed for manufacturing, animals used in research, delays in site activations and enrollment of clinical trials;
- any impact of the military conflicts in Ukraine or the Middle East or the imposition of sanctions against certain countries as a result thereof;
- the ability and willingness of third parties to engage in research and development activities on our behalf involving our product candidates, and our ability to leverage those activities;
- our expectations regarding the ease of administration associated with our product candidates;
- our expectations regarding the patient compatibility associated with our product candidates;
- our beliefs regarding the potential markets for our product candidates and our ability to serve those markets;
- the ability to obtain and maintain regulatory approval of any of our product candidates, and any related restrictions, limitations and/or warnings in the label of any approved product candidate;
- our ability to commercialize any approved products;
- the rate and degree of market acceptance of approved products, if any;
- our ability to attract and retain key personnel;
- the accuracy of our estimates regarding our cash position, future revenue, operating expenses, capital requirements and needs for additional financing;

- our ability to obtain funding for our operations, including funding necessary to complete further development and any commercialization of our product candidates;

- our ability to obtain, maintain, protect and enforce intellectual property protection for our product candidates and not infringe, misappropriate or otherwise violate the intellectual property of others; and

- regulatory developments in the United States and foreign countries.

You should refer to Part II, Item 1A (Risk Factors) of this Quarterly Report for a discussion of other important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Quarterly Report will prove to be accurate.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Ventyx Biosciences, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share amounts and par value data)
(unaudited)

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 61,765	$ 51,579
Marketable securities	213,060	200,641
Prepaid expenses and other assets	14,583	12,125
Total current assets	289,408	264,345
Property and equipment, net	703	762
Operating lease right-of-use assets	9,918	11,509
Restricted cash	975	975
Other long-term assets	96	102
Total assets	$ 301,100	$ 277,693
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,286	$ 5,756
Accrued expenses	9,006	15,508
Current portion of operating lease liabilities	1,011	1,001
Total current liabilities	12,303	22,265
Operating lease liabilities, net of current portion	10,025	11,505
Total liabilities	22,328	33,770
Commitments and contingencies (Note 5)		
Stockholders' equity:		

Series A non-voting convertible preferred stock, $ 0.0001 par value; 100,000,000 shares authorized at September 30, 2024 and December 31, 2023; 70,601 and 0 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	—	—
Common stock, $ 0.0001 par value; 900,000,000 shares authorized at September 30, 2024 and December 31, 2023; 70,669,131 shares issued and outstanding at September 30, 2024; 59,252,349 and 59,239,113 shares issued and outstanding, respectively, at December 31, 2023	7	6
Additional paid-in capital	802,850	663,154
Accumulated other comprehensive loss	873	(50)
Accumulated deficit	(524,958)	(419,187)
Total stockholders' equity	278,772	243,923
Total liabilities and stockholders' equity	$ 301,100	$ 277,693

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

Ventyx Biosciences, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development (includes related party amounts of $ 249 , $ 417 , $ 752 and $ 776 , respectively)	$ 30,629	$ 49,750	$ 92,181	$ 133,747
General and administrative	7,923	8,201	23,851	23,901
Total operating expenses	38,552	57,951	116,032	157,648
Loss from operations	(38,552)	(57,951)	(116,032)	(157,648)
Other (income) expense:				
Interest income	(3,350)	(3,932)	(10,360)	(11,453)
Other expense	47	8	99	14
Total other (income) expense	(3,303)	(3,924)	(10,261)	(11,439)
Net loss	($ 35,249)	($ 54,027)	($ 105,771)	($ 146,209)
Unrealized gain on marketable securities	922	192	741	544
Foreign currency translation	199	11	182	72
Comprehensive loss	($ 34,128)	($ 53,824)	($ 104,848)	($ 145,593)
Net loss per share, basic and diluted	($ 0.50)	($ 0.92)	($ 1.56)	($ 2.51)

Weighted average common shares outstanding, basic and diluted	70,667,570	58,880,427	67,694,970	58,363,174

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

Ventyx Biosciences, Inc.
Condensed Consolidated Statements of Stockholders' Equity
For the Three Months Ended September 30, 2024 and 2023
(in thousands, except share amounts)
(unaudited)

	Series A Non-Voting Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at June 30, 2024	—	$ —	70,662,806	$ 7	$ 770,745	$ (248)	$ (489,709)	$ 280,795
Issuance of Series A non-voting convertible preferred stock from private placement, net of issuance costs	70,601	—	—	—	26,642	—	—	26,642
Issuance of common stock upon exercise of stock options	—	—	5,575	—	12	—	—	12
Issuance of common stock upon vesting of restricted common stock	—	—	750	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	5,451	—	—	5,451
Unrealized gain on marketable securities	—	—	—	—	—	922	—	922
Foreign currency translation	—	—	—	—	—	199	—	199
Net loss	—	—	—	—	—	—	(35,249)	(35,249)
Balance at September 30, 2024	70,601	$ —	70,669,131	$ 7	$ 802,850	$ 873	$ (524,958)	$ 278,772

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at June 30, 2023	58,713,982	$ 6	$ 646,918	$ (710)	$ (318,407)	$ 327,807
Issuance of common stock upon exercise of stock options	249,257	—	1,649	—	—	1,649
Issuance of common stock upon vesting of restricted common stock	8,692	—	—	—	—	—

Stock-based compensation expense	—	—	8,008	—	—	8,008
Unrealized gain on marketable securities	—	—	—	192	—	192
Foreign currency translation	—	—	—	11	—	11
Net loss	—	—	—	—	(54,027)	(54,027)
Balance at September 30, 2023	58,971,931	$ 6	$ 656,575	$ (507)	$ (372,434)	$ 283,640

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

Ventyx Biosciences, Inc.
Condensed Consolidated Statements of Stockholders' Equity
For the Nine Months Ended September 30, 2024 and 2023
(in thousands, except share amounts)
(unaudited)

	Series A Non-Voting Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2023	—	$ —	59,239,113	$ 6	$ 663,154	$ (50)	$ (419,187)	$ 243,923
Issuance of Series A non-voting convertible preferred stock from private placement, net of issuance costs	70,601	—	—	—	26,642	—	—	26,642
Issuance of common stock from private placement, net of issuance costs	—	—	11,174,000	1	95,045	—	—	95,046
Issuance of common stock upon exercise of stock options	—	—	133,571	—	130	—	—	130
Issuance of common stock upon vesting of restricted common stock	—	—	65,544	—	—	—	—	—
Shares issued under employee stock purchase plan	—	—	56,903	—	114	—	—	114
Stock-based compensation expense	—	—	—	—	17,765	—	—	17,765
Unrealized gain on marketable securities	—	—	—	—	—	741	—	741
Foreign currency translation	—	—	—	—	—	182	—	182
Net loss	—	—	—	—	—	—	(105,771)	(105,771)
Balance at September 30, 2024	70,601	$ —	70,669,131	$ 7	$ 802,850	$ 873	$ (524,958)	$ 278,772

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				

Balance at December 31, 2022	56,980,845	$ 6	$ 581,237	$ (1,123)	$ (226,225)	$ 353,895
Issuance of common stock from at-the-market offering, net of commissions and offering expenses	1,176,470	—	48,408	—	—	48,408
Issuance of common stock upon exercise of stock options	770,934	—	4,273	—	—	4,273
Issuance of common stock upon vesting of restricted common stock	33,917	—	—	—	—	—
Shares issued under employee stock purchase plan	9,765	—	214	—	—	214
Stock-based compensation expense	—	—	22,443	—	—	22,443
Unrealized gain on marketable securities	—	—	—	544	—	544
Foreign currency translation	—	—	—	72	—	72
Net loss	—	—	—	—	(146,209)	(146,209)
Balance at September 30, 2023	58,971,931	$ 6	$ 656,575	$ (507)	$ (372,434)	$ 283,640

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

Ventyx Biosciences, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	Nine months ended September 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (105,771)	$ (146,209)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	201	98
Loss on disposal of fixed assets	100	—
Gain on lease termination	(88)	—
Loss on impairment	—	285
Amortization of operating lease right-of-use assets	832	440
Stock-based compensation	17,765	22,443
Accretion of marketable securities, net	(7,404)	(6,989)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(2,474)	5,679
Operating lease liabilities	(607)	(234)
Accounts payable	(3,468)	2,839
Accrued expenses	(6,710)	6,781
Net cash used in operating activities	(107,624)	(114,867)
Cash flows from investing activities:		
Purchases of marketable securities, available-for-sale	(208,413)	(243,607)
Proceeds from maturities of marketable securities, available-for-sale	204,140	298,725
Purchases of property and equipment	(235)	(303)

Net cash (used in) provided by investing activities	(4,508)	54,815
Cash flows from financing activities:		
Proceeds from issuance of common stock from private placement, net of offering costs	95,046	—
Proceeds from issuance of Series A non-voting convertible preferred stock from private placement, net of offering costs	26,850	—
Proceeds from issuance of common stock from at-the-market offering, net of commissions and offering expenses	—	48,408
Proceeds from exercise of stock options	130	4,273
Proceeds from issuance of common stock under employee stock purchase plan	114	214
Deferred offering costs	—	(151)
Net cash provided by financing activities	122,140	52,744
Effect of exchange rates on cash, cash equivalents and restricted cash	178	74
Net increase (decrease) in cash, cash equivalents and restricted cash	10,186	(7,234)
Cash, cash equivalents and restricted cash, beginning of period	52,554	64,819
Cash, cash equivalents and restricted cash, end of period	$ 62,740	$ 57,585
Supplemental disclosure for investing and financing non-cash activities:		
Purchases of property and equipment included in accounts payable and accrued expenses	$ —	$ 103
Unpaid deferred offering costs	$ —	$ 59
Unpaid costs associated with the issuance of Series A non-voting convertible preferred stock from private placement	$ 208	$ —

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

Ventyx Biosciences, Inc.
Notes to Unaudited Condensed Consolidated Financial Statements

1. Organization and Business

Organization

Ventyx Biosciences, Inc. ("Ventyx" or "the Company") is a clinical-stage biopharmaceutical company developing a pipeline of novel small molecule product candidates to address a range of inflammatory diseases with significant unmet medical need. The Company was incorporated in the State of Delaware in November 2018, with its principal operations in California. The Company leverages its drug discovery and development expertise to develop novel and differentiated therapeutics that target both the innate and adaptive immune system.

March 2024 Private Placement

On March 11, 2024, the Company issued and sold

11,174,000
shares of common stock through a private placement. The common stock had a purchase price of $

8.95
per share for aggregate gross proceeds of approximately $

100.0
million. The Company received approximately $

95.0
million in net proceeds after deducting fees to the placement agents and offering expenses payable by the Company.

September 2024 Issuance of Series A Non-Voting Convertible Preferred Stock from Private Placement

On September 23, 2024, the Company entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") with Aventis Inc., a wholly-owned subsidiary of Sanofi, a global healthcare and pharmaceutical company (together with Aventis Inc., "Sanofi"), pursuant to which the Company issued an aggregate of

70,601
shares of Series A non-voting convertible preferred stock, par value $

0.0001
per share (the "Series A Preferred Stock"), each convertible into

100
shares of common stock, at an as-converted price of $

3.8243
per common share, for gross proceeds of approximately $

27.0
million, in a private placement (the "Series A Private Placement").

In connection with the Securities Purchase Agreement, the Company granted Sanofi a right of first negotiation ("ROFN") for a license, grant or transfer, including by option or sale, or any rights to research, develop, commercialize, or otherwise exploit VTX3232, the Company's CNS-penetrant NLRP3 inhibitor. The Company evaluated the ROFN for performance obligations under Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers* ("ASC 606") concluding that there were none. As a result, the Company recognized the Series A Preferred Stock as permanent equity within the condensed consolidated financial statements as of September 30, 2024. The Company received approximately $

26.6
million in net proceeds after deducting issuance costs payable by the Company.

2. Summary of Significant Accounting Policies

Basis of Presentation

The presentation of the Company's condensed consolidated financial statements as of and for the three and nine months ended September 30, 2024 and 2023 reflect the financial results of Ventyx Biosciences, Inc. on a consolidated basis. All intercompany transactions and balances have been eliminated in consolidation.

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP") and with the rules and regulations of the U.S. Securities and Exchange Commission ("SEC") regarding interim financial information. The condensed consolidated balance sheet data as of December 31, 2023 were derived from the Company's audited financial statements. Certain information and disclosures normally included in consolidated financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. Accordingly, these condensed consolidated financial statements and notes thereto should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2023 and the notes thereto included in the Company's annual report on Form 10-K filed with the SEC on February 27, 2024.

The Company's significant accounting policies are detailed in "Note 2: Summary of Significant Accounting Policies" of the Company's Annual Report on Form 10-K for the year ended December 31, 2023. There have been no changes to the Company's significant accounting policies from those disclosed in the annual report.

The unaudited financial information for the interim periods presented herein reflects all adjustments which, in the opinion of management, are necessary for a fair presentation of the financial condition and results of operation for the periods presented, with such adjustments consisting only of normal recurring adjustments. The results for the three and nine months ended September 30, 2024 are not necessarily indicative of the results expected for the full year ending December 31, 2024 or any future period.

Cash, Cash Equivalents and Restricted Cash

A reconciliation of the cash, cash equivalents and restricted cash reported in our condensed consolidated balance that sum to the total of the amounts shown in the condensed consolidated statements of cash flows is as follows (in thousands):

	Nine months ended September 30,	
	2024	**2023**
Cash and cash equivalents	$ 61,765	$ 56,610
Restricted cash	975	975
Total cash, cash equivalents and restricted cash	$ 62,740	$ 57,585

Net Loss Per Share

Basic net loss per share is computed using the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed using the sum of the weighted average number of common shares outstanding during the period, plus the weighted average number of potential shares of common stock from the assumed conversion of the Series A Preferred Stock, exercise of stock options, the assumed vesting of restricted stock awards and restricted stock units and the number of shares purchasable under the 2021 Employee Stock Purchase Plan (“2021 ESPP”), if dilutive. Because the Company was in a net loss position, basic and diluted net loss per share were the same for all periods presented.

Recent Accounting Pronouncements

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. The ASU expands public entities’ segment disclosures by requiring disclosure of significant segment expenses that are regularly reviewed by the chief operating decision maker (“CODM”) and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items, and interim disclosures of a reportable segment’s profit or loss and assets. The ASU also allows, in addition to the measure that is most consistent with U.S. GAAP, the disclosure of additional measures of segment profit or loss that are used by the CODM in assessing segment performance and deciding how to allocate resources. All disclosure requirements under ASU 2023-07 are also required for public entities with a single reportable segment. The ASU is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, on a retrospective basis, with early adoption permitted. The Company is currently evaluating the potential impact that this standard may have on its consolidated financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures.* The update requires a public business entity to disclose, on an annual basis, a tabular rate reconciliation using both percentages and currency amounts, broken out into specified categories with certain reconciling items further broken out by nature and jurisdiction to the extent those items exceed a specified threshold. In addition, all entities are required to disclose income taxes paid, net of refunds received disaggregated by federal, state/local, and foreign and by jurisdiction if the amount is at least

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% of total income tax payments, net of refunds received. Adoption of the ASU allows for either the prospective or retrospective application of the amendment and is effective for annual periods beginning after December 15, 2024, with early adoption permitted. The Company has not yet completed its assessment of the impact of ASU 2023-09 on the Company’s consolidated financial statements.

Recently Issued Accounting Pronouncements Adopted

In August 2020, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in Entity’s Own Equity* (“ASU 2020-06”), which, among other things, provides guidance on how to account for contracts on an entity’s own equity. This ASU simplifies the accounting for certain financial instruments with characteristics of liabilities and equity. Specifically, the ASU eliminated the need for the Company to

assess whether a contract on the entity's own equity (1) permits settlement in unregistered shares, (2) whether counterparty rights rank higher than shareholder's rights, and (3) whether collateral is required. In addition, this ASU requires incremental disclosure related to contracts on the entity's own equity and clarifies the treatment of certain financial instruments accounted for under this ASU on earnings per share. This ASU may be applied on a full retrospective or modified retrospective basis. The amendments within this ASU are effective for the Company's fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption of the ASU is permitted to fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The Company adopted this standard on January 1, 2024 and as the Company does not have convertible debt and contracts in the Company's own equity, the adoption of this standard did no t have a material impact to the consolidated financial statements at the adoption date.

3. Fair Value Measurements

Fair Value Measurements-Recurring Basis

Fair value is defined as the exchange price that would be received to sell an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy is as follows:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Inputs, other than the quoted prices included in Level 1, that are either directly or indirectly observable.

Level 3: Unobservable inputs in which there is little or no market activity, which require the reporting entity to develop its own assumptions.

The following tables present information about the fair value measurements of the Company's financial assets and liabilities which are measured at fair value on a recurring basis, and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	September 30, 2024			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets:				
Cash equivalents				
Money market fund	$ 24,276	$ —	$ —	$ 24,276
Total cash equivalents	24,276	—	—	24,276
Marketable securities				
U.S. Treasury securities	20,762	—	—	20,762
U.S. government agency securities	—	34,674	—	34,674
Corporate debt securities	—	18,820	—	18,820
Commercial paper	—	132,436	—	132,436
Asset backed securities	—	6,368	—	6,368
Total marketable securities	20,762	192,298	—	213,060
Total assets	$ 45,038	$ 192,298	$ —	$ 237,336

	December 31, 2023			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets:				
Cash equivalents				
Money market fund	$ 40,241	$ —	$ —	$ 40,241

Commercial paper	—	7,468	—	7,468
Total cash equivalents	40,241	7,468	—	47,709
Marketable securities				
U.S. government agency securities	—	67,208	—	67,208
Commercial paper	—	118,465	—	118,465
Asset backed securities	—	14,968	—	14,968
Total marketable securities	—	200,641	—	200,641
Total assets	$ 40,241	$ 208,109	$ —	$ 248,350

In determining the fair value of its Level 2 investments, the Company relied on the most recent observable inputs for similar instruments in active markets or quoted prices for identical or similar instruments in markets that are not active or are directly or indirectly observable. These quoted prices were obtained by the Company with the assistance of a third-party pricing service based on available trade, bid and other observable market data for identical or similar securities. During the nine months ended September 30, 2024 and 2023, there were

no

transfers between Level 1, Level 2 and Level 3.

As of September 30, 2024 and December 31, 2023, the fair value of the Company's available-for-sale marketable securities by type of security was as follows (in thousands):

	September 30, 2024			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
U.S. Treasury securities	$ 20,570	$ 192	$ —	$ 20,762
U.S. government agency securities	34,446	228	—	34,674
Corporate debt securities	18,750	73	(3)	18,820
Commercial paper	132,169	270	(3)	132,436
Asset backed securities	6,354	14	—	6,368
Total marketable securities	$ 212,289	$ 777	$ (6)	$ 213,060

	December 31, 2023			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
U.S. government agency securities	$ 67,310	$ —	$ (102)	$ 67,208
Commercial paper	118,323	143	(1)	118,465
Asset backed securities	14,979	2	(13)	14,968
Total marketable securities	$ 200,612	$ 145	$ (116)	$ 200,641

All of the Company's marketable securities as of September 30, 2024 have maturity dates of less than one year.

As of September 30, 2024,

two

available-for-sale marketable securities were in an unrealized loss position. Of the

two
available-for-sale marketable securities in an unrealized loss position, both had been in an unrealized loss position for less than 12 months. As of December 31, 2023,

ten
available-for-sale marketable securities were in an unrealized loss position. Of the

ten
available-for-sale marketable securities in an unrealized loss position,

eight
had been in an unrealized loss position for less than 12 months and

two
had been in an unrealized loss position for greater than 12 months.

The following table presents available-for-sale marketable securities that were in an unrealized loss position as of September 30, 2024, aggregated by major security type and length of time in a continuous loss position (in thousands):

	Less than 12 Months		12 Months or Longer		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate debt securities	$ 3,908	$ (3)	$ —	$ —	$ 3,908	$ (3)
Commercial paper	$ 3,873	$ (3)	$ —	$ —	$ 3,873	$ (3)

The following table presents available-for-sale marketable securities that were in an unrealized loss position as of December 31, 2023, aggregated by major security type and length of time in a continuous loss position (in thousands):

	Less than 12 Months		12 Months or Longer		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
U.S. government agency securities	$ 47,242	$ (79)	$ 19,966	$ (23)	$ 67,208	$ (102)
Commercial paper	$ 9,965	$ (1)	$ —	$ —	$ 9,965	$ (1)
Asset backed securities	$ 9,854	$ (13)	$ —	$ —	$ 9,854	$ (13)

The Company reviews its marketable securities at each reporting date to determine if any security is impaired, which would require the Company to record an allowance for credit losses in that respective period. The Company evaluated the securities individually for impairment and considered factors such as the severity of the impairment, changes in underlying credit ratings, forecasted recovery, the Company's intent to sell or the likelihood that the Company would be required to sell the security before its anticipated recovery in market value and the probability that the scheduled cash payments will continue to be made. Based on the Company's review of these marketable securities, the Company believes none of the unrealized losses are the result of a credit loss as of September 30, 2024. These marketable securities are of high credit quality, and the Company does not intend to sell these securities prior to maturity and it is not more-likely-than-not that the Company will be required to sell these securities before the recovery of their amortized cost basis. As such, the Company did

no

t record an allowance for credit losses as of September 30, 2024. During the nine months ended September 30, 2024, the immaterial unrealized losses were due to market fluctuations and were only sustained for a short period of time. During the year ended December 31, 2023, the decline in market value in the Company's marketable securities was primarily attributable to an increase in interest rates.

Accrued interest receivable on available-for-sale marketable securities, included in prepaid expenses and other assets on the Company's condensed consolidated balance sheets, was $

0.4

million and $

0.8

million at September 30, 2024 and December 31, 2023, respectively. The Company does not measure an allowance for credit losses for accrued interest receivables. For the purposes of identifying and measuring an impairment, accrued interest is excluded from both the fair value and amortized cost basis of the available-for-sale marketable security. Uncollectible accrued interest receivables associated with an impaired available-for-sale marketable security are reversed against interest income upon identification of the impairment.

No

accrued interest receivables were written off during the nine months ended September 30, 2024 or 2023.

4. Consolidated Balance Sheet Details

Property and Equipment, net

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

	September 30, 2024	December 31, 2023
Internal-use software	$ 491	$ 491
Leasehold improvements	283	—
Laboratory equipment	155	178
Furniture and fixtures	92	137
Computer hardware and software	58	58

Construction in progress	36	157
Property and equipment, gross	1,115	1,021
Less: accumulated depreciation	(412)	(259)
Property and equipment, net	$ 703	$ 762

During the three and nine months ended September 30, 2024, depreciation expense was $

0.1
million and $

0.2
million, respectively. During the three and nine months ended September 30, 2023, depreciation expense was immaterial.

Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2024	December 31, 2023
Accrued research and development costs	$ 907	$ 1,868
Accrued clinical trial costs	2,014	4,831
Accrued payroll liabilities	4,407	7,742
Other accrued liabilities	1,595	984
Accrued related party liabilities	83	83
Total accrued expenses	$ 9,006	$ 15,508

On December 5, 2023, the Company committed to and implemented a reduction in force ("RIF") and incurred one-time termination benefits associated with severance payment obligations and continued healthcare benefits for employees terminated under the RIF of $ 2.2 million during the year ended December 31, 2023. Accrued severance costs associated with the RIF are included in accrued expenses on the condensed consolidated balance sheets as of September 30, 2024 and December 31, 2023. A summary of accrued severance costs associated with the RIF as of September 30, 2024 is shown in the table below (in thousands):

	September 30, 2024
Accrued severance costs as of December 31, 2023	$ 2,178
Reduction in estimate for continued healthcare benefits	(114)
Cash payments	(2,061)
Accrued severance costs as of September 30, 2024	$ 3

5. Commitments and Contingencies

Litigation

Securities Class Action

On March 1, 2024, a putative securities class action complaint, captioned *Yuksel v. Ventyx Biosciences, Inc., et al.*, No. 3:24-cv-00415-AGA-DDL, was filed in the U.S. District Court for the Southern District of California against the company and certain of its current and former officers and directors, asserting violations of Sections 11 and 15 of the Securities Act and Sections 10(b) and 20(a) of the Securities Exchange Act. Stemming from the Company's disclosure on November 6, 2023 of the results of its Phase 2 SERENITY trial of VTX958 and its decision to terminate ongoing activities and clinical trials for the development of VTX958 for the treatment of plaque psoriasis and psoriatic arthritis, the complaint alleges that that the defendants issued materially false and misleading statements and/or failed to disclose material adverse facts in connection with its October 21, 2021 initial public offering and in public statements from October 21, 2021 through November 6, 2023 regarding the effectiveness and clinical and commercial prospects of VTX958, the Company's ability to develop and commercialize product candidates, and its business prospects. On April 30, 2024, a motion for appointment of a lead plaintiff was filed. The lead plaintiff motion remains pending. The Company intends to defend the case vigorously. The Company is unable to estimate a range of loss, if any, that could result were there to be an adverse final decision in this action. If an unfavorable outcome were to occur, it is possible that the impact could be material to the Company's results of operations in the period(s) in which any such outcome becomes probable and estimable.

Additionally, in the ordinary course of its business, the Company may be involved in various legal proceedings involving contractual and employment relationships, patent or other intellectual property rights, and a variety of other matters. The Company is not aware of any pending legal proceedings that would reasonably be expected to have a material impact on the Company's financial position or results of operations.

6. Stockholders' Equity

March 2024 Private Placement

See Note 1, “Organization and Business,” for more information regarding the March 2024 private placement.

September 2024 Issuance of Series A Non-Voting Convertible Preferred Stock from Private Placement

See Note 1, “Organization and Business,” for more information regarding the September 2024 issuance of Series A Preferred Stock from private placement.

ATM Sales Agreement

In December 2022, the Company entered into a Sales Agreement with Jefferies, as sales agent, pursuant to which the Company may offer and sell in an at-the-market offering, from time to time through Jefferies, shares of common stock providing for aggregate sales proceeds of up to $

150.0

million. The Company has no obligation to sell any shares under the Sales Agreement, and could at any time suspend solicitations and offers under the Sales Agreement. During the year ended December 31, 2023, the Company issued and sold

1,176,470

shares of common stock for aggregate gross proceeds of $

50.0

million through the Sales Agreement.

No

shares of common stock were issued under the Sales Agreement during the nine months ended September 30, 2024.

Common Stock

The Company is authorized to issue up to

900,000,000

shares of common stock having a par value of $

0.0001

as of September 30, 2024 and December 31, 2023. Holders of outstanding shares of common stock are entitled to one vote for each share of common stock held at all meetings of stockholders. Subject to the rights of the holders of any class of the Company’s capital stock having any preference or priority over common stock, the holders of common stock are entitled to receive dividends that are declared by the Company’s board of directors out of legally available funds.

Common stock reserved for future issuance is as follows (in common stock equivalent shares) as of September 30, 2024:

	September 30, 2024
Shares issuable upon conversion of Series A non-voting preferred stock	7,060,100
Issued and outstanding:	
Stock options	10,483,769
Restricted stock units	429,042
Authorized for future issuance:	
2021 Equity Incentive Plan	3,050,378
2021 Employee Stock Purchase Plan	1,567,281
Total	22,590,570

Series A Preferred Stock

The Company is authorized to issue up to

100,000,000

shares of preferred stock having a par value of $

0.0001

as of September 30, 2024 and December 31, 2023. On September 23, 2024, the Company filed a Certificate of Designations of Preferences, Rights and Limitations of Series A Non-Voting Convertible Preferred Stock (the “Certificate of Designations”) with the Secretary of State of the State of Delaware, effective as of the time of filing, designating

70,601

shares of its authorized and unissued preferred stock as Series A Preferred Stock and setting forth the powers, preferences, rights, qualifications, limitations and restrictions of the Series A Preferred Stock. The following is a description of the terms of the Series A Preferred Stock:

Conversion. The Series A Preferred Stock is convertible at the option of each holder at any time into

100

shares of Common Stock for each share of Series A Preferred Stock , subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization. The Series A Preferred Stock will not be convertible by a holder to the extent that such holder or any of its affiliates would beneficially own in excess of

4.99

% (the “Maximum Percentage”) of the common stock outstanding immediately after giving effect to such conversion, as further described in the Certificate of Designations. A holder may increase or decrease the Maximum Percentage to any other percentage (not in excess of

19.99

% of the issued and outstanding common stock immediately after giving effect to the issuance of the common stock issuable upon conversion of the Series A Preferred Stock) by delivering a written notice to the Company, provided that (i) any such increase in the Maximum Percentage will not be effective until the 61st day after such notice is delivered to the Company and (ii) any such increase or decrease does not apply to any other holder of Series A Preferred Stock or the validity of any prior conversion of the Series A Preferred Stock.

Voting. Holders of shares of Series A Preferred Stock shall have no voting rights on any Company matter.

Dividends. Holders to Series A Preferred Stock shall be entitled to receive, only when, as and if declared by the Company's board of directors, out of any funds and assets legally available therefore, a dividend on each outstanding share of Series A Preferred Stock equal to $

0.0001

per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series A Preferred Stock), prior and in preference to any declaration or payment of any dividend (other than dividends on shares of common stock payable in shares of common stock) on common stock during the same calendar year. The right to receive dividends on shares of Series A Preferred Stock is non-cumulative, and no right to dividends shall accrue to holders of Series A Preferred Stock by reason of the fact that dividends on such shares are not declared or paid. Subject to the preferential rights described above, holders of the Series A Preferred Stock are entitled to receive dividends on shares of Series A Preferred Stock equal (on an as-converted to common stock basis) to and in the same form as dividends actually paid on shares of the common stock.

Liquidation. In the event of any liquidation as defined in the Certificate of Designation, the assets of the Company shall be distributed, after payment in full of any dividends declared by unpaid on the Series A Preferred Stock, among the holders of the shares of Series A Preferred Stock and common stock pro rata based on the number of shares held by each such holder (on an as-converted to common stock basis), after payment in full of any dividends declared by unpaid on the Series A Preferred Stock.

7. Leases

In July 2023, the Company entered into a Sublease with Neurocrine Biosciences, Inc. for office space in San Diego, California which became the Company's headquarters in August 2023. Under the terms of the Sublease, the Company leased the second floor of the building, including certain furniture and fixtures, located at 12790 El Camino Real in San Diego, California consisting of approximately

35,016

rentable square feet of office space. The term of this non-cancellable lease commenced on July 21, 2023 , and will end on July 31, 2031 . The Company is subleasing the premises for approximately $

2.0

million per year with

3

% annual increases in each subsequent year. The Company subleased the premises for approximately $

1.0

million in the first year, which included the rent abatement for the second through the seventh full calendar months of the lease term. In lieu of a cash security deposit under the Sublease, Bank of America issued on the Company's behalf an irrevocable standby letter of credit in the amount of $

0.5

million. The letter of credit is secured by a deposit of $

0.5

million with the same bank and included in restricted cash on the Company's condensed consolidated balance sheet at September 30, 2024. The Company used its incremental borrowing rate available at commencement date in determining the present value of lease payments and recognized an operating lease liability of $

11.0

million and a corresponding operating lease right-of-use ("ROU") asset of approximately $

11.0

million on the condensed consolidated balance sheet during the year ended December 31, 2023.

In March 2021, the Company signed a three-year operating lease for a multi-function ventilated research laboratory and office space in Ghent, Belgium. The non-cancellable lease expired on June 30, 2024 . The Company exercised its option to extend the lease term through June 30, 2026 , resulting in an immaterial operating lease liability and corresponding operating lease ROU asset.

Lease Terminations

In February 2024, the Company entered into

two

separate lease termination agreements related to non-cancellable leases entered into in February 2021, September 2021 and May 2022, each expiring on June 30, 2026 . These leases are for office facilities in Encinitas, California and the associated furniture and fixtures (the "Encinitas Asset Group"). The Company wrote off the ROU assets and operating lease liabilities associated with the Encinitas Asset Group of $

0.8

million and $

0.9

million, respectively, during the first quarter of 2024.

The Company's leases have remaining terms ranging between one year and seven years . The leases contain various termination options . The Company's leases do not contain any residual value guarantees or material restrictive covenants.

The weighted average remaining lease term and discount rate for the Company's operating leases were approximately 6.8 years and

10.1

%, respectively, at September 30, 2024.

During the three and nine months ended September 30, 2024, the Company recognized operating lease costs of $

0.6

million and $

1.8
million, respectively, and variable lease costs of $

0
and $

0.2
million, respectively. During the three and nine months ended September 30, 2023, the Company recognized operating lease costs of $

0.5
million and $

0.8
million, respectively, and an immaterial amount of variable lease costs in both periods. In addition, the Company made cash payments of $

1.5
million and $

0.6
million for operating leases during the nine months ended September 30, 2024 and 2023, respectively, which are included in cash flows from operating activities in the condensed consolidated statements of cash flows.

Future minimum payments under non-cancellable leases as of September 30, 2024 were as follows (in thousands):

Years ending December 31,	
2024 (3 months remaining)	$ 513
2025	2,073
2026	2,135
2027	2,199
2028	2,265
Thereafter	6,162
Total future minimum lease payments	15,347
Less: imputed interest	(4,311)
Present value of lease liabilities	11,036
Less: lease liabilities, current	(1,011)
Lease liabilities, net of current portion	$ 10,025

8. Stock-Based Compensation

Equity Incentive Plans

In February 2019, the Company adopted its 2019 Equity Incentive Plan (the “2019 Plan”). In October 2021, the 2019 Plan was terminated as to new awards upon the Company’s adoption of the 2021 Equity Incentive Plan (the “2021 Plan”), which became effective on October 19, 2021. The 2021 Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units and performance awards to employees, directors or consultants of the Company.

The number of common shares available for issuance under the 2021 Plan is

5,612,000
shares of common stock plus any common shares subject to stock options, restricted stock units or similar awards granted under the 2019 Plan that expire, are forfeited or otherwise terminate without having been exercised in full, are tendered to or withheld by the Company for payment of an exercise price or for tax withholding obligations or are forfeited to or repurchased by the Company due to failure to vest, with the maximum number of common shares to be added to the 2021 Plan equal to

4,978,561
common shares. Additionally, shares available for issuance under the 2021 Plan automatically increase on the first day of each fiscal year, beginning with the Company’s 2023 fiscal year, equal to the lesser of

5,102,000
common shares,

5
% of the outstanding common shares on the last day of the immediately preceding fiscal year, or such number of common shares determined by the board of directors. On January 1, 2024, the number of shares of common stock that may be issued under the 2021 Plan was automatically increased by

2,962,617
shares.

Options granted under the 2019 Plan and 2021 Plan (collectively, the “Plans”) generally vest over a period of between one and four years and expire ten years from grant date. As of September 30, 2024 and December 31, 2023, the Company had

12,102,048
and

9,018,173
shares, respectively, authorized for issuance under the Plans, and

3,050,378
and

317,001
shares, respectively, remained available for grant under the 2021 Plan.

Total stock-based compensation expense related to share-based awards was comprised of the following (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Research and development	$ 2,648	$ 4,112	$ 8,082	$ 11,443
General and administrative	2,803	3,896	9,683	11,000
Total stock-based compensation expense	$ 5,451	$ 8,008	$ 17,765	$ 22,443

Stock-based compensation expense by type of share-based award (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Stock options	$ 4,619	$ 6,864	$ 14,981	$ 19,103
Restricted stock awards	—	27	37	82
Restricted stock units	792	1,051	2,655	3,097
Employee Stock Purchase Plan	40	66	92	161
Total stock-based compensation expense	$ 5,451	$ 8,008	$ 17,765	$ 22,443

Stock Options

The following table summarizes stock option activity for the nine months ended September 30, 2024:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2023	10,338,724	$ 14.42	8.24	$ 1,737
Granted	2,739,250	2.88		
Exercised	(133,571)	0.97		
Forfeited and cancelled	(2,460,634)	15.28		
Outstanding as of September 30, 2024	10,483,769	$ 11.37	7.75	$ 920
Vested and expected to vest as of September 30, 2024	10,483,769	$ 11.37	7.75	$ 920
Exercisable as of September 30, 2024	4,921,703	$ 12.92	6.55	$ 747

The weighted average grant date fair value of stock options granted during the nine months ended September 30, 2024 and 2023 was $ 2.34

and $

22.56

per share, respectively. The intrinsic value of a stock option is the difference between the market price of the common stock at measurement date and the exercise price of the option. The total intrinsic value of stock options exercised during the nine months ended September 30, 2024 and 2023 was $

0.5

million and $

22.5

million, respectively.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model. The following assumptions were used in the Black-Scholes option pricing model to estimate the fair value of stock options granted to employees under the Company's Plans during the periods presented:

	Nine months ended September 30,	
	2024	**2023**
Risk-free interest rate	3.5% - 5.2%	3.4% - 4.8%
Expected volatility	99.7% - 102.6%	68.4% - 73.5%
Expected term (in years)	0.3 - 10.0	0.4 - 10.0
Expected dividend yield	—	—

During the three and nine months ended September 30, 2024, the Company recorded a net decrease to stock-based compensation expense of approximately $

0.1

million. The net decrease of approximately $

0.1

million was comprised of the reversal of approximately $

0.3

million of stock-based compensation expense associated with the acceleration of unvested options in connection with the termination of

one

employee, offset by the recognition of $

0.2

million of stock-based compensation expense associated with the extended term of vested and unvested options resulting from an amended consulting agreement for

one

consultant. The resulting net decrease to stock-based compensation expense was recognized immediately.

During the nine months ended September 30, 2023, the Company recorded incremental stock-based compensation expense of approximately $

0.1

million pertaining to the modification of stock options in connection with the termination of

one

employee. The modification during the nine months ended September 30, 2023 provided for an acceleration of unvested options, resulting in a change in compensation expense that was immediately recognized.

As of September 30, 2024, unrecognized stock-based compensation was $

32.8

million which is expected to be recognized over the weighted average period of 2.3 years.

Restricted Stock Awards

The Company grants restricted stock awards pursuant to the Plans and satisfies such grants through the issuance of new shares. Restricted stock awards generally vest over a period of three years . Upon the termination of service of a restricted stockholder, the Company has the option to repurchase any unvested shares and based on this, restricted stock awards are not included in outstanding common stock until fully vested. During the nine months ended September 30, 2024 and 2023, the Company did

no

t repurchase any unvested shares.

The following table summarizes restricted stock award activity for the nine months ended September 30, 2024:

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Unvested balance as of December 31, 2023	13,236	$ 3.45
Vested	(13,236)	3.45
Unvested balance as of September 30, 2024	—	$ —

The Company records a liability for unvested restricted stock awards subject to repurchase and reduces the liability as the underlying shares vest. The

liability was $

0

as of September 30, 2024 and immaterial as of September 30, 2023. The total fair value of restricted stock awards vested during the nine months ended September 30, 2024 and 2023 was immaterial. As of September 30, 2024, all stock-based compensation expense pertaining to restricted stock awards was recognized.

Restricted Stock Units

The Company grants restricted stock units pursuant to the Plans and satisfies such grants through the issuance of new shares as they vest. Restricted stock units generally vest over a period of four years . The following table summarizes restricted stock unit activity for the nine months ended September 30, 2024:

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Unvested Balance as of December 31, 2023	530,726	$ 21.11
Granted	—	$ —
Vested	(52,308)	$ 31.42
Forfeited	(49,376)	$ 29.71
Unvested balance as of September 30, 2024	429,042	$ 18.86

As of September 30, 2024, there was approximately $

5.0

million of unrecognized stock-based compensation cost pertaining to restricted stock units that will be recognized over a weighted average period of 1.5 years.

Employee Stock Purchase Plan

In October 2021, the board of directors and stockholders approved the 2021 ESPP which became effective on October 19, 2021. The maximum number of shares of common stock that will be made available for sale under the ESPP is equal to

510,000
shares of common stock. In addition, the number of shares of common stock available for issuance under the ESPP will be increased on the first day of each fiscal year, beginning with fiscal year 2023, in an amount equal to the lesser of

1,020,000
shares of common stock,

1
% of the outstanding shares of common stock on the last day of the immediately preceding fiscal year or such number of common shares determined by the board of directors. On January 1, 2024, the number of shares of common stock that are available for sale under the ESPP was automatically increased by

592,523
shares.

Participating employees purchase stock under the ESPP at a price equal to the lower of

85
% of the closing price on the applicable offering commencement date or

85
% of the closing price on the applicable offering termination date. The ESPP provides for

two
offering periods of six months ' duration with purchase periods terminating on either May 15 or November 15. Contributions under the ESPP are limited to a maximum of

15
% of an employee's eligible compensation and a maximum of

3,000
shares per year. During the nine months ended September 30, 2024 and 2023,

56,903
and

9,765
shares, respectively, were issued under the ESPP at average share prices of $

2.01
and $

21.91
, respectively.

9. Net Loss Per Share

Basic net loss per share of common stock is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. The following table sets forth the computation of basic and diluted net loss per share attributable to common shareholders:

	Three months ended September 30,		Nine months ended September 30,	
(in thousands, except share and per share amounts)	2024	2023	2024	2023
Numerator:				
Net loss	(	(	(	(
	$ 35,249)	$ 54,027)	$ 105,771)	$ 146,209)
Denominator:				
Weighted average common shares outstanding, basic and diluted	70,667,570	58,880,427	67,694,970	58,363,174
Net loss per share, basic and diluted	(	(	(	(
	$ 0.50)	$ 0.92)	$ 1.56)	$ 2.51)

The table below provides potentially dilutive securities not included in the calculation of the diluted net loss per share (in common stock equivalent shares) at September 30, 2024 and 2023, because to do so would be anti-dilutive:

	September 30,	
	2024	2023
Shares issuable upon exercise of stock options	10,483,769	8,975,249
Shares issuable upon conversion of Series A non-voting preferred stock	7,060,100	—
Unvested restricted stock units	429,042	752,737
Unvested restricted stock awards	—	21,177
Shares purchasable under the 2021 Employee Stock Purchase Plan	55,590	12,297
Total	18,028,501	9,761,460

10. Related Party Transactions

On October 17, 2019, the Company entered into a Research and Development Support Services Agreement with Bayside Pharma, LLC (“Bayside”) that outlined the terms of services provided by Bayside to the Company, as well as the fees charged for such services. Bayside is a research and development services company that provides certain research and development support services and facilities. Bayside is owned by an employee of the Company. The Company pays Bayside monthly for costs incurred under the agreement. Either party may terminate the support services agreement by giving 30 days’ prior notice.

Expense recognized by the Company under the related party Support Services Agreement with Bayside was as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Research and development - Bayside	$ 249	$ 417	$ 752	$ 776
Total research and development - related party	$ 249	$ 417	$ 752	$ 776

At September 30, 2024 and December 31, 2023, the Company had accounts payable and accrued expenses due to related parties of $

0.2
million and $

0.1
million, respectively. At September 30, 2024 and December 31, 2023, the Company had $

0

and an immaterial amount, respectively, of prepaid expenses and other current assets due from related parties.

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

The following discussion and analysis of financial condition and results of operations should be read together with our condensed consolidated financial statements and the related notes included elsewhere in this Quarterly Report on Form 10-Q, as well as our audited consolidated financial statements and the related notes for the year ended December 31, 2023, which are included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on February 27, 2024. In addition to historical financial information, the following discussion and analysis and other parts of this Quarterly Report on Form 10-Q contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, based upon current expectations that involve risks and uncertainties. As a result of many factors, including those factors set forth in Part II, Item 1A (Risk Factors) of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Please also see the section titled "Special Note Regarding Forward-Looking Statements."

Overview

We are a clinical-stage biopharmaceutical company developing a pipeline of novel small molecule product candidates to address a range of inflammatory diseases with significant unmet need. We leverage the substantial experience of our team in immunology to identify important new targets and to develop differentiated therapeutics against these targets. Our clinical product candidates address therapeutic indications with substantial commercial opportunity for novel small molecules. For example:

- We are developing a portfolio of clinical-stage small molecule inhibitors of the NOD-like receptor protein 3 (NLRP3) inflammasome, including VTX3232, our CNS-penetrant NLRP3 inhibitor, and VTX2735, our peripheral NLRP3 inhibitor. In the first quarter of 2024, we reported positive topline results from a Phase 1 trial of VTX3232 in adult healthy volunteers. In August 2024, we initiated a Phase 2a trial of VTX3232 in participants with early Parkinson's disease. We expect to report topline results from this trial in the first half of 2025. We also expect to initiate a Phase 2 trial of VTX3232 in participants with obesity and certain additional risk factors for cardiovascular disease during the fourth quarter of 2024. Topline results from this trial are anticipated in the second half of 2025.

- During the first quarter of 2024, we also reported positive topline results from a Phase 2 proof of concept trial of VTX2735 in cryopyrin-associated periodic syndromes (CAPS) patients. We plan to evaluate VTX2735 for further development in cardiovascular diseases, with an initial focus on recurrent pericarditis. We expect to initiate a Phase 2 trial of VTX2735 in participants with recurrent pericarditis during the fourth quarter of 2024. Topline results from this trial are anticipated in the second half of 2025.

- We are also developing VTX002, a sphingosine 1 phosphate receptor (S1P1R) modulator for the treatment of moderately to severely active ulcerative colitis (UC). In the fourth quarter of 2023, we announced positive results from the Phase 2 trial of VTX002 in patients with moderately to severely active ulcerative colitis. We intend to identify a partner or other source of non-dilutive financing to support a pivotal Phase 3 trial of VTX002 in ulcerative colitis.

- In the third quarter of 2024, we announced results from a Phase 2 trial of VTX958, an allosteric TYK2 inhibitor, in participants with moderately to severely active Crohn's disease. The study did not meet its primary endpoint of change from baseline in mean CDAI score in either VTX958 dose group. VTX958 did demonstrate dose-dependent, nominally statistically significant endoscopic response rates at Week 12 as measured by SES-CD (an objective endpoint) and showed a greater magnitude of decrease compared to placebo in two key biomarkers of inflammation, C-reactive protein and fecal calprotectin. Based on these results, we are continuing the analysis of the Phase 2 data; however, we do not anticipate committing significant internal resources to further development of VTX958.

We were incorporated in November 2018. To date, we have focused primarily on organizing and staffing our company, business planning, raising capital and identifying our product candidates and conducting preclinical studies and clinical trials. We have funded our operations primarily through equity and debt financings. We do not have any products approved for sale and have not generated any revenue from product sales.

We have incurred significant operating losses since our inception and expect to continue to incur significant operating losses for the foreseeable future. Our net losses were $193.0 million and $108.4 million for the years ended December 31, 2023 and December 31, 2022, respectively. Our net losses were $35.2 million and $54.0 million for the three months ended September 30, 2024 and 2023, respectively, and $105.8 million and $146.2 million for the nine months ended September 30, 2024 and 2023, respectively. We had an accumulated deficit of $525.0 million as of September 30, 2024. Our net losses may fluctuate significantly from quarter-to-quarter and

year-to-year, depending on a variety of factors, including the timing and scope of our preclinical studies and clinical trials and our expenditures on other research and development activities.

We do not expect to generate any revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, until such time as we can generate substantial product revenues to support our cost structure, if ever, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to raise additional capital when needed, we could be forced to delay, limit, reduce or terminate our product candidate development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

September 2024 Private Placement

On September 23, 2024, we entered into a Securities Purchase Agreement (Securities Purchase Agreement) with Aventis Inc., a wholly-owned subsidiary of Sanofi, a global healthcare and pharmaceutical company (together with Aventis Inc., Sanofi), pursuant to which we issued an aggregate of 70,601 shares of Series A non-voting convertible preferred stock, par value $0.0001 per share (Series A Preferred Stock), each convertible into 100 shares of common stock, at an as-converted price of $3.8243 per common share, for gross proceeds of approximately $27.0 million, in a private placement (Series A Private Placement).

In connection with the Securities Purchase Agreement, we granted Sanofi a right of first negotiation (ROFN) for a license, grant or transfer, including by option or sale, or any rights to research, develop, commercialize, or otherwise exploit VTX3232, our CNS-penetrant NLRP3 inhibitor. We received approximately $26.6 million in net proceeds after deducting issuance costs payable by us.

March 2024 Private Placement

In March 2024, we issued and sold 11,174,000 shares of our common stock in a private placement at an offering price of $8.95 per share for aggregate gross proceeds of approximately $100.0 million. We received $95.0 million in net proceeds after deducting fees to the placement agents and offering expenses payable by us.

ATM Sales Agreement

In December 2022, we entered into an Open Market Sales Agreement℠ (Sales Agreement) with Jefferies LLC (Jefferies), as sales agent, pursuant to which we could offer and sell, from time to time through Jefferies, shares of common stock providing for aggregate sales proceeds of up to $150.0 million. We have no obligation to sell any shares under the Sales Agreement, and could at any time suspend solicitations and offers under the Sales Agreement. During the year ended December 31, 2023, we issued and sold 1,176,470 shares of common stock for aggregate gross proceeds of $50.0 million through the Sales Agreement. No shares of common stock were issued under the Sales Agreement during the nine months ended September 30, 2024.

Impact of Macroeconomic Factors

Economic uncertainty in various global markets, including the U.S. and Europe, caused among other things by political instability and conflict, such as the military conflicts in Ukraine and the Middle East, have led to market disruptions, including significant volatility in commodity prices, credit and capital market instability and supply chain interruptions, which have caused volatile changes to inflation globally. Our business, financial condition and results of operations could be materially and adversely affected by further negative impact on the global economy and capital markets resulting from these or future global economic conditions, particularly if such conditions are prolonged or worsen.

Although, to date, our business has not been materially impacted by these global economic and geopolitical conditions, we are unable to predict the extent to which our operations will be impacted in the short and long term, or the ways in which such instability could impact our business and results of operations. The extent and duration of these market disruptions, whether as a result of the military conflicts in Ukraine and the Middle East and effects of related sanctions, geopolitical tensions, volatile changes to inflation or otherwise, are impossible to predict, but could be substantial. Any such disruptions may also magnify the impact of other risks described in this report.

Financial Operations Overview

Revenues

We have not generated any revenue since our inception and do not expect to generate any revenue from the sale of products for the foreseeable future. We may also generate revenues in the future from payments or royalties associated with potential partnering or collaboration agreements, but have no plans to enter into such arrangements at this time.

Research and Development Expenses

Research and development expenses consist of expenses incurred while performing research and development activities to discover and develop our product candidates. Direct research and development costs include external research and development expenses incurred under agreements with contract research organizations, consultants and other vendors that conduct our preclinical and clinical activities, expenses related to manufacturing our product candidates for preclinical and clinical studies, laboratory supplies and license fees. Indirect research and development costs include personnel-related expenses, consisting of employee salaries, payroll taxes, bonuses, benefits and stock-based compensation charges for those individuals involved in research and development efforts. Costs incurred in our research and development efforts are expensed as incurred.

We typically use our employee, consultant and infrastructure resources across our research and development programs. We track outsourced development costs by product candidate or development program, but we do not allocate personnel costs, other internal costs or certain external consultant costs to specific product candidates or development programs. These costs are included in unallocated research and development expenses. The following table summarizes research and development expenses by product candidate or development program (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
VTX958	$ 4,538	$ 23,281	$ 21,115	$ 62,604
VTX002	10,015	10,642	30,040	28,776
VTX2735	2,716	908	5,360	2,401
VTX3232	4,031	1,644	9,236	3,711
Unallocated research and development expenses	9,329	13,275	26,430	36,255
Total research and development expenses	$ 30,629	$ 49,750	$ 92,181	$ 133,747

Substantially all of our research and development expenses to date have been incurred in connection with the discovery and development of our product candidates. The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. The successful development of product candidates is highly uncertain and subject to numerous risks and uncertainties. Accordingly, at this time, we cannot reasonably estimate the nature, timing or costs required to complete the remaining development of any product candidates and to obtain regulatory approval for one or more of these product candidates.

The costs of clinical trials may vary significantly over the life of a project owing to, but not limited to, the following:

- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the clinical trials;
- the countries in which the clinical trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the clinical trials and the drop-out or discontinuation rates of such patients;
- the number of doses that patients receive;
- the cost of comparative agents used in clinical trials;

- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up;
- the efficacy and safety profile of the product candidate; and
- establishing clinical manufacturing capabilities or making arrangements with third-party manufacturers in order to ensure that we or our third-party manufacturers are able to make product successfully.

We do not expect any of our product candidates to be commercially available for the next several years, if ever.

General and Administrative Expenses

General and administrative expenses are related to legal and patent costs, finance, human resources and other administrative activities. These expenses consist primarily of legal expenses, personnel costs, including stock-based compensation expenses, outside services, management fees and other general and administrative costs.

We expect that our general and administrative expenses may increase in the future as we expand operations, increase our headcount to support our continued research and development activities and operate as a public reporting company (including increased fees for outside consultants, lawyers and accountants, as well as increased directors' and officers' liability insurance premiums). We have also incurred, and expect to continue to incur, increased costs to comply with stock exchange listing and SEC requirements, corporate governance, internal controls, investor relations and disclosure and similar requirements applicable to public companies, particularly as we ceased to be an emerging growth company as of December 31, 2023. Additionally, if and when we believe that regulatory approval of a product candidate appears likely, we may incur significant increases in our general and administrative expenses related to the sales and marketing of any approved product candidate.

Results of Operations

Comparison of Three Months Ended September 30, 2024 to Three Months Ended September 30, 2023

The following table summarizes our condensed consolidated results of operations for the three months ended September 30, 2024 and 2023:

	Three months ended September 30,		
	2024	2023	Change
	(in thousands)		
Operating expenses:			
Research and development (includes related party amounts of $249 and $417, respectively)	$ 30,629	$ 49,750	$ (19,121)
General and administrative	7,923	8,201	(278)
Total operating expenses	38,552	57,951	(19,399)
Loss from operations	(38,552)	(57,951)	19,399
Other (income) expense:			
Interest income	(3,350)	(3,932)	582
Other expense	47	8	39
Total other (income) expense	(3,303)	(3,924)	621
Net loss	$ (35,249)	$ (54,027)	$ 18,778
Unrealized gain on marketable securities	922	192	730
Foreign currency translation	199	11	188
Comprehensive loss	$ (34,128)	$ (53,824)	$ 19,696

Research and Development Expense

Research and development expenses were $30.6 million and $49.8 million for the three months ended September 30, 2024 and 2023, respectively. For the three months ended September 30, 2024 and 2023, most research and development expenses have been related to the development of VTX958, VTX002, VTX2735 and VTX3232.

For the three months ended September 30, 2024 as compared to the three months ended September 30, 2023, there was a net decrease in research and development expenses of approximately $19.1 million. This decrease was comprised of a decrease in costs between periods associated with VTX958 of approximately $18.7 million, primarily due to the conclusion of the Phase 2 trials of VTX958 in psoriasis and psoriatic arthritis and wind down of associated program activities; a decrease in costs associated with VTX002 of approximately $0.6 million; and a decrease in unallocated research and development expenses of approximately $3.9 million, which included decreases in compensation-related expenses of approximately $2.2 million and stock-based compensation expense of $1.5 million. These decreases were partially offset by an increase in costs associated with the VTX2735 program of approximately $1.8 million and an increase in VTX3232 costs of approximately $2.3 million associated with chronic toxicology work and Phase 2 trial start-up costs.

General and Administrative Expense

General and administrative expenses were $7.9 million and $8.2 million for the three months ended September 30, 2024 and 2023, respectively. The decrease of $0.3 million was primarily due to a net decrease in personnel costs, including a decrease in stock-based compensation expense of approximately $1.1 million, offset by increases in compensation-related expenses and professional service fees of approximately $0.4 million and $0.1 million, respectively. The net decrease in personnel costs was further offset by an increase in other general and administrative expenses of approximately $0.3 million, including costs associated with operating as a public company and facility related costs.

Other Income

Other income was $3.3 million and $3.9 million for the three months ended September 30, 2024 and 2023, respectively. During the three months ended September 30, 2024, the other income recognized was associated with net accretion income and interest earned on our available-for-sale marketable securities and dividends received from our cash equivalents.

Comparison of Nine Months Ended September 30, 2024 to Nine Months Ended September 30, 2023

The following table summarizes our condensed consolidated results of operations for the nine months ended September 30, 2024 and 2023:

	Nine months ended September 30,		
	2024	2023	Change
	(in thousands)		
Operating expenses:			
Research and development (includes related party amounts of $752 and $776, respectively)	$ 92,181	$ 133,747	$ (41,566)
General and administrative	23,851	23,901	(50)
Total operating expenses	116,032	157,648	(41,616)
Loss from operations	(116,032)	(157,648)	41,616
Other (income) expense:			
Interest income	(10,360)	(11,453)	1,093
Other expense	99	14	85
Total other (income) expense	(10,261)	(11,439)	1,178
Net loss	$ (105,771)	$ (146,209)	$ 40,438
Unrealized gain on marketable securities	741	544	197
Foreign currency translation	182	72	110
Comprehensive loss	$ (104,848)	$ (145,593)	$ 40,745

Research and Development Expense

Research and development expenses were $92.2 million and $133.7 million for the nine months ended September 30, 2024 and 2023, respectively. For the nine months ended September 30, 2024 and 2023, most research and development expenses have been related to the development of VTX958, VTX002, VTX2735 and VTX3232.

For the nine months ended September 30, 2024 as compared to the nine months ended September 30, 2023, there was a net decrease in research and development expenses of approximately $41.6 million. This decrease was comprised of a decrease in costs between periods

associated with VTX958 of approximately $41.5 million, primarily due to the conclusion of the Phase 2 trials of VTX958 in psoriasis and psoriatic arthritis and wind down of associated program activities, and a decrease in unallocated research and development expenses of approximately $9.8 million, which included decreases in compensation-related expenses of approximately $4.3 million and stock-based compensation expense of $3.4 million, and the receipt of a $2.1 million research and development tax credit from the United Kingdom during the nine months ended September 30, 2024, which is treated as an offset against our research and development expenses. These decreases were partially offset by an increase in costs associated with the VTX2735 program of approximately $3.0 million related primarily to the Phase 2 trial in CAPS patients and preparation for the Phase 2 trial in recurrent pericarditis; an increase in VTX3232 costs of approximately $5.5 million associated with chronic toxicology work, Phase 1 trial costs and Phase 2 preparation activities; and an increase in VTX002 costs of approximately $1.2 million related primarily to Phase 3 readiness activities.

General and Administrative Expense

General and administrative expenses were $23.9 million and $23.9 million for the nine months ended September 30, 2024 and 2023, respectively. The changes between periods were primarily related to a net decrease in personnel costs, including a decrease in stock-based compensation expense of approximately $1.3 million, offset by increases in compensation-related expenses and professional service fees of approximately $0.4 million and $0.3 million, respectively. The net decrease in personnel costs was further offset by an increase in other general and administrative expenses of approximately $0.6 million, including costs associated with operating as a public company and facility related costs.

Other Income

Other income was $10.3 million and $11.4 million for the nine months ended September 30, 2024 and 2023, respectively. During the nine months ended September 30, 2024, the other income recognized was associated with net accretion income and interest earned on our available-for-sale marketable securities and dividends received from our cash equivalents.

Liquidity and Capital Resources

Sources of Liquidity and Capital Resources

From inception through September 30, 2024, we have funded our operations primarily through the issuance of equity and debt securities. Prior to our initial public offering (IPO) in October 2021, we issued an aggregate of $164.2 million of convertible preferred stock, net of offering costs, to outside investors and related parties and $10.3 million in aggregate principal amount of convertible notes and SAFEs issued to related parties. In October 2021, we received net proceeds of approximately $158.8 million, after deducting underwriting discounts and commissions and offering expenses payable by us, from the sale of our shares of common stock in the IPO. In September 2022, through the closing of a private placement of common stock, we received net proceeds of approximately $165.2 million after deducting transaction-related expenses. In February 2023, we received approximately $48.4 million in net proceeds after deducting commissions and offering expenses payable by us from the sale of shares of our common stock through the Sales Agreement. In March 2024, through the closing of a private placement of common stock, we received net proceeds of approximately $95.0 million after deducting transaction-related expenses. In September 2024, we raised gross proceeds of $27.0 million in connection with the sale of Series A non-voting convertible preferred stock in a private placement to Aventis Inc. As of September 30, 2024, we had cash, cash equivalents and marketable securities of $274.8 million, excluding restricted cash of $1.0 million.

We have not entered into any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Future Funding Requirements

To date, we have generated no revenue and do not expect to generate revenue unless and until we obtain regulatory approval of and commercialize any of our product candidates and we do not know when, or if, this will occur. In addition, our expenses may significantly increase in connection with our ongoing development activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, our product candidates. Moreover, we continue to incur additional costs associated with operating as a public company. In addition, subject to obtaining regulatory approval of our product candidates, we may incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. We anticipate that we will need substantial additional funding in connection with our continuing operations. Our expenses may increase substantially if and as we:

- continue research and development, including preclinical and clinical development of our existing product candidates;
- seek regulatory approval for our product candidates;

- seek to discover and develop additional product candidates;
- establish a commercialization infrastructure and scale up our manufacturing and distribution capabilities to commercialize any of our product candidates for which we may obtain regulatory approval;
- seek to comply with regulatory standards and laws;
- maintain, leverage and expand our intellectual property portfolio;
- hire clinical, manufacturing, scientific and other personnel to support our product candidates;
- incur expenses related to development and future commercialization efforts;
- add personnel, financial and management information systems and personnel; and
- incur additional legal, accounting and other expenses in operating as a public company.

Based on our current business plan, we believe that existing cash, cash equivalents, and marketable securities will be sufficient to fund our obligations for at least twelve months from the issuance of these condensed consolidated financial statements. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect.

We enter into contracts in the normal course of business with various third-party consultants, contract research organizations (CRO) and contract manufacturing organizations (CMO) for preclinical research, clinical trials and manufacturing activities. These contracts generally provide for termination upon notice. Payments due upon cancellation consist of cancellation fees and payments for services provided or expenses incurred, including non-cancellable obligations of our service providers, up to the date of cancellation. Actual expenses associated with these arrangements may be higher or lower than anticipated due to various factors, including progress of our development candidates, enrollment in ongoing clinical trials, which may be competitive and challenging and results from our ongoing and planned clinical trials.

Short-term liquidity needs pertaining to our operating leases are approximately $2.2 million. Long-term liquidity needs pertaining to our operating leases are approximately $13.4 million with our last minimum lease payment due in July 2031. Currently, we have no short-term or long-term purchase commitments.

Our capital expenditures to date have been immaterial and we do not expect to incur significant costs related to capital expenditures in the short or long-term.

The successful development of any product candidate is highly uncertain. Due to the numerous risks and uncertainties associated with the development and commercialization of our product candidates, if approved, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of our product candidates.

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

- the timing of, and the costs involved in, preclinical and clinical development and obtaining any regulatory approvals for our product candidates;
- the costs of manufacturing, distributing and processing our product candidates;
- the number and characteristics of any other product candidates we develop or acquire;
- the degree and rate of market acceptance of any approved products;
- the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of other products or treatments;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;

- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing intellectual property claims, including litigation costs and the outcome of such litigation;

- the timing, receipt and amount of sales of, or royalties on, any approved products; and

- any product liability or other lawsuits related to our product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity, equity-linked and debt financings, collaborations, strategic alliances and/or licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with pharmaceutical partners, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates that we would otherwise prefer to develop and market ourselves.

Cash Flows

We have incurred net losses and negative cash flows from operations since our inception and anticipate we will continue to incur net losses for the foreseeable future. As of September 30, 2024, we had cash, cash equivalents and marketable securities of $274.8 million, excluding restricted cash of $1.0 million.

The following table sets forth a summary of the net cash flow activity for each of the periods indicated:

	Nine months ended September 30,	
	2024	2023
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (107,624)	$ (114,867)
Investing activities	$ (4,508)	$ 54,815
Financing activities	$ 122,140	$ 52,744

Operating Activities

Net cash used in operating activities was $107.6 million for the nine months ended September 30, 2024 and was primarily due to our net loss of $105.8 million offset by $11.5 million for noncash items and a net decrease of $13.3 million in operating assets and liabilities. The noncash items included approximately $17.8 million for stock-based compensation expense, approximately $1.1 million for the amortization of operating right-of-use assets and depreciation expense, offset by approximately $7.4 million for the net accretion of investments in available-for-sale marketable securities. The $13.3 million change in operating assets and liabilities was primarily attributable to a decrease in accrued expenses and accounts payable of approximately $10.2 million, an increase in prepaid expenses and other assets of approximately $2.5 million and a decrease in operating lease liabilities of $0.6 million.

Net cash used in operating activities was $114.9 million for the nine months ended September 30, 2023 and was primarily due to our net loss of $146.2 million offset by $16.3 million for noncash items and a net increase of $15.1 million in operating assets and liabilities. The noncash items included approximately $22.4 million for stock-based compensation expense, approximately $0.5 million for the amortization of operating right-of-use assets and depreciation expense and approximately $0.3 million for the loss on impairment of the Encinitas ROU asset and associated furniture and fixtures, offset by approximately $7.0 million for the net accretion of investments in available-for-sale marketable securities. The $15.1 million change in operating assets and liabilities was primarily attributable to an increase in accrued expenses and accounts payable of approximately $9.6 million and a decrease in prepaid expenses and other assets of approximately $5.7 million, offset by a decrease in operating lease liabilities of approximately $0.2 million.

Investing Activities

Net cash used in investing activities was $4.5 million for the nine months ended September 30, 2024 and was primarily related to the purchase of $208.4 million of investments in available-for-sale marketable securities, offset by $204.1 million in proceeds from maturities of available-for-sale marketable securities.

Net cash provided by investing activities was $54.8 million for the nine months ended September 30, 2023 and was primarily related to $298.7 million in proceeds from maturities of available-for-sale marketable securities, offset by the purchase of $243.6 million of investments in available-for-sale marketable securities.

Financing Activities

Net cash provided by financing activities was $122.1 million for the nine months ended September 30, 2024 and was attributable to approximately $95.0 million in net proceeds from the issuance of common stock in our March 2024 private placement, $26.9 million in net proceeds from the issuance of Series A Preferred Stock in our September 2024 private placement, $0.1 million in proceeds from the exercise of stock options and $0.1 million in proceeds from the issuance of common stock under the 2021 Employee Stock Purchase Plan.

Net cash provided by financing activities was $52.7 million for the nine months ended September 30, 2023 and was attributable to approximately $48.4 million in net proceeds from the issuance of common stock under the Sales Agreement and $4.3 million in proceeds from the exercise of stock options.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). The preparation of these condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses, and the disclosure of contingent assets and liabilities in our unaudited condensed consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to prepaid and accrued clinical trial and research and development costs, the measurement of the fair value of stock-based awards, available-for-sale marketable securities, the measurement of operating lease right-of-use assets and operating lease liabilities, and the evaluation of long-lived assets for impairment. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

During the nine months ended September 30, 2024 there have been no material changes to our critical accounting policies and estimates from those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations," included in our Annual Report on Form 10-K filed with the SEC on February 27, 2024.

Other Company Information

Transition from Emerging Growth Company and Smaller Reporting Company Status

On December 31, 2023, we ceased to be an "emerging growth company" ("EGC"), as defined in the JOBS Act, due to our large accelerated filer status. Accordingly, we may no longer take advantage of EGC-related reduced reporting requirements that are otherwise applicable to public companies. For example, we have previously elected to take advantage of the extended transition period for complying with new or revised accounting standards. EGC status also exempted us from having to provide an auditor attestation of internal control over financial reporting under Sarbanes-Oxley Act Section 404(b).

On December 31, 2023, we also ceased to be a "smaller reporting company" ("SRC") because the market value of our stock held by non-affiliates exceeded $700 million as of June 30, 2023. However, on June 30, 2024, the market value of our stock held by non-affiliates was less than $250 million, and thus we regained qualification as a SRC under Rule 12b-2 of the Exchange Act. We are electing to comply with the scaled disclosure relief thereby available to SRCs.

Recent Accounting Pronouncements

A description of recent accounting pronouncements that may potentially impact our financial positions, results of operations or cash flows is disclosed in Note 2 of our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the Exchange Act), and are not required to provide the information required under this item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation and supervision of our Chief Executive Officer and our Interim Principal Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(3) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and our Interim Principal Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specific in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Interim Principal Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended September 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

The information set forth in Note 5 “Commitments and Contingencies,” to the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1, of this Form 10-Q, is incorporated herein by reference.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as all other information included in this Quarterly Report. If any of the following risks actually occurs, our business, financial condition, results of operations, prospects and ability to accomplish our strategic objectives could be materially harmed. As a result, the market price of our common stock could decline and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and the market price of our common stock.

Risk Factors Summary

Our business is subject to numerous risks and uncertainties, including those outside of our control that could cause our actual results to be harmed, including risks regarding the following:

- We have a history of operating losses and have incurred significant losses since our inception. We expect to continue to incur significant losses and we may never be profitable;

- We will need to obtain substantial additional financing for the development and any commercialization of our product candidates, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development efforts or other operations;

- Our limited operating history, and the biotechnology industry in which we operate, make it difficult to evaluate our business plan and our prospects;

- Our business depends entirely on the success of our product candidates and we cannot guarantee that these product candidates will successfully complete development, receive regulatory approval, or be successfully commercialized. If we are unable to develop, receive regulatory approval for, and ultimately successfully commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed;

- Our clinical trials may fail to demonstrate adequately the safety and efficacy of our product candidates, which would prevent or delay regulatory approval and commercialization;

- Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of early, smaller-scale studies and clinical trials with a single or few clinical trial sites may not be predictive of eventual safety or effectiveness in large-scale pivotal clinical trials across multiple clinical trial sites. We may encounter substantial delays in clinical trials, or may not be able to conduct or complete clinical trials on the expected timelines, if at all;

- We face significant competition from other biotechnology and pharmaceutical companies;

- We may use our limited financial and human resources to pursue a particular type of treatment, or treatment for a particular type of disease, and fail to capitalize on programs or treatments of other types of diseases that may be more profitable or for which there is a greater likelihood of success;

- We may develop product candidates in combination with other therapies, which exposes us to additional risks and could result in our products, even if approved, being removed from the market or being less successful commercially;

- It may take longer and cost more to complete our clinical trials than we project, or we may not be able to complete them at all;

- The FDA regulatory approval process is lengthy, time-consuming and unpredictable, and we may experience significant delays in the clinical development and regulatory approval of our product candidates;

- If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, we may not be able to compete effectively or operate profitably; and

- Our stock price has been and may continue to be volatile and could fluctuate widely in response to many factors, including, without limitation, announcements of the results of clinical trials by us, our collaborators or our competitors, or positive or negative developments with respect to similar products, including those being developed by our collaborators or our competitors. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. In the past, following periods of volatility in the market price of our securities, stockholders have instituted class action securities litigation against us, which remains pending.

Risks Related to Our Business

We have a history of operating losses and have incurred significant losses since our inception. We expect to continue to incur significant losses and we may never be profitable.

Since our inception in November 2018, we have incurred significant operating losses, we have not generated any revenue from operations to date and, through the date of this report, have financed our operations primarily through public offerings and private placements of our common stock, private placements of our convertible preferred stock and convertible debt instruments. We do not have any products approved for commercial sale or for which marketing approval has been sought. During the year ended December 31, 2023, we incurred a net loss of $193.0 million, compared with a net loss of $108.4 million for the year ended December 31, 2022. As of September 30, 2024, we had an accumulated deficit of $525.0 million. For the nine months ended September 30, 2024, we incurred a net loss of $105.8 million. We do not expect to generate any meaningful revenue from product sales, unless and until we successfully complete development and obtain marketing approval for one or more of our product candidates, which we do not expect to happen for at least the next several years, if ever. We expect to incur significant and increasing operating losses in the future. The operating losses

we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

Our ability to achieve profitability in the future is dependent upon obtaining regulatory approvals for our products and successfully commercializing our products alone or with third parties. However, our operations may not be profitable even if one or more of our product candidates under development are successfully developed, approved and thereafter commercialized.

We will need to obtain substantial additional financing for the development and any commercialization of our product candidates, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development efforts or other operations.

Since our inception, we have used substantial amounts of cash to fund our operations and expect our expenses may increase substantially in the foreseeable future. As of September 30, 2024, we had an accumulated deficit of $525.0 million. Developing our product candidates and conducting clinical trials requires substantial amounts of capital. Our research and development and our operating costs have also been substantial and are expected to increase. We will also require a significant additional amount of capital to commercialize any approved products.

As of September 30, 2024, we had cash, cash equivalents and marketable securities of $274.8 million, excluding restricted cash of $1.0 million. In September 2021, we raised gross proceeds of $51.0 million in cash in connection with the sale of our Series B Convertible Preferred Stock. In October 2021, we raised gross proceeds of $174.3 million in connection with the sale of common stock in our initial public offering. In September 2022, we raised gross proceeds of $176.6 million in connection with the sale of common stock in a private placement to certain qualified institutional buyers and institutional accredited investors. In February 2023, we raised gross proceeds of $50.0 million in connection with the sale of common stock through our Open Market Sales Agreement℠ (Sales Agreement) with Jefferies LLC (Jefferies), as sales agent. In March 2024, we raised gross proceeds of $100.0 million in connection with the sale of common stock in a private placement to certain qualified institutional buyers and institutional accredited investors. In September 2024, we raised gross proceeds of $27.0 million in connection with the sale of Series A non-voting convertible preferred stock in a private placement to Aventis Inc. We are using and expect to continue to use our existing cash, cash equivalents and marketable securities to fund expenses in connection with our ongoing and any future clinical trials, our third-party manufacturing costs and the hiring of additional personnel, and for other research and development activities, working capital and general corporate purposes. We believe that existing cash, cash equivalents and marketable securities will be sufficient to fund our obligations for at least twelve months from the issuance of this Quarterly Report on Form 10-Q. Our estimate as to how long we expect our existing cash, cash equivalents and marketable securities to be available to fund our operations is based on assumptions that may be proved inaccurate, and we could deplete our available capital resources sooner than we currently expect. We will require additional capital for the further development and any commercialization of our product candidates and will need to raise additional funds sooner than we anticipate if we choose to expand more rapidly.

Our future capital requirements may depend on, and could increase significantly as a result of, many factors, including:

- the timing of, and the costs involved in, preclinical and clinical development and obtaining any regulatory approvals for our product candidates;
- the costs of manufacturing and distributing our product candidates and any products for which we receive regulatory approval, if any;
- any other product candidates we develop or acquire;
- our ability to establish and maintain strategic partnerships, licensing or other commercialization arrangements and the terms and timing of such arrangements;
- the degree and rate of market acceptance of any approved products;
- the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of other products or treatments;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;

- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing intellectual property claims, including litigation costs and the outcome of such litigation;

- the costs related to commercializing product candidates independently;

- the timing, receipt and amount of sales of, or royalties on, any approved products; and

- any product liability or other lawsuits related to our product candidates or the company.

Any fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates we may develop in the future, if approved. Adequate additional financing may not be available to us in sufficient amounts or on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder and the possibility of such issuance may cause the market price of our shares to decline. Debt financing may result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect the conduct of our business. If we raise additional funds through up-front payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to certain of our technologies or our product candidates, or grant licenses on terms that are not favorable to us, which may have a material adverse effect on our business, operating results and prospects. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the conflicts in Eastern Europe and the Middle East, and otherwise. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to significantly delay, reduce the scope of, suspend or eliminate one or more of our research or development programs, clinical trials or future commercialization efforts.

Our limited operating history, and the biotechnology industry in which we operate, make it difficult to evaluate our business plan and our prospects.

We are an early-stage company and were founded in November 2018 and have a limited operating history. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We have only a limited operating history on which a decision to invest in our company can be based and against which we can test the plans and assumptions in our business plan, and investors therefore may have difficulty evaluating the likelihood of our success. The future of our company is dependent upon our ability to implement our business plan, as that business plan may be modified from time to time by our management and board of directors.

We face the problems, expenses, difficulties, complications and delays normally associated with a pre-commercial biotechnology company, many of which are beyond our control. Accordingly, our prospects should be considered in light of the risks, expenses and difficulties frequently encountered in the establishment of a new business developing product candidates in an industry that is characterized by a number of market entrants and intense competition. Because of our size and limited resources, we may not possess the ability to successfully overcome many of the risks and uncertainties frequently encountered by pre-commercial companies involved in the rapidly evolving field of immunology. If we do not address these risks successfully, our business will suffer. In addition, as a new business, we may encounter other unforeseen expenses, difficulties, complications, delays, and other known and unknown factors. Even if our research and development efforts are successful, we may also face the risks associated with the transition from development to commercialization of new products. We may not be successful in such a transition. There can be no assurance that we will be successful in developing our business. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

Our business depends entirely on the success of our product candidates and we cannot guarantee that these product candidates will successfully complete development, receive regulatory approval, or be successfully commercialized. If we are unable to develop, receive regulatory approval for, and ultimately successfully commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

We currently have no products approved for commercial sale or for which regulatory approval to market has been sought. We have invested a significant portion of our efforts and financial resources in the development of our lead product candidates targeting NLRP3 and S1P1R, each of which is in clinical development, and expect that we will continue to invest heavily in these product candidates, as

well as in any future product candidates we may develop. Our business depends entirely on the successful development, regulatory approval and commercialization of our product candidates, each of which may never occur. Our ability to generate revenues, which we do not expect will occur for many years, if ever, is substantially dependent on our ability to develop, obtain regulatory approval for, and then successfully commercialize our product candidates, which may never occur.

Our product candidates will require substantial additional clinical and non-clinical development time, regulatory approval, commercial manufacturing arrangements, establishment of a commercial organization, significant marketing efforts, and further investment before we can generate any revenue from product sales. We currently generate no revenue and we may never be able to develop or commercialize any products. We cannot assure you that we will meet our timelines for our current or future clinical trials, which may be delayed or not completed for a number of reasons. Our product candidates are susceptible to the risks of failure inherent at any stage of product development, including the appearance of unexpected adverse events, failure to achieve primary endpoints in clinical trials or failure to meet certain internal targets to support further development. For example, in the fourth quarter of 2023, we announced topline data from a Phase 2 trial of VTX958 in moderate to severe plaque psoriasis. While the study achieved its primary and key secondary endpoints, the efficacy results did not meet our internal target to support further development of VTX958 in psoriasis. Based on these results, we elected to terminate ongoing activities in the Phase 2 trials of VTX958 in plaque psoriasis and psoriatic arthritis. In the third quarter of 2024, we announced results from a Phase 2 trial of VTX958 in participants with moderately to severely active Crohn's disease. The study did not meet its primary endpoint of change from baseline in mean CDAI score in either VTX958 dose group. VTX958 did demonstrate dose-dependent, nominally statistically significant endoscopic response rates at Week 12 as measured by SES-CD (an objective endpoint) and showed a greater magnitude of decrease compared to placebo in two key biomarkers of inflammation, C-reactive protein and fecal calprotectin. Based on these results, we are continuing the analysis of the Phase 2 data; however, we do not anticipate committing significant internal resources to further development of VTX958.

Even if our product candidates are successful in clinical trials, we are not permitted to market or promote any of our product candidates before we receive regulatory approval from the U.S. Food and Drug Administration, or the FDA, or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates or regulatory approval that will allow us to successfully commercialize our product candidates. If we do not receive FDA or comparable foreign regulatory approval with the necessary conditions to allow commercialization, we will not be able to generate revenue from those product candidates in the United States or elsewhere in the foreseeable future, or at all. Any significant delays in obtaining approval for and commercializing our product candidates will have a material adverse impact on our business and financial condition.

We have not previously submitted a New Drug Application, or NDA, for any small molecule product candidates or similar marketing application to the FDA or comparable foreign regulatory authorities, for any product candidate, and we cannot be certain that our current or any future product candidates will be successful in clinical trials or receive regulatory approval. Furthermore, although we do not expect to submit an NDA with comparisons to existing or more established therapies and we do not expect the FDA to base its determination with respect to product approval on such comparisons, the FDA may factor these comparisons into its decision whether to approve our product candidates. The FDA may also consider its approvals of competing products, which may alter the treatment landscape concurrently with their review of our NDA filings, and which may lead to changes in the FDA's review requirements that have been previously communicated to us and our interpretation thereof, including changes to requirements for clinical data or clinical study design. Such changes could delay approval or necessitate withdrawal of our NDA filings.

If approved for marketing by applicable regulatory authorities, our ability to generate revenues from our product candidates will depend on our ability to:

- price our product candidates competitively such that third-party and government reimbursement leads to broad product adoption;
- prepare a broad network of clinical sites for administration of our product;
- create market demand for our product candidates through our own marketing and sales activities, and any other arrangements to promote these product candidates that we may otherwise establish;
- receive regulatory approval for the targeted patient population(s) and claims that are necessary or desirable for successful marketing;
- effectively commercialize any of our product candidates that receive regulatory approval;

- manufacture product candidates through contract manufacturing organizations, or CMOs, or in our own, or our affiliates', manufacturing facility in sufficient quantities and at acceptable quality and manufacturing cost to meet commercial demand at launch and thereafter;

- establish and maintain agreements with wholesalers, distributors, pharmacies, and group purchasing organizations on commercially reasonable terms;

- obtain, maintain, protect and enforce patent and other intellectual property protection and regulatory exclusivity for our product candidates;

- maintain compliance with applicable laws, regulations, and guidance specific to commercialization including interactions with health care professionals, patient advocacy groups, and communication of health care economic information to payors and formularies;

- achieve market acceptance of our product candidates by patients, the medical community, and third-party payors;

- achieve appropriate reimbursement for our product candidates;

- maintain a distribution and logistics network capable of product storage within our specifications and regulatory guidelines, and further capable of timely product delivery to commercial clinical sites;

- effectively compete with other therapies or competitors; and

- assure that our product candidates will be used as directed and that additional unexpected safety risks will not arise.

It may take longer and cost more to complete our clinical trials than we project, or we may not be able to complete them at all.

For budgeting and planning purposes, we have projected the date for the commencement of future trials, and continuation and completion of our ongoing clinical trials. However, a number of factors, including scheduling conflicts with participating clinicians and clinical institutions, and difficulties in identifying and enrolling patients who meet trial eligibility criteria, may cause significant delays. We may not commence or complete clinical trials involving any of our products as projected or may not conduct them successfully.

Our ability to enroll or treat patients in our clinical trials, or the duration or costs of those clinical trials, could be affected by multiple factors, including, preliminary clinical results, which may include efficacy and safety results, but may not be reflected in the final analyses of these clinical trials. Depending on the outcome of our clinical trials, we may need to conduct one or more follow-up or supporting clinical trials in order to develop our products for FDA approval. Many companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in late-stage clinical trials even after achieving positive results in earlier development, and we cannot be certain that we will not face such setbacks.

Furthermore, the timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Accordingly, we cannot guarantee that the trial will progress as planned or as scheduled. Delays in enrollment may result in increased costs or may affect the timing or outcome of our ongoing clinical trial and planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

Our clinical trials may fail to demonstrate adequately the safety and efficacy of our product candidates, which would prevent or delay regulatory approval and commercialization.

The clinical trials of our product candidates are, and, if approved, the manufacturing and marketing of our products will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. For our small molecule product candidates, we will need to demonstrate that they are safe and effective for their target indications and must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use. Regulatory authorities may ultimately disagree with our chosen endpoints or

may find that our clinical studies or clinical study results do not support product approval. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. For example, in the fourth quarter of 2023, we announced topline data from a Phase 2 trial of VTX958 in moderate to severe plaque psoriasis. While the study achieved its primary and key secondary endpoints, the efficacy results did not meet our internal target to support further development of VTX958 in psoriasis. Based on these results, we elected to terminate ongoing activities in the Phase 2 trials of VTX958 in plaque psoriasis and psoriatic arthritis. In the third quarter of 2024, we announced results from a Phase 2 trial of VTX958 in participants with moderately to severely active Crohn's disease. The study did not meet its primary endpoint of change from baseline in mean CDAI score in either VTX958 dose group. VTX958 did demonstrate dose-dependent, nominally statistically significant endoscopic response rates at Week 12 as measured by SES-CD (an objective endpoint) and showed a greater magnitude of decrease compared to placebo in two key biomarkers of inflammation, C-reactive protein and fecal calprotectin. Based on these results, we are continuing the analysis of the Phase 2 data; however, we do not anticipate committing significant internal resources to further development of VTX958.

There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. Preclinical studies may also reveal unfavorable product candidate characteristics, including safety concerns. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. Our current and future clinical trial results may not be successful. Moreover, should there be a flaw in a clinical trial or cross-site variation that are not properly addressed, it may not become apparent until the clinical trial is well advanced or until data from different sites become available. For example, our clinical trials are conducted at multiple sites in different geographies, with different levels of experience and expertise by medical professionals, and these professionals may make mistakes or introduce site-specific variation that could have an impact on the clinical data or on clinical trials by disqualifying patients or impacting patient ability to continue in a study.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of early, smaller-scale studies and clinical trials with a single or few clinical trial sites may not be predictive of eventual safety or effectiveness in large-scale pivotal clinical trials across multiple clinical trial sites. We may encounter substantial delays in clinical trials, or may not be able to conduct or complete clinical trials on the expected timelines, if at all.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive nonclinical studies and clinical trials that our product candidates are both safe and effective for each target indication. Preclinical and clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the preclinical study and clinical trial processes, and, because our product candidates are in an early stage of development, there is a high risk of failure and we may never succeed in developing marketable products. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Although product candidates may demonstrate promising results in preclinical studies and early clinical trials, they may not prove to be safe or effective in subsequent clinical trials. For example, testing on animals occurs under different conditions than testing in humans and therefore, the results of animal studies may not accurately predict safety and effectiveness in humans. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through preclinical studies and clinical trials.

Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. Likewise, early, smaller-scale studies and clinical trials with a single or few clinical trial sites may not be predictive of eventual safety or effectiveness in large-scale pivotal clinical trials across multiple clinical trial sites. Even if data from a pivotal clinical trial are positive, regulators may not agree that such data are sufficient for approval and may require that we conduct additional clinical trials, which could materially delay our anticipated development timelines, require additional funding for such additional clinical trials, and adversely impact our business. Most product candidates that commence preclinical studies and clinical trials are never approved as products.

In some instances, there can be significant variability in safety or efficacy results between different preclinical studies and clinical trials of the same product candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In

such an event, our clinical trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Drug-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, some of the clinical trials we conduct in the future may be open-label in study design and may be conducted at a limited number of clinical sites on a limited number of patients. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the institutional review boards, or IRBs, of the institutions in which such clinical trials are being conducted, by a data safety monitoring board for such clinical trial or by the FDA or comparable foreign regulatory authorities. Clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the trial design or implementation of our clinical trials;
- changes in governmental regulations, including FDA policies and regulatory requirements for clinical trials and standards or data requirements for pharmaceutical approval or administrative actions;
- delays in our ability to commence a clinical trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining IRB approval at each clinical trial site;
- recruiting an adequate number of suitable patients to participate in a clinical trial;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate;
- having subjects complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from clinical trial protocol or dropping out of a clinical trial;
- failure to demonstrate a clinical benefit from using a product candidate;
- addressing subject safety concerns that arise during the course of a clinical trial;
- adding a sufficient number of clinical trial sites; or
- obtaining sufficient product supply of product candidate for use in preclinical studies or clinical trials from third-party suppliers.

Further, conducting clinical trials in foreign countries can present additional risks that may delay completion of our clinical trials, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;

- diminished protection of intellectual property in some countries;
- the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of cultural differences in medical practices and clinical research;
- managing additional administrative burdens associated with foreign regulatory schemes; and
- interruptions or delays in our clinical trials resulting from geopolitical events, such as war or terrorism.

If our relationships with any of our CROs is terminated, we may be unable to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. Furthermore, the United States and its European allies have imposed significant sanctions against Russia and Belarus, including regional embargoes, full blocking sanctions, and other restrictions targeting major Russian financial institutions. Our ability to conduct clinical trials in Russia, Belarus, Ukraine and elsewhere in the region may also become restricted under applicable sanctions laws.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

If the results of our current and future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may:

- incur unplanned costs;
- be delayed in or prevented from obtaining marketing approval for our product candidates;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings including boxed warnings;
- be subject to changes in the way the product is administered;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw their approval of the product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy, or REMS;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities and receipt of necessary marketing approvals could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients, who remain in the trial until its conclusion. We may experience difficulties or delays in patient enrollment in our clinical trials for a variety of reasons, including:

- the size and nature of the patient population;
- the number of ongoing and planned clinical trials in the indications that we are pursuing, such as UC, which may have very slow enrollment rates;
- the severity of the disease under investigation;
- the patient eligibility criteria defined in the protocol, including biomarker-driven identification and/or certain highly-specific criteria related to stage of disease progression, which may limit the patient populations eligible for our clinical trials to a greater extent than competing clinical trials for the same indication that do not have biomarker-driven patient eligibility criteria;
- the size of the study population required for analysis of the trial's primary or secondary endpoints;
- the proximity of patients to trial sites;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the efforts to facilitate timely enrollment in clinical trials and the effectiveness of recruiting publicity;
- the patient referral practices of physicians;
- physicians' willingness to screen their patients for biomarkers to indicate which patients may be eligible for enrollment in our clinical trials;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate or enrollment in these clinical trials may be slower than we anticipate, potentially affecting our timelines for approval of our product candidates;
- patients that enroll in our clinical trials may misrepresent their eligibility or may otherwise not comply with the clinical trial protocol, resulting in the need to drop such patients from the clinical trial, increase the needed enrollment size for the clinical trial or extend the clinical trial's duration;
- clinical investigators enrolling patients who do not meet the enrollment criteria, requiring the inclusion of additional patients in the clinical trial;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;
- approval of new indications for existing therapies or approval of new therapies in general;
- our contracted clinical sites' or investigators' ability to obtain and maintain patient consents;
- amendments to our clinical protocols, which may affect enrollment in, or results of, our clinical trials, including amendments we have made to further define the patient population to be studied;

- the impact of material adverse events, such as the COVID-19 pandemic, which may affect the conduct of a clinical trial, including by slowing potential enrollment or reducing the number of eligible patients for clinical trials; and

- the risk that patients enrolled in clinical trials will not complete a clinical trial, return for post-treatment follow-up, or follow the required study procedures. For instance, patients, including patients in any control groups, may withdraw from the clinical trial if they are not experiencing improvement in their underlying disease or condition. Withdrawal of patients from our clinical trials may compromise the quality of our data.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators is limited, we may need to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used treatments for inflammatory diseases and autoimmune disorders, potential patients and their doctors may be inclined to use conventional therapies rather than enroll patients in any future clinical trial. Additionally, patients, including patients in any control groups, may withdraw from the clinical trial if they are not experiencing improvement in their underlying disease or condition. Withdrawal of patients from our clinical trials may compromise the quality of our data.

Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment or small population size may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these clinical trials and adversely affect our ability to advance the development of our product candidates.

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

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

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and could have a material adverse effect on the success of our business. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, results of operations, prospects or financial condition. Further, disclosure of interim, top-line or preliminary data by us or by our competitors could result in volatility in the price of our common stock.

We face significant competition from other biotechnology and pharmaceutical companies.

Competition in the treatment of inflammatory diseases and autoimmune disorders is intense and is accentuated by the rapid pace of technological development. Research and discoveries by others may result in breakthroughs which may render our product candidates

obsolete even before they are approved or generate any revenue. There are products that are approved and currently under development by others that could compete with the product candidates that we are developing. Our competitors may:

- develop safer, more convenient or more effective therapeutic products;
- develop therapeutic products that are less expensive or have better reimbursement from private or public payors;
- reach the market more rapidly, reducing the potential sales of our products; or
- establish superior proprietary positions.

Due to the promising clinical therapeutic effect of competitor therapies in clinical trials, we anticipate substantial direct competition from other organizations developing treatments for inflammatory diseases and autoimmune disorders, such as UC and CD. In particular, we expect to compete with other new therapies for our lead indications developed by companies such as Bristol-Myers Squibb (BMS), Pfizer and others. Many of these companies and our other current and potential competitors have substantially greater research and development capabilities and financial, scientific, regulatory, manufacturing, marketing, sales, human resources and experience than we do. Many of our competitors have several therapeutic products that have already been developed, approved and successfully commercialized, or are in the process of obtaining regulatory approval for their therapeutic products in the United States and internationally. Our competitors may obtain regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in competitors establishing a strong market position before we are able to enter the market.

Universities and public and private research institutions in the United States and Europe are also potential competitors. While these universities and public and private research institutions primarily have educational objectives, they may develop proprietary technologies that lead to other FDA approved therapies or that secure patent protection that we may need for the development of our product candidates and that can be licensed or sold to other parties, including our competitors.

We are developing our lead product candidates, VTX3232, VTX2735 and VTX002, for the treatment of inflammatory diseases and autoimmune disorders, including moderately to severely active ulcerative colitis. Currently, there are numerous companies that are developing various alternate treatments for these indications. With respect to VTX002, if approved, it would compete with a number of companies developing product candidates, as well as Zeposia (ozanimod), which is an S1P receptor modulator marketed by BMS, and Velsipity (etrasimod), which is an S1P receptor modulator marketed by Pfizer. With respect to VTX3232 and VTX2735, we are aware of several other NLRP3 inhibitors in clinical or preclinical development, including selnoflast, which is being developed by Roche, VENT-01 and VENT-02, which are being developed by Ventus Therapeutics, NT-0796 and NT-0249, which are being developed by Nodthera, usnoflast, which is being developed by Zydus Lifesciences, and dapansutrile, which is being developed by Olatec. Accordingly, our lead product candidates will face significant competition from multiple companies. Even if we obtain regulatory approval for our lead product candidates, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our products. We may not be able to implement our business plan if the acceptance of our products is inhibited by price competition or the reluctance of physicians to switch from other methods of treatment to our product, or if physicians switch to other new therapies, drugs or biologic products or choose to reserve our product for use in limited circumstances.

In addition, we could face litigation or other proceedings with respect to the scope, ownership, validity and/or enforceability of our patents or other intellectual property relating to our competitors' products, and our competitors may allege that our product candidates infringe, misappropriate or otherwise violate their intellectual property. See "—Risks Related to Intellectual Property."

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We have limited experience as a company conducting clinical trials and have relied and will rely on third parties and related parties to conduct our preclinical studies and clinical trials. Any failure by a third party, related party, or by us to conduct the clinical trials according to Good Clinical Practice and Good Manufacturing Practice, and in a timely manner may delay or prevent our ability to seek or obtain regulatory approval for or commercialize our product candidates.

We expect to rely on medical institutions, academic institutions or contract research organizations, or CROs, to conduct, supervise or monitor some or all aspects of clinical trials involving our product candidates. We will have less control over the timing and other

aspects of these clinical trials than if we conducted them entirely on our own. If we fail to commence or complete, or experience delays in, any of our planned clinical trials, our stock price and our ability to conduct our business as currently planned could be harmed.

We have a limited history of conducting clinical trials and have no experience as a company in filing and supporting the applications necessary to gain marketing approvals. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety or efficacy for that indication. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities and clinical trial sites by, applicable regulatory authorities.

Large-scale clinical trials require significant financial and management resources, and reliance on third-party clinical investigators, CROs, CMOs, partners or consultants. Relying on third-party clinical investigators, CROs or CMOs may force us to encounter delays and challenges that are outside of our control. We may not be able to demonstrate sufficient comparability between products manufactured at different facilities to allow for inclusion of the clinical results from patients treated with products from these different facilities, in our product registrations. Further, our CMOs may not be able to manufacture our product candidates or otherwise fulfill their obligations to us because of interruptions to their business, including the loss of their key staff or interruptions to their raw material supply.

Our reliance on these third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable trial protocol and legal, regulatory and scientific standards, and our reliance on the CROs, clinical trial sites, and other third parties does not relieve us of these responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the clinical trial and for ensuring that our preclinical studies are conducted in accordance with GCP, as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with Good Clinical Practice, or GCP, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections (including pre-approval inspections once an NDA is filed with the FDA) of trial sponsors, clinical investigators, trial sites and certain third parties including CMOs and CROs. If we, our CROs, clinical trial sites, or other third parties fail to comply with applicable GCP or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations.

Our clinical trials must be conducted with product candidates that were produced under current Good Manufacturing Practices, or cGMP, regulations. Our failure to comply or our CMOs' failure to comply with these cGMP regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register certain clinical trials and post the results of certain completed clinical trials on a government sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so could result in enforcement actions and adverse publicity.

We also rely on third parties other than our CMOs to manufacture, package, label and ship our product candidates for the clinical trials that we conduct. We may also find that the manufacture of our product candidates is more difficult than anticipated, resulting in an inability to produce a sufficient amount of our product candidates for our clinical trials or, if approved, commercial supply. Moreover, because of the complexity and novelty of our manufacturing process, there are only a limited number of manufacturers who have the capability of producing our product candidates. Should any of our contract manufacturers no longer produce our product candidates, it may take us significant time to find a replacement, if we are able to find a replacement at all. Any performance failure on the part of these third parties could delay clinical development or marketing approval of our product candidates or commercialization of our product candidates, if approved, producing additional losses and depriving us of potential product revenue.

Our CMOs, CROs, clinical trial sites and other third parties may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting clinical trials or other therapeutic development activities that could harm our competitive position. In addition, these third parties are not our employees, and except for remedies available to us under our agreements with them, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical trials and preclinical programs. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical trial protocols, regulatory requirements or for other reasons, our clinical trials may need to be repeated, extended, delayed or terminated. In the event we need to repeat, extend, delay or terminate our clinical trials, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates, and

we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be materially and adversely affected.

If any of our relationships with these third parties terminate, we may not be able to enter into alternative arrangements or do so on commercially reasonable terms. Switching or adding additional contractors involves additional cost and time and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. In addition, if an agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of those product candidates completely.

We announced positive results from the Phase 2 trial of VTX002 in patients with moderately to severely active ulcerative colitis during the fourth quarter of 2023. We intend to identify a partner or other source of nondilutive financing to support a pivotal Phase 3 trial of VTX002 in ulcerative colitis. In the first quarter of 2024, we announced positive topline results from a Phase 2 trial of our peripheral NLRP3 inhibitor VTX2735 in patients with Cryopyrin-Associated Periodic Syndrome (CAPS) and a Phase 1 trial of our novel CNS-penetrant NLRP3 inhibitor VTX3232 in adult healthy volunteers. We initiated a Phase 2a trial of VTX3232 in participants with early Parkinson's disease in August 2024. We expect to report topline results from this trial in the first half of 2025. We also expect to initiate a Phase 2 trial of VTX3232 in participants with obesity and certain additional risk factors for cardiovascular disease during the fourth quarter of 2024. Topline results from this trial are anticipated in the second half of 2025. We plan to evaluate VTX2735 for further development in cardiovascular diseases, with an initial focus on recurrent pericarditis. We expect to initiate a Phase 2 trial of VTX2735 in participants with recurrent pericarditis during the fourth quarter of 2024. Topline results from this trial are anticipated in the second half of 2025. Our relative lack of experience conducting clinical trials may contribute to our planned clinical trials not beginning or completing on time, if at all. Large-scale clinical trials will require significant additional resources and reliance on CROs, clinical investigators or consultants. Consequently, our reliance on outside parties may introduce delays beyond our control. Our CROs and other third parties must communicate and coordinate with one another in order for our trials to be successful. Additionally, our CROs and other third parties may also have relationships with other commercial entities, some of which may compete with us. If our CROs or other third parties conducting our clinical trials do not perform their contractual duties or regulatory obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical trial protocols, GCP or other regulatory requirements or for any other reason, we may need to conduct additional clinical trials or enter into new arrangements with alternative CROs, clinical investigators or other third parties. We may be unable to enter into arrangements with alternative CROs on commercially reasonable terms, or at all.

We and the third parties upon which we rely are required to comply with GCP. GCP are regulations and guidelines enforced by regulatory authorities around the world, through periodic inspections, for products in clinical development. If we or these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and have to be repeated, and our submission of marketing applications may be delayed or the regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We are subject to the risk that, upon inspection, a regulatory authority will determine that any of our clinical trials fails to comply or failed to comply with applicable GCP regulations. In addition, our clinical trials must be conducted with material produced under GMP regulations, which are enforced by regulatory authorities. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be significantly impacted if our CROs, clinical investigators or other third parties violate federal or state healthcare fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

We also anticipate that part of our strategy for pursuing the wide range of indications potentially addressed by our product candidates may involve further investigator-initiated clinical trials. While these trials generally provide us with valuable clinical data that can inform our future development strategy in a cost-efficient manner, we generally have less control over not only the conduct but also the design of these clinical trials. Third-party investigators may design clinical trials involving our product candidates with clinical endpoints that are more difficult to achieve or in other ways that increase the risk of negative clinical trial results compared to clinical trials we may design on our own. Negative results in investigator-initiated clinical trials, regardless of how the clinical trial was designed or conducted, could have a material adverse effect on our prospects and the perception of our product candidates.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and/or a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

We may be required to conduct additional clinical trials or modify current or future clinical trials.

Clinical testing is expensive, time consuming and subject to uncertainty. We cannot guarantee that any current or future clinical studies will be conducted as planned or completed on schedule, if at all, or that any of our product candidates will receive regulatory approval. We are presently conducting trials in multiple indications, such as moderately to severely active ulcerative colitis. Even as these trials progress, issues may arise that could require us to suspend or terminate such clinical trials or could cause the results of one cohort to differ from a prior cohort. For example, we may experience slower than anticipated enrollment in our clinical trials, which may consequently delay our NDA filing timelines or permit competitors to obtain approvals that may alter our NDA filing strategy. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful. In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the clinical trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional clinical trials in support of potential approval of our product candidates.

Events that may prevent successful or timely initiation or completion of clinical development include:

- regulators or Institutional Review Boards, or IRBs, may not authorize us or our investigators to commence a clinical trial, conduct a clinical trial at a prospective trial site, or amend trial protocols, or regulators or IRBs may require that we modify or amend our clinical trial protocols;
- delays in reaching a consensus or inability to obtain agreement with regulatory agencies on study design or eligibility criteria for patient enrollment;
- the FDA or comparable foreign regulatory authorities may disagree with our intended indications, study design or our interpretation of data from preclinical studies and clinical trials or find that a product candidate's benefits do not outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may not accept data from studies with clinical trial sites in foreign countries (e.g., Australia, Poland, Germany, Belgium, Georgia, Hungary, Israel and Italy);
- the FDA may not allow us to use the clinical trial data from a research institution to support an IND if we cannot demonstrate the comparability of our product candidates with the product candidate used by the relevant research institution in its clinical studies;
- delays in or failure to reach an agreement on acceptable terms with prospective CROs and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- imposition of a temporary or permanent clinical hold, suspensions or terminations by regulatory agencies, IRBs, or us for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate, or due to findings of undesirable effects caused by a biologically or mechanistically similar therapeutic or therapeutic candidate;
- delays in adding new investigators or clinical trial sites, or withdrawal of clinical trial sites from a study;
- failure by our CROs, clinical trial sites or patients, or other third parties, or us to adhere to clinical study requirements, including regulatory, contractual or protocol requirements;
- failure to perform in accordance with the GCP requirements, or applicable regulatory guidelines in other countries;

- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;

- changes in regulatory requirements, policies and guidance that require amending or submitting new clinical protocols to regulatory authorities and IRBs, conducting additional studies, implementation of other changes that alter the data requirements or standards for obtaining regulatory approval, and other regulatory changes which may cause delays in our development programs, or changes to regulatory review times;

- there may be regulatory questions or disagreements regarding interpretations of data and results, or new information may emerge regarding our product candidates;

- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;

- the cost of clinical studies of our product candidates being greater than we anticipate, or we may have insufficient funds for a clinical trial or to pay the substantial user fees required by the FDA upon the filing of an NDA;

- clinical trials of our product candidates producing negative or inconclusive results may fail to provide sufficient data and information to support product approval, or our clinical trials may fail to reach the necessary level of statistical or clinical significance, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials, or preclinical studies, or abandon product development programs;

- interruption of, or delays in receiving, supplies of our product candidates or other drugs or components of our therapies due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;

- early results from our clinical trials of our product candidates may be negatively affected by changes in efficacy measures, such as overall response rate and duration of response, as more patients are enrolled in our clinical trials or as new cohorts of our clinical trials are tested, and overall response rate and duration of response may be negatively affected by the inclusion of unconfirmed responses in preliminary results that we report if such responses are not later confirmed;

- we may not be able to demonstrate that a product candidate provides an advantage over current standards of care or current or future competitive therapies in development;

- there may be changes to the therapeutics or their regulatory status, which we are administering in combination with our product candidates;

- the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or our manufacturing facilities for clinical and future commercial supplies;

- the FDA or comparable regulatory authorities may take longer than we anticipate making a decision on our product candidates;

- transfer of our manufacturing processes to our CMOs or other larger-scale facilities operated by a CMO or by us and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process;

- our use of different manufacturing processes within our clinical trials, and any effects that may result from the use of different processes on the clinical data that we have reported and will report in the future;

- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing, including as a result of any quality issues associated with the CMO; and

- business interruptions, changes in export regulation and controls, trade restrictions with companies based in certain countries, such as Russia or China, and other domestic and foreign regulations or restrictions resulting from geopolitical actions or national security concerns, including war, regional conflicts, terrorism, or natural disasters.

We also may conduct clinical and preclinical research in collaboration with other academic, pharmaceutical and biotechnology entities in which we combine our technologies with those of our collaborators. Such collaborations may be subject to additional delays because of the management of the trials, contract negotiations, the need to obtain agreement from multiple parties and the necessity of obtaining

additional approvals for therapeutics used in the combination trials. These combination therapies will require additional testing and clinical trials will require additional FDA regulatory approval and will increase our future cost of expenses.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing changes to our product candidates, we may be required to, or we may elect to, conduct additional studies to bridge our modified product candidates to earlier versions. These changes may require FDA approval or notification and may not have their desired effect. The FDA may also not accept data from prior versions of the product to support an application, delaying our clinical trials or programs or necessitating additional clinical trials or preclinical studies. We may find that this change has unintended consequences that necessitates additional development and manufacturing work, additional clinical trials and preclinical studies, or that results in refusal to file or non-approval of an NDA.

Clinical trial delays could shorten any periods during which our product candidates have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. The number and types of preclinical studies and clinical trials that will be required for regulatory approval also vary depending on the product candidate, the disease or condition that the product candidate is designed to address and the regulations applicable to any particular product candidate. Approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. It is possible that any product candidates we may seek to develop in the future will never obtain the appropriate regulatory approvals necessary for us or any future collaborators to commence product sales. Any delay in completing development or obtaining, or failing to obtain, required approvals could also materially adversely affect our ability or that of any of our collaborators to generate revenue from any such product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price.

In addition to U.S. regulatory requirements, we are also subject to regulation by foreign regulatory authorities, ethics committees, and other governmental entities with respect to clinical trials we conduct or sponsor outside of the U.S. For example, the EU Clinical Trials Regulation, or CTR, became applicable on January 31, 2022, repealing the EU Clinical Trials Directive. The implementation of the CTR also includes the implementation of the Clinical Trials Information System, a new clinical trial portal and database that will be maintained by the EMA in collaboration with the European Commission and the EU Member States. Complying with changes in regulatory requirements can incur additional costs, delay our clinical development plans, or expose us to greater liability if we are slow or unable to adapt to changes in existing requirements or new requirements or policies governing our business operations, including our clinical trials.

Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences, which could harm our business, financial condition, results of operations, and prospects significantly.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects, adverse events or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us, IRBs, Drug Safety Monitoring Boards, or DSMBs, or the FDA or comparable foreign regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Even if we were to receive product approval, such approval could be contingent on inclusion of unfavorable information in our product labeling, such as limitations on the indicated uses for which the products may be marketed or distributed, a label with significant safety warnings, including boxed warnings, contraindications, and precautions, a label without statements necessary or desirable for successful commercialization, or requirements for costly post marketing testing and surveillance, or other requirements, including a Risk Evaluation and Mitigation Strategy, or REMS, to monitor the safety or efficacy of the products, and in turn prevent us from commercializing and generating revenues from the sale of our current or future product candidates.

If unacceptable toxicities or side effects arise in the development of our product candidates, IRBs, DSMBs or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials, order our clinical trials to be placed on clinical hold, or deny approval of our product candidates for any or all targeted indications. The FDA or comparable foreign regulatory authorities may also require additional data, clinical, or pre-clinical studies if unacceptable toxicities arise. We may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk/benefit perspective. Toxicities associated with our clinical trials and products

may also negatively impact our ability to conduct clinical trials in larger patient populations, such as in patients that have not yet been treated with other therapies or have not yet progressed on other therapies.

Treatment-emergent adverse events could also affect patient recruitment or the ability of enrolled subjects to complete our clinical trials or could result in potential product liability claims. Potential side effects associated with our product candidates may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from our product candidates may not be normally encountered in the general patient population and by medical personnel. Any of these occurrences could harm our business, financial condition, results of operations, and prospects significantly.

In addition, even if we successfully advance our product candidates or any future product candidates through clinical trials, such trials will only include a limited number of patients and limited duration of exposure to our product candidates. As a result, we cannot be assured that adverse effects of our product candidates will not be uncovered when a significantly larger number of patients are exposed to the product candidate after approval. Further, any clinical trials may not be sufficient to determine the effect and safety consequences of using our product candidates over a multi-year period.

If any of our product candidates receives marketing approval and we or others later identify undesirable side effects caused by such products or products with similar mechanism of action, a number of potentially significant negative consequences could result, including:

- regulatory authorities may suspend, limit or withdraw approvals of such product, or seek an injunction against its manufacture or distribution;
- we may be required to conduct additional clinical trials or post-approval studies;
- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as a black box warning or a contraindication or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to implement a REMS or create a Medication Guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients;
- we may be subject to fines, injunctions or the imposition of criminal penalties;
- the product may become less competitive; and
- our reputation may suffer.

If any of the foregoing events occur, it could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, if one or more of our product candidates prove to be unsafe, our entire pipeline could be affected, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

The manufacturing of our product candidates is complex, and we may encounter difficulties in production, particularly with respect to process development, quality control, and scaling-up of our manufacturing capabilities. If we or our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to achieve and maintain a commercially viable cost structure.

Currently, our product candidates are manufactured using processes developed by our third-party CMOs that we may not intend to use for more advanced clinical trials or commercialization. We may ultimately be unable to reduce the cost of goods for our product candidates to levels that will allow for an attractive return on investment if and when those product candidates are commercialized.

Our product candidates may compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing for us and willing to do so. If our CMOs should cease manufacturing for us, we would experience delays in obtaining sufficient quantities of our product candidates for clinical trials and, if approved, commercial supply. Further, our CMOs may breach, terminate or not renew these agreements. If we were to need to find alternative manufacturing facilities it would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. The commercial terms of any new arrangement could be less favorable than our existing arrangements and the expenses relating to the transfer of necessary technology and processes could be significant.

Reliance on third-party manufacturers entails exposure to risks to which we would not be subject if we manufactured the product candidate ourselves, including:

- inability to negotiate manufacturing and quality agreements with third parties under commercially reasonable terms;
- reduced day-to-day control over the manufacturing process for our product candidates as a result of using third-party manufacturers for all aspects of manufacturing activities;
- reduced control over the protection of our trade secrets, know-how and other proprietary information from misappropriation or inadvertent disclosure or from being used in such a way as to expose us to potential litigation;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that may be costly or damaging to us or result in delays in the development or commercialization of our product candidates; and
- disruptions to the operations of our third-party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier.

Any problems or delays we or our CMOs experience in preparing for commercial scale manufacturing of a product candidate may result in a delay in the FDA approval of the product candidate or may impair our ability to manufacture commercial quantities or such quantities at an acceptable cost, which could result in the delay, prevention or impairment of clinical development and commercialization of our product candidates and could adversely affect our business. Furthermore, if our product candidates are approved and we or our commercial manufacturers fail to deliver the required commercial quantities of our product candidates on a timely basis and at reasonable costs, we would likely be unable to meet demand for our products and we would lose potential revenues, which would adversely affect our business, financial condition, results of operations, and prospects.

In addition, the manufacturing process and facilities for any product candidates that we may develop is subject to FDA and foreign regulatory authority approval processes, and we or our CMOs will need to meet all applicable FDA and foreign regulatory authority requirements, including cGMP, on an ongoing basis. The cGMP requirements include quality control, quality assurance and the maintenance of records and documentation. The FDA and other regulatory authorities enforce these requirements through facility inspections. Manufacturing facilities must submit to pre-approval inspections by the FDA that will be conducted after we submit our marketing applications, including our NDAs, to the FDA. Manufacturers are also subject to continuing FDA and other regulatory authority inspections following marketing approval. Further, we, in cooperation with our CMOs, must supply all necessary chemistry, manufacturing and quality control documentation in support of an NDA on a timely basis. There is no guarantee that we or our CMOs will be able to successfully pass all aspects of a pre-approval inspection by the FDA or other foreign regulatory authorities.

Our CMOs' manufacturing facilities may be unable to comply with our specifications, cGMP, or with other FDA, state, and foreign regulatory requirements. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of product candidate that may not be detectable in final product testing. If we or our CMOs are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, or in

accordance with the strict regulatory requirements, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Deviations from manufacturing requirements may further require remedial measures that may be costly and/or time-consuming for us or a third party to implement and may include the temporary or permanent suspension of a clinical trial or, if approved, commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business, financial condition, results of operations, and prospects.

Even to the extent we use and continue to use CMOs, we are ultimately responsible for the manufacture of our products and product candidates. A failure to comply with these requirements may result in regulatory enforcement actions against our manufacturers or us, including fines and civil and criminal penalties, which could result in imprisonment, suspension or restrictions of production, injunctions, delay or denial of product approval or supplements to approved products, clinical holds or termination of clinical trials, warning or untitled letters, regulatory authority communications warning the public about safety issues, refusal to permit the import or export of the products, product seizure, detention, or recall, operating restrictions, suits under the civil False Claims Act, corporate integrity agreements, consent decrees, or withdrawal of product approval.

Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and prospects.

Additionally, there is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross-border operations. The U.S. government has made and continues to make significant additional changes in U.S. trade policy and may continue to take future actions that could negatively impact U.S. trade. For example, legislation has been introduced in Congress to limit certain U.S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers' ability to engage in business in the U.S. We contract with various Chinese biotechnology companies to manufacture raw materials and to conduct non-clinical research for our product candidates. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. If we are unable to obtain or use services from existing service providers or become unable to export or sell our products to any of our customers or service providers, our business, liquidity, financial condition, and/or results of operations would be materially and adversely affected.

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

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

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with will likely expect to be granted rights to publish data arising out of such collaboration and any joint research and development programs may require us to share trade secrets under the terms of our research and development or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

Small molecule therapeutics rely on the availability of reagents, intermediates, specialized equipment and other specialty materials, which may not be available to us on acceptable terms or at all. For some of these reagents, intermediates, specialized equipment and other specialty materials, we rely or may rely on sole source vendors or a limited number of vendors, which could impair our ability to manufacture and supply our product candidates.

Manufacturing our product candidates requires many reagents, which are substances used in our manufacturing processes to bring about chemical reactions, intermediates, specialized equipment and other specialty materials, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial production. We currently depend on a limited number of vendors for certain intermediates, specialized equipment and other specialty materials used in the manufacture of our product candidates. Some of these suppliers may not have the capacity to support clinical trials and commercial products manufactured under cGMP or may otherwise be ill-equipped to support our needs. Accordingly, we may experience delays in receiving key intermediates, materials and equipment to support clinical or commercial manufacturing.

For some of these reagents, intermediates, equipment and materials, we currently rely and may in the future rely on sole source vendors or a limited number of vendors. An inability to continue to source product from any of these suppliers, which could be due to a number of issues, including regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands or quality issues, could adversely affect our ability to satisfy demand for our product candidates. If our product candidates are approved, such inability to source product from our suppliers could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business. As we continue to develop and scale our manufacturing process, we expect that we will need to obtain rights to and supplies of certain reagents, intermediates, equipment and materials to be used as part of that process. We may not be able to obtain rights to such reagents, intermediates, equipment and materials on commercially reasonable terms, or at all, and if we are unable to alter our process in a commercially viable manner to avoid the use of such reagents, intermediates, equipment or materials or find a suitable substitute, it would have a material adverse effect on our business. Even if we are able to alter our process so as to use other reagents, intermediates, equipment or materials, such a change may lead to a delay in our clinical development and, if approved, commercialization plans. If such a change occurs for a product candidate that is already in clinical testing, the change may require us to perform comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials, which may cause delays in our clinical development and commercialization plans.

Changes in the manufacturing process or formulation may result in additional costs or delay.

As product candidates progress through preclinical studies and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates, if approved, and generate revenue. If we or our CMOs are not able to successfully manufacture our product candidates in sufficient quality and quantity, clinical development and timelines for our product candidates and subsequent approval could be adversely impacted.

We will be unable to commercialize our products if our clinical trials are not successful.

Our research and development programs are at an early stage. We must demonstrate our products' safety and efficacy in humans through extensive clinical testing. We may experience numerous unforeseen events during, or as a result of, the clinical testing process that could delay or prevent commercialization of our products, including but not limited to the following:

- safety and efficacy results in various human clinical trials reported in scientific and medical literature may not be indicative of results we obtain in our clinical trials;
- after reviewing test results, we or our collaborators may abandon projects that we might previously have believed to be promising;
- we, our collaborators or regulators may suspend or terminate clinical trials if the participating subjects or patients are being exposed to unacceptable health risks;
- the standard of care may change as the result of new technology or therapies in our target clinical indications, precluding regulatory approval or limited commercial use if approved;
- the effects our product candidates have may not be the desired effects or may include undesirable side effects or other characteristics that preclude regulatory approval or limit their commercial use if approved;
- manufacturers may not meet the necessary standards for the production of the product candidates or may not be able to supply the product candidates in a sufficient quantity; and
- regulatory authorities may find that our clinical trial design or conduct does not meet the applicable approval requirements.

Clinical testing is very expensive, can take many years and the outcome is uncertain. The data collected from our clinical trials may not be sufficient to support approval by the FDA of our product candidates for the treatment of inflammatory diseases and autoimmune disorders. The clinical trials for our product candidates under development may not be completed on schedule and the FDA may not ultimately approve any of our product candidates for commercial sale. If we fail to adequately demonstrate the safety and efficacy of any product candidate under development, we may not receive regulatory approval for such product candidate, which would prevent us from generating revenues or achieving profitability.

We may use our limited financial and human resources to pursue a particular type of treatment, or treatment for a particular type of disease, and fail to capitalize on programs or treatments of other types of diseases that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and human resources, we must choose to pursue and fund the development of specific types of treatment, or treatment for a specific type of disease, and may forego or delay pursuit of opportunities with other programs, investigational medicines, or treatment for other types of diseases, which could later prove to have greater commercial potential. Moreover, given the rapidly evolving competitive landscape and the time it takes to advance a product through clinical development, an incorrect decision to pursue a particular type of treatment or disease may have a material adverse effect on our results of operation and negatively impact our future clinical strategies. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for investigational medicines or clinical trials may not yield any commercially viable products. If we do not accurately evaluate and anticipate the commercial potential or target market for a particular type of treatment or disease, we may choose to spend our limited resources on a particular treatment, or treatment for a particular type of disease, and then later learn that another type of treatment or disease that we previously decided not to pursue would have been more advantageous. We may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights. Any such event could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may develop product candidates in combination with other therapies, which exposes us to additional risks and could result in our products, even if approved, being removed from the market or being less successful commercially.

We may develop product candidates in combination with one or more other therapies. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be

subject to the risks that the FDA or comparable foreign regulatory authorities could revoke approval of the therapy used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing therapies. If the therapies we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA or comparable foreign regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, even if approved, being removed from the market or being less successful commercially.

We also may choose to evaluate product candidates in combination with one or more therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market and sell any product candidate we develop in combination with an unapproved therapy for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our product. In addition, unapproved therapies face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA approval. If the FDA or comparable foreign regulatory authorities do not approve these other drugs or revoke their approval of, or if safety, efficacy, quality, manufacturing or supply issues arise with, the drugs we choose to evaluate in combination with our product candidate we develop, we may be unable to obtain approval of or market such combination therapy.

The use of our net operating loss carryforwards may be limited.

Our net operating loss carryforwards may expire and not be used. As of December 31, 2023, we had U.S. federal net operating loss carryforwards of approximately $30.4 million. Our U.S. federal net operating loss carryforwards arising in taxable years beginning after December 31, 2017 are not subject to expiration under the Internal Revenue Code of 1986, as amended, or the “Code”. The deductibility of U.S. federal net operating losses arising in taxable years beginning after December 31, 2017 is limited to 80% of our current year taxable income for taxable years beginning after December 31, 2020. Additionally, our ability to use any net operating loss carryforwards to offset taxable income in the future will also be limited under Section 382 of the Code, if we undergo an “ownership change” (generally defined as a cumulative change in ownership by “5-percent shareholders” of more than 50% within a rolling three-year period).

We may have experienced ownership changes in the past and any such ownership change could result in increased future tax liability. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. Furthermore, since we will need to raise substantial additional funding to finance our operations, we may undergo ownership changes in the future. Any such annual limitation may significantly reduce the utilization of the net operating loss carryforwards before they expire. Depending on our future tax position, limitation of our ability to use net operating loss carryforwards in jurisdictions in which we are subject to income tax could have an adverse impact on our results of operations and financial condition.

There is also a risk that due to regulatory changes, such as suspensions on the use of net operating losses by certain jurisdictions, possibly with retroactive effect, or other unforeseen reasons, our existing net operating losses could expire or otherwise be unavailable to offset future income tax liabilities. For example, California recently enacted legislation that limits the use of state net operating losses for tax years beginning on or after January 1, 2024 and before January 1, 2027.

We may experience fluctuations in our tax obligations and effective tax rate, which could materially affect our results.

We are subject to income- and non-income-based taxes in the United States under federal, state, and local jurisdictions and in certain foreign jurisdictions in which we operate. Tax laws, regulations and administrative practices in various jurisdictions may be subject to significant change, with or without advance notice, due to economic, political and other conditions, and significant judgment is required in evaluating and estimating our provision and accruals for these taxes. Our effective tax rates could be affected by numerous factors, such as changes in tax, accounting and other laws, regulations, administrative practices, principles and interpretations, the mix and level of earnings in a given taxing jurisdiction or our ownership or capital structures.

For example, U.S. federal income tax legislation signed into law in 2017 referred to as the Tax Cuts and Jobs Act, is highly complex, is subject to interpretation, and contains significant changes to U.S. tax law, including, but not limited to, a reduction in the corporate tax rate, significant additional limitations on the deductibility of interest, substantial revisions to the taxation of international operations, and limitations on the use of certain net operating losses. Beginning in 2022, the Tax Cuts and Jobs Act eliminated the option to deduct research and development expenditures currently and requires taxpayers to capitalize and amortize them over five or fifteen years pursuant to Section 174 of the Code.

In addition, in 2022, the Inflation Reduction Act of 2022 (the “IRA”), was signed into law, with tax provisions primarily focused on implementing a 15% minimum tax on global adjusted financial statement income, effective for tax years beginning after December 31,

2022, and a 1% excise tax on share repurchases occurring after December 31, 2022. It is unclear at this time what, if any, impact the IRA will have on our tax rate and financial results. We will continue to evaluate the IRA's impact (if any) as further information becomes available.

Our international operations subject us to potentially adverse tax consequences.

We generally conduct our international operations through subsidiaries and report our taxable income in various jurisdictions worldwide based upon our business operations in those jurisdictions. Our intercompany relationships are subject to complex transfer pricing regulations administered by taxing authorities in various jurisdictions. The relevant taxing authorities may disagree with our determinations as to the value of assets sold or acquired or income and expenses attributable to specific jurisdictions. If such a disagreement were to occur, and our position were not sustained, we could be required to pay additional taxes, interest and penalties, which could result in one-time tax charges, higher effective tax rates, reduced cash flows, and lower overall profitability of our operations.

There is also a high level of uncertainty in today's tax environment stemming from both global initiatives put forth by the Organisation for Economic Co-operation and Development, or the OECD, and unilateral measures being implemented by various countries due to a lack of consensus on these global initiatives. As an example, the OECD has put forth two proposals—Pillar One and Pillar Two—that revise the existing profit allocation and nexus rules (profit allocation based on location of sales versus physical presence) and ensure a minimal level of taxation, respectively. The Council of the European Union has adopted the global corporate 15% minimum tax as provided for in Pillar Two and directed EU member states to implement legislation enacting Pillar Two by December 31, 2023. Further, unilateral measures such as digital services tax and corresponding tariffs in response to such measures are creating additional uncertainty. If these proposals are passed, it is possible that we will have to pay higher taxes in countries where such rules are applicable.

Our projections regarding the market opportunities for our product candidates may not be accurate, and the actual market for our products may be smaller than we estimate.

We do not have verifiable internal marketing data regarding the potential size of the commercial market for our product candidates, nor have we obtained current independent marketing surveys to verify the potential size of the commercial markets for our current product candidates or any future product candidates. Since our current product candidates and any future product candidates will represent novel approaches to treating various conditions, it may be difficult, in any event, to accurately estimate the potential revenues from these product candidates. Accordingly, we may spend significant capital trying to obtain approval for product candidates that have an uncertain commercial market. Our projections of both the number of people who have inflammatory diseases and autoimmune disorders we are targeting, as well as the subset of people with these diseases who are in a position to receive second- or third-line therapy, and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research by third parties, and may prove to be incorrect. Further, new studies or approvals of new therapeutics may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates and may also be limited by the cost of our treatments and the reimbursement of those treatment costs by third-party payors. Even if we obtain significant market share for our product candidates, because the potential target populations may be small, we may never achieve profitability without obtaining regulatory approval for additional indications.

Because our current product candidates represent, and our other potential product candidates will represent, novel approaches to the treatment of disease, there are many uncertainties regarding the development, the market acceptance, third-party reimbursement coverage and the commercial potential of our product candidates.

There are many uncertainties related to development, marketing, reimbursement and the commercial potential for our product candidates. There can be no assurance as to the length of the trial period, the number of patients the FDA will require to be enrolled in the trials in order to establish the safety and efficacy of our product candidates, or that the data generated in these clinical trials will be acceptable to the FDA to support marketing approval. The FDA may take longer than usual to come to a decision on any NDA that we submit and may ultimately determine that there is not enough data, information or experience with our product candidates to support an approval decision. The FDA may also require that we conduct additional post-marketing studies or implement risk management programs, such as REMS, until more experience with our product candidates is obtained. Finally, after increased usage, we may find

that our product candidates do not have the intended effect, do not work with other combination therapies or have unanticipated side effects, potentially jeopardizing initial or continuing regulatory approval and commercial prospects.

There is no assurance that our product candidates will gain broad acceptance among doctors or patients or that governmental agencies or third-party medical insurers will be willing to provide reimbursement coverage for proposed product candidates. The market for any product candidates that we develop, if approved, will also depend on the cost of the product candidate. We do not yet have sufficient information to reliably estimate what it will cost to commercially manufacture our current product candidates, and the actual cost to manufacture these products could materially and adversely affect the commercial viability of these products. Unless we can reduce manufacturing costs to an acceptable amount, we may never be able to develop a commercially viable product. If we do not successfully develop and, if approved, commercialize products based upon our approach or find suitable and economical sources for materials used in the production of our products, we will not become profitable, which would materially and adversely affect the value of our common stock, our business, financial condition, results of operations, and prospects.

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

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products, if approved. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection laws. Large judgments have also been awarded in class action lawsuits based on therapeutics that had unanticipated side effects. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease the commercialization of our product candidates, if approved. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products, if approved;
- injury to our reputation or significant negative media attention;
- withdrawal of clinical trial participants or sites and potential termination of clinical trial sites or entire clinical programs;
- initiation of investigations by regulators, refusal to approve marketing applications or supplements, and withdrawal or limitation of product approvals;
- costs to defend litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- decrease in the price of our stock and overall value of our company;
- exhaustion of our available insurance coverage and our capital resources; or
- the inability to commercialize our product candidates.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we may develop, alone or with corporate collaborators. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. While we have obtained clinical trial insurance for our clinical trials, we may have to pay amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Public opinion and scrutiny of immunology treatments may impact public perception of our company and product candidates, or may adversely affect our ability to conduct our business and our business plans.

Public perception may be influenced by claims, such as claims that our product candidates are unsafe, unethical or immoral and, consequently, our approach may not gain the acceptance of the public or the medical community. Negative public reaction to new immunology treatments in general could result in greater government regulation and stricter labeling requirements of products to treat inflammatory diseases and autoimmune disorders, including any of our product candidates, if approved, and could cause a decrease in the demand for any product candidates we may develop. Adverse public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians specializing in the treatment of those diseases that our product candidates target prescribing, and their patients being willing to receive, treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments they are already familiar with and for which greater clinical data may be available. Adverse events in our clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates. More restrictive government regulations or negative public opinion could have an adverse effect on our business, financial condition, results of operations and prospects, and may delay or impair the development and, if approved, commercialization of our product candidates or demand for any products we may develop.

We may be unable to establish effective marketing and sales capabilities or enter into agreements with third parties or related parties to market and sell our product candidates, if they are approved, and as a result, we may be unable to generate product revenues.

We currently do not have a commercial infrastructure for the marketing, sale and distribution of products. If approved, in order to commercialize our products, we must build our marketing, sales and distribution capabilities or make arrangements with third parties to perform these services, which will take time and require significant financial expenditures and we may not be successful in doing so. There are risks involved with establishing our own marketing and sales capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have incurred these commercialization expenses prematurely or unnecessarily. These efforts may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Even if we are able to effectively establish a sales force and develop a marketing and sales infrastructure, our sales force and marketing teams may not be successful in commercializing our current or future product candidates. To the extent we rely on third parties to commercialize any products for which we obtain regulatory approval, we would have less control over their sales efforts and could be held liable if they failed to comply with applicable legal or regulatory requirements.

We have little to no prior experience in the marketing, sale and distribution of biopharmaceutical products, and there are significant risks involved in the building and managing of a commercial infrastructure. The establishment and development of commercial capabilities, including a comprehensive healthcare compliance program, to market any product candidates we may develop will be expensive and time consuming and could delay any product launch, and we may not be able to successfully develop this capability. We, or our collaborators, will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train, manage and retain medical affairs, marketing, sales and commercial support personnel. In the event we are unable to develop a commercial infrastructure, we may not be able to commercialize our current or future product candidates, which would limit our ability to generate product revenues. Factors that may inhibit our efforts to commercialize our current or future product candidates and generate product revenues include:

- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe our current or future product candidates;
- our inability to effectively oversee a geographically dispersed sales and marketing team;
- the costs and time associated with the initial and ongoing training of sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions;
- an inability to secure adequate coverage and reimbursement by government and private health plans;
- intense competition in the clinical indications for which the products are approved and any restrictions on the scope of claims that we may make for the products;
- limitations or warnings, including distribution or use restrictions, contained in the products' approved labeling;

- any distribution and use restrictions imposed by the FDA or to which we agree as part of a mandatory REMS or voluntary risk management plan;
- liability for sales or marketing personnel who fail to comply with the applicable legal and regulatory requirements;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization or engaging a contract sales organization; and
- if a health epidemic or other outbreak, such as COVID-19 occurs, it may negatively impact our ability to establish commercial operations, educate and interact with healthcare professionals, and successfully launch our product on a timely basis.

If our product candidates, if approved, do not achieve broad market acceptance, the revenues that we generate from their sales will be limited.

We have never commercialized a product candidate for any indication. Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors and others in the medical community. If any product candidate for which we obtain regulatory approval does not gain an adequate level of market acceptance, we may not generate sufficient product revenues or become profitable. Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. The degree of market acceptance of any of our product candidates will depend on a number of factors, some of which are beyond our control, including:

- the safety and efficacy of our product candidates;
- the prevalence and severity of adverse events associated with our product candidates;
- the clinical indications for which the products are approved and the approved claims that we may make for the products;
- limitations or warnings contained in the product's FDA-approved labeling, including potential limitations or warnings for such products that may be more restrictive than other competitive products;
- distribution and use restrictions imposed by the FDA with respect to such product candidates or to which we agree as part of a mandatory risk evaluation and mitigation strategy or voluntary risk management plan;
- changes in the standard of care for the targeted indications for such product candidates;
- the relative difficulty of administration of such product candidates;
- cost of treatment as compared to the clinical benefit in relation to alternative treatments or therapies;
- the availability of adequate coverage and reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicare and Medicaid;
- the extent and strength of our marketing and distribution of such product candidates;
- the safety, efficacy and other potential advantages of, and availability of, alternative treatments already used or that may later be approved for any of our intended indications;
- the timing of market introduction of such product candidates, as well as competitive products;
- the reluctance of physicians to switch their patients' therapeutics;
- the reluctance of patients to switch from their existing therapeutics regardless of the safety and efficacy of newer therapeutics;
- our ability to offer such product candidates for sale at competitive prices;

- the extent and strength of our third-party manufacturer and supplier support;
- adverse publicity about our product or favorable publicity about competitive products; and
- potential product liability claims.

Our efforts to educate the medical community and third-party payors as to the benefits of our product candidates may require significant resources and may never be successful. Even if the medical community accepts that our product candidates are safe and effective for their approved indications, physicians and patients may not immediately be receptive to such product candidates and may be slow to adopt them as an accepted treatment of the approved indications. If our current or future product candidates are approved, but do not achieve an adequate level of acceptance among physicians, patients, and third-party payors, we may not generate meaningful revenues from our product candidates and may never become profitable.

Our product candidates may face competition sooner than anticipated.

For small molecular product candidates, the Federal Food, Drug, and Cosmetic Act, or FDCA, provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for a generic version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. As such, we may face competition from generic versions of our small molecule product candidates, which will negatively impact our long-term business prospects and marketing opportunities.

We will need to obtain FDA approval of any proposed branded product names, and any failure or delay associated with such approval may adversely affect our business.

Any name we intend to use for our product candidates in the United States will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office, or USPTO. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims or contributes to an overstatement of efficacy. If the FDA objects to any of our proposed product names, we may be required to adopt alternative names for our product candidates. If we adopt alternative names, we will lose the benefit of any existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe or otherwise violate the existing rights of third parties, and be acceptable to the FDA. We may be unable to build a successful brand identity for a new product name in a timely manner or at all, which would limit our ability to commercialize our product candidates.

We are dependent on information technology, systems, infrastructure and data. Our internal computer systems, or those used by our CROs, CMOs, clinical sites or other contractors or consultants, may fail or suffer security breaches, which could result in a material adverse effect, including without limitation, a material operational or service interruption, harm to our reputation, significant fines, penalties and liability, breach or triggering of data protection laws, or loss of customers or sales.

We are dependent upon information technology systems, infrastructure and data. In the ordinary course of our business, we directly or indirectly collect, use, generate, transfer, disclose, maintain, dispose of, or otherwise process (collectively, "Process" or "Processing") sensitive data, including intellectual property, confidential information, preclinical and clinical trial data, proprietary business information, personal data and personally identifiable health information of our clinical trial subjects and employees, in our data centers and on our networks, or on those of third-party service providers. The secure Processing of this information is critical to our operations. Our obligations under applicable laws, regulations, contracts, industry standards, and other documentation may include maintaining the confidentiality, integrity, and availability of such data in our possession or control, maintaining reasonable and appropriate security safeguards as part of an information security program, and restrictions on the use and disclosure of such data. These obligations create potential liability to regulators, business partners, personnel, and other relevant stakeholders. The multitude and complexity of our computer systems and those of our CROs, CMOs, clinical sites or other contractors or consultants make them inherently vulnerable to service interruption or destruction, malicious intrusion attempts and other attacks, and random attacks. Security breaches or incidents, whether resulting from inadvertent or intentional acts or omissions by third-party service providers, employees, contractors or others pose a risk that sensitive data, including our intellectual property, trade secrets or personal information of our employees, patients, business partners, or others could have been and may be exposed to unauthorized persons or to the public or otherwise lost, destroyed, altered, disclosed, disseminated, damaged, made unavailable or otherwise Processed without authorization.

Although we take measures designed to protect such information from unauthorized Processing, our internal computer systems and those of our CROs, CMOs, clinical sites and other contractors and consultants are vulnerable to cyberattacks, computer viruses, bugs or worms, and other attacks by computer hackers, cracking, application security attacks, social engineering, supply chain attacks and vulnerabilities through our third-party service providers, denial-of-service attacks (such as credential stuffing), extortion, and intentional disruptions of service; computer and network vulnerabilities or the negligence and malfeasance of individuals with authorized access to our information, failure or damage from natural disasters, terrorism, war, fire and telecommunication and electrical failures. Ransomware attacks, including those from organized criminal threat actors, nation-states and nation-state supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, loss of data (including sensitive customer information), loss of income, significant extra expenses to restore data or systems, reputational loss and the diversion of funds. To alleviate the financial, operational and reputational impact of a ransomware attack, it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws or regulations prohibit such payments). Third parties may also attempt to fraudulently induce our employees, contractors, consultants, or third-party service providers into disclosing sensitive information such as usernames, passwords, or other information or otherwise compromise the security of our computer systems, networks, and/or physical facilities in order to gain access to our data. Cyberattacks are increasing in their frequency, sophistication and intensity. The techniques used by cyber criminals change frequently, may not be recognized until launched and can originate from a wide variety of sources, including outside groups, such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. Geopolitical tensions or conflicts have in the past led to, and may in the future lead to, increased risk of cybersecurity attacks. Moreover, advancements in technology, such as artificial intelligence and machine learning, are changing and may continue to change the way companies are subjected to attempts to gain unauthorized access and disrupt systems, thereby increasing the risks of security threats and attacks. Additionally, some of our employees work remotely, which may pose additional data security risks. While we have invested, and continue to invest, in the protection of our data and information technology infrastructure, there can be no assurance that our efforts, or the efforts of our partners, vendors, CROs, CMOs, clinical sites and other contractors and consultants will prevent service interruptions, or identify breaches or incidents in our or their systems, that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm to us. Furthermore, we may not have adequate insurance coverage to protect us from, or adequately mitigate, liabilities or costs resulting from security breaches and incidents. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

If any such event were to occur and cause interruptions in our operations, it could result in a disruption of our drug development programs. For example, the loss or unauthorized modification or unavailability of clinical trial data from completed or ongoing clinical trials for a product candidate could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data, or may limit our ability to effectively execute a product recall, if required. We expect to incur significant costs in an

effort to detect and prevent security breaches and incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security breach or incident. To the extent that any disruption or security breach or incident were to result in a loss of or damage to our data or applications, or the loss, destruction, alteration, prevention of access to, disclosure, or dissemination of, or damage or unauthorized access to, our data (including trade secrets or other confidential information, intellectual property, proprietary business information, and personal, confidential, or proprietary information) processed or maintained on our behalf, or any of these is perceived or believed to have occurred, we could incur liability and the further development of any product candidates could be delayed. Any such event or the perception that it has occurred, could also result in legal claims, demands, litigation or other proceedings by private actors, regulatory investigations or other proceedings, liability under laws that protect the privacy of personal information and significant regulatory penalties, injunctive relief, mandatory corrective action, and other remedies, and damage to our reputation and a loss of confidence in us and our ability to conduct clinical trials, which could delay the clinical development of our product candidates.

We face risks related to health epidemics and other outbreaks, such as COVID-19, which could significantly disrupt our operations or otherwise result in material adverse impacts to us.

Our business could be adversely impacted by the effects of health epidemics and other outbreaks, including:

- delays or difficulties in enrolling and retaining patients in our ongoing and planned clinical trials, and incurrence of additional costs as a result of any preclinical study and clinical trial delays and adjustments;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- shutdowns or continued business disruptions experienced by suppliers and other third parties with whom we conduct business;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of clinical trials;
- interruption or delays of key clinical trial activities, such as clinical trial site monitoring and collecting sufficient clinical data, patient safety considerations or limitations on travel imposed or recommended by federal or state governments, employers and others;
- other limitations on resources that would otherwise be focused on the conduct of our business or our current or planned clinical trials or preclinical research, including because of sickness, the desire to avoid contact with large groups of people or government restrictions;
- delays in receiving approval from regulatory authorities to initiate our planned clinical trials;
- delays in receiving the supplies, materials and services needed to conduct clinical trials and preclinical research or to support manufacturing activities of our business and that of our suppliers or contractors;
- changes in clinical site policies and procedures for conducting clinical trials during the pandemic;
- changes in regulations as part of a response to health epidemics or other outbreaks which may require us to change the ways in which our clinical trials are conducted and incur unexpected costs, or require us to discontinue the clinical trials altogether; and
- delays in necessary interactions with regulators, ethics committees and other important agencies and contractors.

We are actively monitoring, evaluating, and responding to developments relating to COVID-19, including new strains of the disease that have emerged in certain locations, vaccination status both locally and globally, and changing restrictions on travel and other protocols as set forth by the Centers for Disease Control and Prevention and other government authorities. The extent to which COVID-19, including any variants that have emerged or may emerge in the future, or any other health epidemic impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of a particular virus and its variants and the actions to contain it or treat its impact, among others. We cannot at this time quantify or forecast the business impact of COVID-19, and there can be no assurance that we will be able to avoid a material impact on our business, financial condition and operating results from the spread of COVID-19 or its consequences, including disruption to our

business and downturns in business sentiment generally or in our industry. In addition, the COVID-19 pandemic increases the likelihood and potential severity of other risks described in the “Risk Factors” section. Although the COVID-19 national emergency ended on May 11, 2023, we can provide no assurance on the impact of any future public health concerns or related disruptions, including resurgence of COVID-19 cases, will have on our business or operations

Our failure to comply with state, national and/or international data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

Numerous laws and legislative and regulatory initiatives at the federal and state levels address privacy and security concerns, and some state privacy laws apply more broadly than the Health Insurance Portability and Accountability Act, or HIPAA, and associated regulations. For example, California has enacted legislation—the California Consumer Privacy Act, or CCPA—which went into effect on January 1, 2020. The CCPA, among other things, creates new data privacy and security obligations for covered companies and provides new privacy rights to California consumers, including the right to opt out of certain disclosures of their information. The CCPA also provides for civil penalties as well as a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for certain information collected as part of clinical trials as specified in the law, it may regulate or impact our Processing of personal information depending on the context. Further, California voters approved the California Privacy Rights Act of 2020, or CPRA, in November 2020. The CPRA went into effect on January 1, 2023. The CPRA, among other things, gives California residents the ability to limit the use of their sensitive information, provides for penalties for CPRA violations concerning California residents under the age of 16, and establishes a new California Privacy Protection Agency to implement and enforce the law. Other states, have considered or have enacted legislation addressing privacy and security. For example, Washington has enacted the My Health, My Data Act, which includes a private right of action. Additionally, numerous states, including Colorado, Virginia, Utah, Connecticut, Iowa, Indiana, Tennessee, Florida, Texas, Oregon, Delaware, Montana, New Jersey, Kentucky, Maryland, Minnesota, Nebraska, New Hampshire, and Rhode Island, have considered or have enacted legislation similar to the CCPA and CPRA. These developments create the possibility for a patchwork of overlapping but different state laws, potentially resulting in further uncertainty and requiring us to incur additional costs and expenses in an effort to comply. The U.S. federal government also is contemplating federal privacy legislation. We cannot yet determine the impact these laws and regulations or any future laws, regulations and standards may have on our business.

There are also various laws and regulations in other jurisdictions relating to privacy, data protection, and security. For example, the European Union, or EU, member states, the United Kingdom and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations on us. Moreover, the EU Data Protection Directive, which formerly governed the collection, Processing and other use of personal health or other data in the EU, was replaced with the EU General Data Protection Regulation, or the GDPR, in May 2018. The GDPR, which is wide-ranging in scope and applies extraterritorially, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to such individuals, the security and confidentiality of the personal data, data breach notification, the adoption of appropriate privacy governance, including policies, procedures, training and audits, and the use of third-party processors in connection with the Processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EU, including to the U.S. In July 2020, in its Schrems II ruling, the Court of Justice of the EU invalidated the EU-U.S. Privacy Shield data transfer mechanism, limiting how organizations could lawfully transfer personal data from the EEA to the U.S. Other data transfer mechanisms such as the Standard Contractual Clauses approved by the European Commission have faced challenges in European courts (including being called into question in Schrems II), may require additional risk analysis and supplemental measures to be used, and may be challenged, suspended or invalidated. In addition, the European Commission provided updated versions of the Standard Contractual Clauses in June 2021 that are required to be implemented. These and other developments relating to cross-border transfers of personal data may cause us to have to make further expenditures on local infrastructure, limit our ability to Process personal data, change internal business processes or otherwise affect or restrict sales and operations. Notably, the GDPR provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant entity, whichever is greater.

The United Kingdom implemented the Data Protection Act, effective May 2018 and statutorily amended in 2019, that contains provisions, including its own derogations, for application of the GDPR in the United Kingdom, and the United Kingdom has implemented a version of the GDPR referred to as the UK GDPR, which provides for fines of up to the greater of £17.5 million or 4% of annual global revenues. These developments could increase the risk of non-compliance and the costs of providing our products and services in a compliant manner. On June 28, 2021, the European Commission issued an adequacy decision in respect of the United Kingdom’s data protection framework, allowing personal data transfers from EU member states to the United Kingdom to continue without requiring additional contractual or other measures in order to lawfully transfer personal data between the territories. This decision is subject to renewal after four years, however, and may be revisited by the European Commission at any time. The United

Kingdom also has adopted updated standard contractual clauses, effective in March 2022, that are required to be implemented. We may incur substantial expense in complying with obligations under United Kingdom laws and regulations relating to privacy, data protection, and data security, and we may be required to make significant changes in our business operations, all of which may adversely affect our revenues and our business overall.

Complying with these numerous, complex and often changing regulations is expensive and difficult, and failure to comply with any privacy or data protection laws or data security laws or any security incident or breach involving the misappropriation, loss or other unauthorized Processing, use or disclosure of sensitive or confidential patient, consumer or other personal information, whether by us, one of our CROs or business associates or another third party, or the perception that any of these have occurred, could adversely affect our business, financial condition and results of operations, including but not limited to: costs associated with any investigation or other regulatory proceeding, or private claims or demands; material fines and penalties; compensatory, special, punitive and statutory damages; litigation; consent orders regarding our privacy and security practices; requirements that we provide notices, credit monitoring services and/or credit restoration services or other relevant services to impacted individuals; adverse actions against our licenses to do business; reputational damage; and injunctive relief. The recent implementation of the CCPA and GDPR has increased our responsibility and liability in relation to personal data that we process, including in clinical trials, and we may in the future be required to put in place additional mechanisms to ensure compliance with the CCPA, GDPR and other applicable laws and regulations, which could divert management's attention and increase our cost of doing business. In addition, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. In this regard, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the EU, the United Kingdom and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

We cannot assure you that our CROs or other third-party service providers with access to our or our customers', suppliers', trial patients' and employees' personally identifiable and other sensitive or confidential information in relation to which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security breaches, which could have a corresponding effect on our business, including putting us in breach of our obligations under laws and regulations relating to privacy, data protection, or data security and/or which could in turn adversely affect our business, results of operations and financial condition. We cannot assure you that our contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party Processing of such information. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition to our legal obligations, our contractual obligations relating to privacy, data protection and data security have become increasingly stringent. Furthermore, we may make numerous statements in our privacy policies and in our marketing materials providing assurances about the security of our data. If any of these statements prove to be untrue or are perceived as untrue regardless of whether the circumstances are beyond our reasonable control, we may face claims, investigations or other proceedings by the U.S. Federal Trade Commission, state and foreign regulators, our customers and private litigants.

While we maintain insurance coverage, we cannot assure that such coverage will be adequate or otherwise protect us from or adequately mitigate liabilities or damages with respect to claims, costs, expenses, litigation, fines, penalties, business loss, data loss, regulatory actions or material adverse effects arising out of our privacy and security practices or otherwise relating to any actual or perceived privacy or data security breach or incident, or that such coverage will continue to be available on acceptable terms or at all. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

Our success is highly dependent on our ability to attract and retain highly skilled executive officers, key scientific personnel and employees.

Competition for qualified personnel in the biotechnology and pharmaceuticals industry is intense due to the limited number of individuals who possess the skills and experience required. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided, and plan to continue providing, equity incentive awards that vest over time. The value to employees of equity incentive awards that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. We face significant competition for employees, particularly scientific personnel, from other biopharmaceutical companies, which include both publicly traded and privately held companies, and we may not be able to hire new employees quickly enough to meet our needs. All of our employees are hired on an "at-will" basis, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees. We may not be able to attract and retain quality personnel on acceptable terms, or at all, which may cause our business, financial conditions, results of operations and prospects to suffer.

Additionally, if we lose members of our senior management for a short or an extended time, we may not be able to find appropriate replacements on a timely basis, and our business could be adversely affected. Our existing operations and continued future development depend to a significant extent upon the performance and active participation of certain key individuals, including our chief executive officer, Dr. Raju Mohan.

Dr. Mohan, our president and chief executive officer, and Dr. Nuss, our chief scientific officer, have significant interests in other companies which may conflict with our interests.

Our chief executive officer, Dr. Mohan, serves as a Partner and Senior Advisor at New Science Ventures, and Dr. Mohan and Dr. Nuss, our chief scientific officer, serve as officers of, and hold ownership interests in, Escalier Biosciences BV and Vimalan Biosciences, Inc. Escalier Biosciences and Vimalan Biosciences are in the business of discovering and developing therapies for the treatment of inflammatory diseases and autoimmune disorders. As a result, they or other companies affiliated with Dr. Mohan and Dr. Nuss may compete with us for business opportunities or, in the future, develop products that are competitive with ours (including products in other therapeutic fields which we may target in the future). As a result, the interests of Dr. Mohan and Dr. Nuss may not be aligned with our other stockholders and they may from time to time be incentivized to take certain actions that benefit their other interests and that our other stockholders do not view as being in their interest as investors in our company. Moreover, even if they do not directly relate to us, actions taken by Dr. Mohan and Dr. Nuss and the companies with which they are involved could impact us.

We will need to grow our size and capabilities, and we may experience difficulties in managing this growth, which could disrupt our operations.

Our operations are dependent upon the services of our executives and our employees who are engaged in research and development. The loss of the services of our executive officers or senior research personnel could delay our product development programs and our research and development efforts. In order to develop our business in accordance with our business plan, we will have to hire additional qualified personnel, including in the areas of research, manufacturing, clinical trials management, regulatory affairs, and sales and marketing. We are continuing our efforts to recruit and hire the necessary employees to support our planned operations in the near term. However, competition for qualified employees among companies in the biotechnology and biopharmaceutical industry is intense, and no assurance can be given that we will be able attract, hire, retain and motivate the highly skilled employees that we need. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

As of September 30, 2024, we had 75 full-time employees, compared to 79 full-time employees as of December 31, 2023. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage

the expected expansion of our operations or recruit and train additional qualified personnel. Moreover, the expected physical expansion of our operations may lead to significant costs and may divert our management resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Our future financial performance and our ability to commercialize our product candidates, if approved, will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain research and clinical development services. There can be no assurance that the services of these independent organizations, advisors and consultants will continue to be available to us on a timely basis, or at all, when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality, compliance or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals on a timely basis, or at all.

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

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses from time to time. Any potential acquisition or strategic partnership may entail numerous risks, including:

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

Depending on the size and nature of future strategic acquisitions, we may acquire assets or businesses that require us to raise additional capital or to operate or manage businesses in which we have limited experience. Making larger acquisitions that require us to raise additional capital to fund the acquisition will expose us to the risks associated with capital raising activities. Acquiring and thereafter operating larger new businesses will also increase our management, operating and reporting costs and burdens. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

If we decide to establish collaborations but are not able to establish those collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may seek to selectively form collaborations to expand our capabilities, potentially accelerate research and development activities and provide for commercialization activities by third parties. Any of these relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business.

We would face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, EMA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Even if we are successful in entering into a collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements on certain terms with potential collaborators.

If and when we seek to enter into collaborations, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay our development program or one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

We expect to rely on third parties to perform many essential services for any products, if approved, that we commercialize, including services related to distribution, government price reporting, customer service, accounts receivable management, cash collection and adverse event reporting. If these third parties fail to perform as expected or to comply with legal and regulatory requirements, our ability to commercialize our current or future product candidates, if any are approved, will be significantly impacted and we may be subject to regulatory sanctions.

We expect to retain third-party service providers to perform a variety of functions related to the sale of our current or future product candidates, if any are approved, key aspects of which will be out of our direct control. These service providers may provide key services related to distribution, customer service, accounts receivable management and cash collection. If we retain a service provider, we will substantially rely on it as well as other third-party providers that perform services for us, including entrusting our inventories of products to their care and handling. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines or otherwise do not carry out their contractual duties to us, or encounter physical or natural damage at their facilities, our ability to deliver product to meet commercial demand would be significantly impaired and we may be subject to regulatory enforcement action.

In addition, we may engage in the future with third parties to perform various other services for us relating to adverse event reporting, safety database management, fulfillment of requests for medical information regarding our product candidates and related services. If the quality or accuracy of the data maintained by these service providers is insufficient, or these third parties otherwise fail to comply with regulatory requirements related to adverse event reporting, then we could be subject to regulatory sanctions.

Additionally, we may contract in the future with a third party to calculate and report pricing information mandated by various government programs. If a third party fails to timely report or adjust prices as required or errs in calculating government pricing

information from transactional data in our financial records, then it could impact our discount and rebate liability, and potentially subject us to regulatory sanctions or False Claims Act lawsuits.

We may not be able to obtain or maintain orphan drug designations for certain of our product candidates, and we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a product as an orphan product if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population of greater than 200,000 individuals in the United States, but for which there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, the European Medicines Agency's, or the EMA's, Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union. There can be no assurance that the FDA or the EMA's Committee for Orphan Medicinal Products will grant orphan designation for any indication for which we apply, or that we will be able to maintain such designation.

In the United States, orphan designation entitles a party to financial incentives such as opportunities for grant funding toward clinical trial costs, tax advantages and user-fee waivers. In addition, if a product candidate that has orphan designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including an NDA, to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity. The applicable exclusivity period is ten years in Europe, but such exclusivity period can be reduced to six years if a product no longer meets the criteria for orphan designation or if the product is sufficiently profitable so that market exclusivity is no longer justified.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA or comparable foreign regulatory authority can subsequently approve the same drug for the same condition if such regulatory authority concludes that the later drug is clinically superior, if it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

In *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), the court disagreed with the FDA's longstanding position that the orphan drug exclusivity only applies to the approved use or indication within an eligible disease. This decision created uncertainty in the application of the orphan drug exclusivity. On January 24, 2023, the FDA published a notice in the Federal Register to clarify that while the agency complies with the court's order in *Catalyst*, FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order – that is, the agency will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. It is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of the orphan drug exclusivity.

Risks Related to Government Regulation

The FDA regulatory approval process is lengthy, time-consuming and unpredictable, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.

We have not previously submitted an NDA to the FDA, or similar approval filings to comparable foreign authorities. NDAs must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and efficacy for NDAs for each desired indication. Our current beliefs regarding the registration pathway for our product candidates are based on our interpretation of communications with the FDA to date and our efforts to address such communications, which may be incorrect. Further, enrollment in our trials may need to be further adjusted based on future feedback from the FDA or other regulatory agency input, which could result in significant delays to our currently anticipated timeline for development and approval of our product candidates or prevent their approval entirely.

We may also experience delays, including delays arising from the need to increase enrollment, in completing planned clinical trials for a variety of reasons, including delays related to:

- the availability of financial resources to commence and complete the planned clinical trials;
- reaching agreement on acceptable contract terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval at each clinical trial site by an IRB or central IRB;
- recruiting suitable patients to participate in a clinical trial;
- having patients complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a clinical trial;
- adding new clinical trial sites;
- manufacturing sufficient quantities of qualified materials under cGMP and applying them on a subject by subject basis for use in clinical trials; or
- timely implementing or validating changes to our manufacturing or quality control processes and methods needed to address FDA feedback.

We could also encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted, by the FDA or other regulatory authorities, or recommended for suspension or termination by DSMBs due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

The clinical and commercial utility of our product candidates are uncertain and may never be realized.

Our product candidates are in clinical development. In the first quarter of 2024, we reported positive topline results from a Phase 1 trial of VTX3232 in adult healthy volunteers. In August 2024, we initiated a Phase 2a trial of VTX3232 in participants with early Parkinson's disease. We expect to report topline results from this trial in the first half of 2025. We also expect to initiate a Phase 2 trial of VTX3232 in participants with obesity and certain additional risk factors for cardiovascular disease during the fourth quarter of 2024. Topline results from this trial are anticipated in the second half of 2025. During the first quarter of 2024, we also reported positive topline results from a Phase 2 proof of concept trial of VTX2735 in cryopyrin-associated periodic syndromes (CAPS) patients. We expect to initiate a Phase 2 trial of VTX2735 in participants with recurrent pericarditis during the fourth quarter of 2024. Topline results from this trial are anticipated in the second half of 2025. In the fourth quarter of 2023, we announced positive results from the Phase 2 trial of VTX002 in patients with moderately to severely active ulcerative colitis. We intend to identify a partner or other source of non-dilutive financing to support a pivotal Phase 3 trial of VTX002 in ulcerative colitis. We will not be able to treat patients if we cannot manufacture a sufficient quantity of VTX002, VTX2735, VTX3232 or other product candidates that meets our minimum specifications. In addition, VTX002, VTX2735 and VTX3232 have only been tested in a small number of trial subjects. Results from these clinical trials may not necessarily be indicative of the safety and tolerability or efficacy of VTX002, VTX2735 and VTX3232 as we expand into larger clinical trials. As noted above, to the extent the FDA considers any of our product candidates to share the same mechanism of action as other drug products with known safety concerns that warrant black box warnings, the FDA may require black box warnings for our product candidates, which would limit the market acceptance of our product candidates and negatively impact the future commercial prospects of our product candidates, if approved.

We may not ultimately be able to provide the FDA with substantial clinical evidence to support a claim of safety or efficacy sufficient to enable the FDA to approve our product candidates for any indication. This may be because later clinical trials fail to reproduce favorable data obtained in earlier clinical trials, because the FDA disagrees with how we interpret the data from these clinical trials or because the FDA does not accept these therapeutic effects as valid endpoints in pivotal clinical trials necessary for market approval. We will also need to demonstrate that our product candidates are safe. We do not have data on possible harmful long-term effects of our product candidates and do not expect to have this data in the near future. As a result, our ability to generate clinical safety and effectiveness data sufficient to support submission of a marketing application or commercialization of our product candidates is uncertain and is subject to significant risk.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

In order to market and sell our products outside the United States, we or our third-party collaborators may be required to obtain separate marketing approvals and comply with numerous and varying regulatory requirements. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval policies and requirements may vary among jurisdictions. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. We or our collaborators may not be able to file for regulatory approval of our product candidates in international jurisdictions or obtain approvals from regulatory authorities outside the United States on a timely basis, if at all.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.

We plan to seek regulatory approval of our product candidates outside of the U.S. and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems, and price controls;
- potential liability under the U.S. Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;

- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- the impact of public health epidemics on the global economy, such as the COVID-19 pandemic; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with international operations may materially adversely affect our ability to attain or maintain profitable operations.

In particular, there is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross-border operations. The U.S. government has made and continues to make significant additional changes in U.S. trade policy and may continue to take future actions that could negatively impact U.S. trade. For example, legislation has been introduced in Congress to limit certain U.S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers' ability to engage in business in the U.S. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. If we are unable to obtain or use services from existing service providers or become unable to export or sell our products to any of our customers or service providers, our business, liquidity, financial condition, and/or results of operations would be materially and adversely affected.

We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.

We have never commercialized a product candidate, and we currently have no sales force, marketing or distribution capabilities. To achieve commercial success for the product candidates, which we may license to others, we will rely on the assistance and guidance of those collaborators. For product candidates for which we retain commercialization rights and marketing approval, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party.

Factors that may affect our ability to commercialize our product candidates, if approved, on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, developing adequate educational and marketing programs to increase public acceptance of our approved product candidates, ensuring regulatory compliance of our company, employees and third parties under applicable healthcare laws and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of our product candidates upon approval. We may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may not generate revenues from them or be able to reach or sustain profitability.

We are, and if we receive regulatory approval of our product candidates, will continue to be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of such product candidates. The FDA may also require a REMS to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA may also require post-approval Phase 4 studies. Moreover, the FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may withdraw approval, require labeling changes, such as black box warnings, or establishment of a REMS or similar strategy, impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. Any such restrictions could limit sales of the product.

In addition, we, our contractors, and our collaborators are and will remain responsible for FDA compliance, including requirements related to product design, testing, clinical and pre-clinical trials approval, manufacturing processes and quality, labeling, packaging, distribution, adverse event and deviation reporting, storage, advertising, marketing, promotion, sale, import, export, submissions of safety and other post-marketing information and reports, such as deviation reports, registration, product listing, annual user fees and recordkeeping for our product candidates. We and any of our collaborators, including our contract manufacturers, could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with regulatory requirements. Application holders must further notify the FDA, and depending on the nature of the change, obtain FDA pre-approval for product and manufacturing changes. The cost of compliance with post-approval regulations may have a negative effect on our results of operations and financial condition.

Later discovery of previously unknown problems with our product candidates or safety concerns with other products in the same drug class or sharing the same mechanism of action as our product candidates, including adverse events of unanticipated severity or frequency, that the product candidate is less safe or effective than previously thought, problems with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing, distribution, or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- imposition of a REMS, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- restrictions on the labeling of our product candidates, including required additional warnings, such as black box warnings, contraindications, precautions and restrictions on the approved indication or use;
- modifications to promotional pieces;
- changes to product labeling or the way the product is administered;
- liability for harm caused to patients or subjects;
- fines, restitution, disgorgement, warning letters, untitled letters or holds on or termination of clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates;
- injunctions or the imposition of civil or criminal penalties, including imprisonment;
- FDA debarment, debarment from government contracts, and refusal of future orders under existing contracts, exclusion from federal healthcare programs, consent decrees, or corporate integrity agreements;
- regulatory authority issuance of safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information about the product candidate;
- reputational harm; or
- the product becoming less competitive.

Any of these events could further have other material and adverse effects on our operations and business and could adversely impact our stock price and could significantly harm our business, financial condition, results of operations, and prospects.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. Recently, the U.S. Supreme Court overruled the *Chevron* doctrine, which gives deference to regulatory agencies' statutory interpretations in litigation against federal government agencies, such as the FDA, where the law is ambiguous. This landmark Supreme Court decision may invite more companies and other stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, including FDA's statutory interpretations of

market exclusivities and the “substantial evidence” requirements for drug approvals, which could undermine the FDA’s authority, lead to uncertainties in the industry, and disrupt the FDA’s normal operations, any of which could delay the FDA’s review of our regulatory submissions. We cannot predict the full impact of this decision, future judicial challenges brought against the FDA, or the nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, be subject to other regulatory enforcement action, and we may not achieve or sustain profitability.

We are subject to governmental export and import controls that could impair our ability to compete in international markets due to licensing requirements and subject us to liability if we are not in compliance with applicable laws. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations and various economic and trade sanctions regulations administered by the U.S. Treasury Department’s Office of Foreign Assets Control. Exports of our product candidates outside of the United States must be made in compliance with these laws and regulations. If we fail to comply with these laws and regulations, we and certain of our employees could be subject to substantial civil or criminal penalties, including the possible loss of export or import privileges; fines, which may be imposed on us and responsible employees or managers; and, in extreme cases, the incarceration of responsible employees or managers.

In addition, changes in our product candidates or changes in applicable export or import laws and regulations may create delays in the introduction, provision or sale of our product candidates in international markets, prevent customers from using our product candidates or, in some cases, prevent the export or import of our product candidates to certain countries, governments or persons altogether. Any limitation on our ability to export, provide or sell our product candidates could adversely affect our business, financial condition and results of operations.

We are subject to U.S. and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. §201, the U.S. Travel Act, the USA PATRIOT Act and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We have used contract research organizations abroad for clinical trials. In addition, we may engage third-party intermediaries to sell our product candidates abroad once we enter a commercialization phase for our product candidates and/or to obtain necessary permits, licenses, and other regulatory approvals. We or our third-party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

We have adopted an anti-corruption policy which mandates compliance with the FCPA and other anti-corruption laws applicable to our business throughout the world. However, there can be no assurance that our employees and third-party intermediaries will comply with this policy or such anti-corruption laws. Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other investigations or other enforcement actions. If such actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management’s attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor, which can result in added costs and administrative burdens.

If we fail to comply with environmental, health, and safety laws and regulations, including regulations governing the handling, storage or disposal of hazardous materials, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous materials, including chemicals and biological materials. Our operations also may produce hazardous waste products. We generally

contract with third parties for the disposal of these materials and wastes. We will not be able to eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from any use by us of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Changes in funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the FDA, the Securities and Exchange Commission, or the SEC, and other government agencies on which our operations may rely is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies, including delays or disruptions due to staffing shortages, travel restrictions, or public health concerns, including resurgence of COVID-19 cases, may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns and disruptions could potentially impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

If we fail to comply with applicable federal and state healthcare laws, including FDA, healthcare fraud and abuse, pharmaceutical marketing and advertising, and information privacy and security laws, we could face substantial penalties and our business, financial condition, results of operations, and prospects could be adversely affected.

As a biopharmaceutical company, we, as well as any of our contractors who conduct business for or on our behalf, are subject to many federal and state healthcare laws, including the federal Anti-Kickback Statute, or AKS, the federal civil and criminal False Claims Act, or FCA, the Civil Monetary Penalties Statute, the Medicaid Drug Rebate statute and other price reporting requirements, the federal Physician Payment Sunshine Act, the Veterans Health Care Act of 1992, HIPAA (as amended by the Health Information Technology for Economics and Clinical Health Act), the U.S. Foreign Corrupt Practices Act of 1977, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2020, or collectively, the ACA, and similar state laws. Even though we do not make referrals of healthcare services or bill directly to Medicare, Medicaid, or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. If we do not comply with all applicable fraud and abuse laws, we may be subject to healthcare fraud and abuse enforcement by both the federal government and the states in which we conduct our business.

Laws and regulations require calculation and reporting of complex pricing information for prescription drugs, and compliance will require us to invest in significant resources and develop a price reporting infrastructure, or depend on third parties to compute and report our drug pricing. Pricing reported to the Centers for Medicare & Medicaid Services, or CMS, must be certified. Non-compliant activities expose us to FCA risk if they result in overcharging agencies, underpaying rebates to agencies, or causing agencies to overpay providers.

If we or our operations are found to be in violation of any federal or state healthcare law, or any other governmental regulations that apply to us, we may be subject to significant penalties, including civil, criminal, and administrative penalties, damages, fines, disgorgement, debarment from government contracts, refusal of orders under existing contracts, exclusion from participation in U.S. federal or state health care programs, corporate integrity agreements and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare

providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including, but not limited to, exclusions from participation in government healthcare programs, which could also materially affect our business.

In particular, if we are found to have impermissibly promoted any of our product candidates, we may become subject to significant liability and government fines. We, and any of our collaborators, must comply with requirements concerning advertising and promotion for any of our product candidates for which we or they obtain marketing approval. Promotional communications with respect to therapeutics are subject to a variety of legal and regulatory restrictions and continuing review by the FDA, Department of Justice, Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress, and the public. When the FDA or comparable foreign regulatory authorities issue regulatory approval for a product candidate, the regulatory approval is limited to those specific uses and indications for which a product candidate is approved. If we are not able to obtain FDA approval for desired uses or indications for our product candidates, we may not market or promote our product candidates for those indications and uses, referred to as off-label uses, and our business may be adversely affected. We further must be able to sufficiently substantiate any claims that we make for our product candidates, including claims comparing our products candidates to other companies' products and must abide by the FDA's strict requirements regarding the content of promotion and advertising.

While physicians may choose to prescribe products for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, we are prohibited from marketing and promoting our product candidates for indications and uses that are not specifically approved by the FDA. These off-label uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the United States generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine. Regulatory authorities do, however, restrict communications by biopharmaceutical companies concerning off-label use.

The FDA and other agencies actively enforce the laws and regulations regarding product promotion, particularly those prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted a product may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed. Thus, we and any of our collaborators will not be able to promote any product candidates we develop for indications or uses for which they are not approved. In the United States, engaging in the impermissible promotion of our product candidates, following approval, for off-label uses can also subject us to false claims and other litigation under federal and state statutes, including fraud and abuse and consumer protection laws, which can lead to significant civil and criminal penalties and fines, agreements with governmental authorities that materially restrict the manner in which we promote or distribute our product candidates and do business through, for example, corporate integrity agreements, suspension or exclusion from participation in federal and state healthcare programs, and debarment from government contracts and refusal of future orders under existing contracts. These false claims statutes include the FCA, which allows any individual to bring a lawsuit against a biopharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims or causing others to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government decides to intervene and prevails in the lawsuit, the individual will share in the proceeds from any fines or settlement funds. If the government declines to intervene, the individual may pursue the case alone. These FCA lawsuits against manufacturers of drugs and biologics have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements in the hundreds of millions or billions of dollars, pertaining to certain sales practices and promoting off-label uses. In addition, FCA lawsuits may expose manufacturers to follow-on claims by private payors based on fraudulent marketing practices. This growth in litigation has increased the risk that a biopharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid, or other federal and state healthcare programs. If we or our future collaborators do not lawfully promote our approved product candidates, if any, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations and prospects.

Although an effective compliance program can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Moreover, achieving and sustaining compliance with applicable federal and state fraud laws may prove costly. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates profitably.

In both domestic and foreign markets, sales of our product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third-party payors. Such third-party payors include government health programs such as Medicare and Medicaid, managed care providers, private health insurers and other organizations.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Obtaining coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

Government authorities and third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. If reimbursement is not available, or is available only to limited levels, our product candidates may be competitively disadvantaged, and we, or our collaborators, may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us, or our collaborators, to establish or maintain a market share sufficient to realize a sufficient return on our or their investments. Alternatively, securing favorable reimbursement terms may require us to compromise pricing and prevent us from realizing an adequate margin over cost. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our product candidates. Even if we obtain coverage for a given product candidate, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Moreover, the factors noted above have continued to be the focus of policy and regulatory debate that has, thus far, shown the potential for movement towards permanent policy changes; this trend is likely to continue, and may result in more or less favorable impacts on pricing. Patients are unlikely to use our product candidates, unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our product candidates.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Prices paid for a drug also vary depending on the class of trade. Prices charged to government customers are subject to price controls, including ceilings, and private institutions obtain discounts through group purchasing organizations. Net prices for drugs may be further reduced by mandatory discounts or rebates required by government healthcare programs and demanded by private payors. It is also not uncommon for market conditions to warrant multiple discounts to different customers on the same unit, such as purchase discounts to institutional care providers and rebates to the health plans that pay them, which reduces the net realization on the original sale.

In addition, federal programs impose penalties on manufacturers of drugs marketed under an NDA, in the form of mandatory additional rebates and/or discounts if commercial prices increase at a rate greater than the Consumer Price Index-Urban, and these rebates and/or discounts, which can be substantial, may impact our ability to raise commercial prices. Regulatory authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability or that of our collaborators to sell our product candidates profitably. These payors may not view our product candidates, if any, as cost-effective, and coverage and reimbursement may not be available to our customers, or those of our collaborators, or may not

be sufficient to allow our product candidates, if any, to be marketed on a competitive basis. Cost control initiatives could cause us, or our collaborators, to decrease, discount, or rebate a portion of the price we, or they, might establish for our product candidates, which could result in lower than anticipated product revenues. If the realized prices for our product candidates, if any, decrease or if governmental and other third-party payors do not provide adequate coverage or reimbursement, our prospects for revenue and profitability will suffer. Moreover, the recent and ongoing series of congressional hearings relating to drug pricing has presented heightened attention to the biopharmaceutical industry, creating the potential for political and public pressure, while the potential for resulting legislative or policy changes presents uncertainty.

Assuming coverage is approved, the resulting reimbursement payment rates might not be adequate. If payors subject our product candidates to maximum payment amounts or impose limitations that make it difficult to obtain reimbursement, providers may choose to use therapies, that are less expensive when compared to our product candidates. Additionally, if payors require high copayments, beneficiaries may decline prescriptions and seek alternative therapies. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to the satisfaction of hospitals and other target customers and their third-party payors. Such studies might require us to commit a significant amount of management time and financial and other resources. Our future products might not ultimately be considered cost-effective. Adequate third-party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, third-party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging the prices charged. We, and our collaborators, cannot be sure that coverage will be available for any product candidate that we, or they, commercialize and, if available, that the reimbursement rates will be adequate. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for any of our product candidates for which we obtain marketing approval could have a material adverse effect on our results of operations, our ability to raise capital needed to commercialize products, and our overall financial condition.

There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our product candidates;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

We are subject to new legislation, regulatory proposals and healthcare payor initiatives that may increase our costs of compliance, and adversely affect our ability to market our products, obtain collaborators and raise capital.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities, and affect our ability, or the ability of our collaborators, to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or our collaborators, may receive for any approved product candidates.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, in June 2021 the U.S. Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the

case on procedural grounds without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and healthcare measures initiated by the Biden administration will impact the ACA, our business, financial condition and results of operations. Complying with any new legislation or change in regulatory requirements could be time-intensive and expensive, resulting in a material adverse effect on our business.

Additional federal and state healthcare reform measures may be adopted in the future that may result in more rigorous coverage criteria, increased regulatory burdens and operating costs, decreased net revenue from our biopharmaceutical products, decreased potential returns from our development efforts, and additional downward pressure on the price that we receive for any approved drug. For example, the American Rescue Plan of 2021 eliminated the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. Further any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

Legislative and regulatory proposals may also be made to expand post-approval requirements and restrict sales and promotional activities for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance, or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In addition, there have been a number of other policy, legislative and regulatory proposals aimed at changing the pharmaceutical industry, including heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. In August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. In an effort to curb Medicare Patients' out-of-pocket costs for prescription drugs, the Part D redesign legislation requires manufacturers to contribute to the catastrophic coverage phase for Part D drugs, as discounts through a manufacturer discount program. Furthermore, any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. Various industry stakeholders, including certain pharmaceutical companies and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. The impact of these judicial challenges and any future legislative, executive, and administrative actions and agency rules implemented by the government on us and the biopharmaceutical industry as a whole is unclear. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, a number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws once we begin commercialization after obtaining regulatory approval for any of our products. Further, FDA recently authorized the state of Florida to import certain prescription drugs from Canada for a period of two years to help reduce drug costs, provided that Florida's Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida. Any reduction in reimbursement from Medicare or other government programs may result in a reduction in payments from private payors.

We are unable to predict the future course of federal or state healthcare legislation in the United States directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The ACA and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In international markets, reimbursement and health care payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In some countries, particularly the countries of the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. There can be no assurance that our product candidates will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be available, or that the third-party payors' reimbursement policies will not adversely affect our ability to sell our product candidates profitably. If reimbursement of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

If our employees, independent contractors, consultants, commercial partners or vendors engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, we, directly or indirectly, could be exposed to significant losses and liability, including, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

We are exposed to the risk of fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws of the FDA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter misconduct or other improper activities by our employees or third parties that we engage for our business operations, including independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our, or our employees', consultants', collaborators', contractors', or vendors' business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, compliance agreements, withdrawal of product approvals, and curtailment of our operations, among other things, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Risks Related to Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, we may not be able to compete effectively or operate profitably.

We rely upon a combination of patents, know-how and confidentiality agreements to protect the intellectual property related to our product candidates and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our market.

Our success is dependent in large part on our obtaining, maintaining, protecting and enforcing patents and other proprietary rights in the United States and other countries with respect to our product candidates and on our ability to avoid infringing the intellectual property and other proprietary rights of others. Furthermore, patent law relating to the scope of claims in the biotechnology field in which we operate is still evolving and, consequently, patent positions in our industry may not be as strong as in other more well-established fields. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date.

We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates and novel discoveries that are important to our business. Our pending and future patent applications may not result in patents being issued or issued patents may not afford sufficient protection of our product candidates or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive products.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

Composition of matter patents for pharmaceutical product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our pending patent applications directed to composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office (USPTO) or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their products for our targeted indications, physicians may prescribe these products “off-label.” Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. For example, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, inventorship, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending patent applications may be challenged in patent offices in the United States and abroad. Even issued patents may later be found invalid or unenforceable or may be modified or

revoked in proceedings instituted by third parties before various patent offices or in courts. For example, our pending patent applications may be subject to third-party pre-issuance submissions of prior art to the USPTO or our issued patents may be subject to post-grant review (PGR) proceedings, oppositions, derivations, reexaminations, or inter partes review (IPR) proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical products, or limit the duration of the patent protection of our product candidates. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such candidates are commercialized. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Any failure to obtain or maintain patent protection with respect to our product candidates or their uses could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. We may also rely on trade secret protection as temporary protection for concepts that may be included in a future patent filing. However, trade secret protection will not protect us from innovations that a competitor develops independently of our proprietary know how. If a competitor independently develops a technology that we protect as a trade secret and files a patent application on that technology, then we may not be able to patent that technology in the future, may require a license from the competitor to use our own know-how, and if the license is not available on commercially-viable terms, then we may not be able to launch our product candidate. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, and this scenario could materially adversely affect our business, financial condition and results of operations.

We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that patents based on our patent applications will not be challenged and rendered invalid and/or unenforceable.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. We have pending U.S. and foreign patent applications in our portfolio; however, we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- whether the patent applications that we own will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries; and/or
- whether we may experience patent office interruption or delays to our ability to timely secure patent coverage to our product candidates.

We cannot be certain that the claims in our pending patent applications directed to our product candidates will be considered patentable by the USPTO or by patent offices in foreign countries. There can be no assurance that any such patent applications will issue as granted patents. One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our product candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries.

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

Patents are of national or regional effect, and although we currently have issued patents and pending applications in the United States, filing, prosecuting and defending patents on all of our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These competitor products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Various companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights.

Various countries outside the United States have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. As a result, a patent owner may have limited remedies in certain circumstances, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our product candidates. While we will endeavor to try to protect our product candidates with intellectual property rights, such as patents, as appropriate, the process of obtaining patents is time consuming, expensive and unpredictable.

In addition, geo-political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the United States and foreign government actions related to the military conflict in Ukraine may limit or prevent filing, prosecution, and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

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

- others may be able to make product candidates that are similar to ours, but that are not covered by the claims of the patents that we own;
- we or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own;
- we or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that noncompliance with the USPTO and foreign governmental patent agencies requirement for a number of procedural, documentary, fee payment and other provisions during the patent process can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own may be revoked, modified or held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own will result in issued patents with claims directed to our product candidates or uses thereof in the United States or in other foreign countries;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our patents are valid, enforceable and infringed;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property;
- we may fail to adequately protect and police our trademarks and trade secrets; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications.

If any of these or similar events occur, then they could significantly harm our business, results of operations and prospects.

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

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. There can be no assurance that our operations do not, or will not in the future, infringe existing or future third-party patents. Identification of third-party patent rights that may be relevant to our operations is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

Numerous U.S. and foreign patents and pending patent applications exist in our market that are owned by third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the U.S. can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These patent applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our product candidates.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, including our research programs, product candidates, their respective methods of use, manufacture and formulations thereof, and could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

We may be involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors or other third parties may infringe our patents, trademarks or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or insufficient written description. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35

U.S.C. §271(e)(1). An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, we cannot assure you that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third-party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders, or it may be otherwise impractical or undesirable to enforce our intellectual property against some third parties. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in-license needed technology or other product candidates, or enter into development partnerships that would help us bring our product candidates to market.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates without infringing the intellectual property and other proprietary rights of third parties. Third parties may allege that we have infringed or misappropriated their intellectual property. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and, even if resolved in our favor, is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our products candidates. We cannot be certain that our product candidates will not infringe existing or future patents owned by third parties. Third parties may assert infringement claims against us based on existing or future intellectual property rights. We may decide in the future to seek a license to those third-party intellectual property patents, but we might not be able to do so on reasonable terms. Proving invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue

developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business.

We may not be aware of patents that have already been issued and that a third party, for example, a competitor in the fields in which we are developing our product candidates, might assert are infringed by our current or future product candidates, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our product candidates. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates, could be found to be infringed by our product candidates. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates. The pharmaceutical and biotechnology industries have produced a considerable number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates or methods of use either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents, and there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business and operations. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

We may choose to challenge the enforceability or validity of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an ex-parte re-exam, inter partes review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the EPO, or other foreign patent office. The costs of these opposition proceedings could be substantial and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates.

If we are found to infringe a third-party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate. Alternatively, we may be required to obtain a license from such third-party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, and could divert the time and attention of our technical personnel and management, cause development delays, and/or require us to develop non-infringing technology, which may not be possible on a cost-effective basis, any of which could materially harm our business. In the event of a successful claim of infringement against us, we may have to pay substantial monetary damages, including treble damages and attorneys' fees for willful infringement, pay royalties and other fees, redesign our infringing drug or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of a patent. The USPTO and various foreign governmental patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market with similar or identical products, which would have a material adverse impact on our business, financial condition, results of operations and prospects.

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

As is the case with other biopharmaceutical companies, our success is dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first-to-file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either file any patent application related to our product candidates or other technologies or invent any of the inventions claimed in our patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Further, because of a lower evidentiary standard in these USPTO post-grant proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned patent applications and the enforcement or defense of our owned issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Additionally, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. While we do not believe that any of the patents owned by us will be found invalid based on the foregoing, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents.

In addition, as of June 1, 2023, European patent applications and patents may be subject to the jurisdiction of the European Unified Patent Court (UPC). Further, European patent applications have the option, upon grant of a patent, of becoming a Unitary Patent, which is subject to the jurisdiction of the UPC. The establishment of the UPC and Unitary Patent are significant changes in European patent practice. As the UPC is an only recently established court system, there is limited precedent for the court, creating uncertainty for any

litigation in the UPC. As the UPC, as a single court system, can invalidate a European patent, we, where applicable, have opted out of the UPC and as such, each European patent would need to be challenged in each individual country.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

As is common in the pharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies, including our competitors or potential competitors. We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may become subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor.

While we may litigate to defend ourselves against these claims, even if we are successful, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

We may not be able to license or acquire new or necessary intellectual property rights or technology from third parties.

Other parties, including our competitors, may have patents and have filed and are likely filing patent applications potentially relevant to our business. In order to avoid infringing these patents, we may find it necessary or prudent to obtain licenses to such patents from such parties. The licensing or acquisition of intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. No assurance can be given that we will be successful in licensing any additional rights or technologies from third parties. Our inability to license the rights and technologies that we have identified, or that we may in the future identify, could have a material adverse impact on our ability to complete the development of our product candidates or to develop additional product candidates. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. Failure to obtain any necessary rights or licenses may detrimentally affect our planned development of our current or future product candidates and could increase the cost, and extend the timelines associated with our development, of such other product candidates, and we may have to abandon development of the relevant program or product candidate. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Patent rights are of limited duration. In the United States, if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years after its first effective filing date. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic products. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours. Upon issuance in the United States, the term of a patent can be increased by patent term adjustment, which is based on certain delays caused by the USPTO, but this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. The term of a United States patent may also be shortened if the patent is terminally disclaimed over an earlier-filed patent. A patent term extension (PTE) based on regulatory delay may be available in the United States. However, only a single patent can be extended for each marketing approval, and

any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the PTE does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous PTEs in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain PTE or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration and may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to launch their product earlier than might otherwise be the case, and our revenue could be reduced, possibly materially.

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

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Our inventors may have performed work for other portfolio companies as part of their employment with Kalika Biosciences, Inc., or Kalika. While Kalika previously had a services agreement in place with each of its portfolio companies, which included the segregation of services and ownership of intellectual property for each portfolio company, including the ability of inventors to assign inventions, work product and intellectual property directly to us, disputes about ownership between us and Kalika and/or other portfolio companies of Kalika may arise in the future, which may have a material adverse effect on our business.

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

Our reliance on third parties can also present intellectual property-related risks. For example, collaborators may not properly obtain, maintain, enforce or defend intellectual property or proprietary rights relating to our product candidates or may use our proprietary information in such a way as to expose us to potential litigation or other intellectual property-related proceedings, including proceedings challenging the scope, ownership, validity and enforceability of our intellectual property. Collaborators may also own or co-own intellectual property covering our product candidates that results from our collaboration with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property or such product candidates. Collaborators may also gain access to our trade secrets or formulations and impact our ability to commercialize our product candidates. We may also need the cooperation of our collaborators to enforce or defend any intellectual property we contribute to or that arises out of our collaborations, which may not be provided to us.

We may rely on trade secrets and proprietary know-how which can be difficult to trace and enforce and, if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for our product candidates, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Elements of our product candidates, including processes for their preparation and manufacture, may involve proprietary know-how, information or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants

and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Because we expect to rely on third parties in the development and manufacture of our product candidates, we must, at times, share trade secrets with them. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Trade secrets and know-how can be difficult to protect. We require our employees to enter into written employment agreements containing provisions of confidentiality and obligations to assign to us any inventions generated in the course of their employment. We and any third parties with whom we share facilities enter into written agreements that include confidentiality and intellectual property obligations to protect each party's potential trade secrets, proprietary know-how and information. We further seek to protect our potential trade secrets, proprietary know-how and information in part, by entering into non-disclosure and confidentiality agreements with parties who are given access to them, such as our corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. With our consultants, contractors and outside scientific collaborators, these agreements typically include invention assignment obligations. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. We cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third-party, our competitive position would be harmed.

We may be subject to claims that we or our employees, consultants or advisors have wrongfully used or disclosed alleged confidential information or trade secrets.

We have entered into and will enter in the future into non-disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, potential partners, and other third parties. We may become subject to litigation where a third party asserts that we or our employees, consultants or advisors inadvertently or otherwise breached the agreements and used or disclosed trade secrets or other information proprietary to the third parties. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product or product candidates and technology. Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our developmental and commercialization efforts, which could adversely affect our business.

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

Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Although these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Moreover, any name we have proposed to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, it may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Risks Related to Our Common Stock

An active, liquid and orderly trading market may not be developed or sustained for our common stock, and, as a result, it may be difficult for you to sell your shares of our common stock.

The trading market for our common stock on the Nasdaq Global Select Market has been limited and an active trading market for our common stock may never develop or be sustained. If a market for our common stock does not develop or is not sustained, it may be difficult for you to sell your shares of common stock at an attractive price or at all. We cannot predict the prices at which our common stock will trade. It is possible that in one or more future periods our results of operations and progression of our product pipeline may not meet the expectations of public market analysts and investors, and, as a result of these and other factors, the price of our common stock may fall.

Our stock price has been and may continue to be volatile, and you could lose all or part of your investment.

The market price of our common stock has been and is likely to continue to be volatile and could fluctuate widely in response to many factors, including but not limited to:

- announcements of the results of clinical trials by us, our collaborators or our competitors, or positive or negative developments with respect to similar products, including those being developed by our collaborators or our competitors;
- volatility and instability in the financial markets and capital markets, including any impact of adverse developments effecting the financial services industry, such as those based on liquidity constraints or concerns;
- developments with respect to patents or proprietary rights;
- announcements of technological innovations by us or our competitors;
- announcements of new products or new contracts by us or our competitors;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by equities research analysts and whether our earnings meet or exceed such estimates;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders, or other stockholders, or the perception or anticipation thereof;
- expiration of market standoff or lock-up agreements;
- conditions and trends in the pharmaceutical, biotechnology and other industries;
- receipt, or lack of receipt, of funding in support of conducting our business;

- regulatory developments within, and outside of, the United States, including changes in the structure of health care payment systems;
- litigation or arbitration;
- natural disasters or major catastrophic events, such as the COVID-19 pandemic;
- general economic, political and market conditions and other factors; and
- the occurrence of any of the risks described in this “Risk Factors” section.

From September 30, 2023 until September 30, 2024, the closing price of our common stock has ranged from a low of $1.85 to a high of $31.18. In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance.

Additionally, a decrease in trading price of our common stock may cause our common stock to no longer satisfy the continued listing standards of Nasdaq. If we are not able to maintain the requirements for listing on Nasdaq, we could be delisted, which could have a materially adverse effect on our ability to raise additional funds as well as on the price and liquidity of our common stock.

Subject to various spending levels approved by our board of directors, our management will have broad discretion in the use of the net proceeds from our capital raises and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from our capital raises and our stockholders will not have the opportunity as part of their investment decision to assess whether the net proceeds from our capital raises are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from our capital raises, their ultimate use may vary substantially from their currently intended use. You may not agree with our decisions, and our use of the proceeds from our capital raises may not yield any return to stockholders. Our failure to apply the net proceeds of our capital raises effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of those net proceeds. Stockholders will not have the opportunity to influence our decisions on how to use our net proceeds from our capital raises. Pending their use, we may invest the net proceeds from our capital raises in interest and non-interest bearing cash accounts, short-term, investment-grade, interest-bearing instruments and U.S. government securities. These temporary investments are not likely to yield a significant return.

You may experience future dilution as a result of future equity offerings or other equity issuances.

We will have to raise additional capital in the future. To raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may be lower than the price you paid per share. In addition, investors purchasing shares or other securities in the future could have rights superior to those of other investors. Any such issuance could result in substantial dilution to investors.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of our common stock intend to sell shares, could reduce the market price of our common stock.

As of November 4, 2024, we had 70,710,667 outstanding shares of common stock and 70,601 shares of Series A Non-Voting Convertible Preferred Stock which are convertible into 100 shares of common stock for each share of Series A Non-Voting Convertible Preferred Stock. All outstanding shares of common stock are available for sale in the public market, subject to limitations under Rule 144 with respect to affiliates of our company.

On February 13, 2024, we filed a Post-Effective Amendment No. 1 to our shelf registration statement on Form S-3 with the Securities and Exchange Commission, to register the offering, sale and issuance of up to $300.0 million in aggregate of our common stock, preferred stock, debt securities, guarantees of debt securities, warrants and units from time to time in one or more offerings. This Post-Effective Amendment No. 1 was filed due to our expectation that we would cease to be a well-known seasoned issuer (as such term is defined in Rule 405 under the Securities Act) upon the filing of our Annual Report on Form 10-K. After we were no longer a

well-known seasoned issuer, on February 28, 2024, we filed a Post-Effective Amendment No. 2 to our shelf registration statement on Form S-3 to convert our shelf registration statement from a Form S-3ASR (automatic shelf registration statement) to a Form S-3 (non-automatic shelf registration statement), which was declared effective by the Securities and Exchange Commission on April 26, 2024.

Each time we offer to sell securities under the registration statement, we will provide a prospectus supplement that will contain specific information about the terms of that offering and the securities being offered.

For example, pursuant to the Post-Effective Amendment No. 2 to Form S-3, we may sell shares of common stock under our Sales Agreement with Jefferies, as sales agent, pursuant to which we could offer and sell, from time to time through Jefferies, shares of common stock providing for aggregate sales proceeds of up to $100,000,025.

On March 6, 2024, we entered into a stock purchase agreement for a private placement with certain qualified institutional buyers and institutional accredited investors. Pursuant to the stock purchase agreement, we agreed to sell to the purchasers 11,174,000 shares of our common stock, par value of $0.0001 per share, at an offering price of $8.95 per share. The private placement closed on March 11, 2024. On April 9, 2024, we filed a registration statement on Form S-3 to register the offer and resale of the shares sold in the private placement, and on April 29, 2024, that registration statement was declared effective by the Securities and Exchange Commission.

Additionally, on September 23, 2024, we entered into a securities purchase agreement for a private placement with Aventis Inc. Pursuant to the securities purchase agreement, we agreed to sell to Aventis 70,601 shares of Series A Non-Voting Convertible Preferred Stock, par value $0.0001 per share, at a purchase price of $3.8243 per share. The Series A Non-Voting Convertible Preferred Stock is convertible at the option of Aventis, or any subsequent holder, at any time into 100 shares of common stock for each share of Series A Non-Voting Convertible Preferred Stock. The private placement closed on September 23, 2024. On or about the date of this report, we expect to file a registration statement on Form S-3 to register the offer and resale of the shares issuable upon conversion Series A Non-Voting Convertible Preferred Stock.

In addition, we have filed registration statements on Form S-8 under the Securities Act registering the issuance of 18,077,251 shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under the registration statements on Form S-8 can be freely sold in the public market upon issuance, subject to volume limitation applicable to affiliates and the lock-up agreements described above.

We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options, or the perception that such sales may occur, could adversely affect the market price of our common stock.

Our board of directors is authorized to issue and designate shares of our preferred stock in additional series without stockholder approval under our charter documents or Delaware law.

Our amended and restated certificate of incorporation authorizes our board of directors, without the approval of our stockholders, to issue shares of our preferred stock, subject to limitations prescribed by applicable law, rules and regulations (including Nasdaq rules) and the provisions of our amended and restated certificate of incorporation, as shares of preferred stock in series, to establish from time to time the number of shares to be included in each such series and to fix the designation, powers, preferences and rights of the shares of each such series and the qualifications, limitations or restrictions thereof. The powers, preferences and rights of these additional series of preferred stock may be senior to or on parity with our common stock, which may reduce its value. For example, we have issued Series A Non-Voting Convertible Preferred Stock (“Series A Preferred”) which is convertible at the option of each holder at any time into one hundred (100) shares of our common stock for each share of Series A Preferred, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization. This may result in substantial dilution to holders of our common stock. In the event our board of directors approves dividends, holders of Series A Preferred are entitled to receive a dividend on each outstanding share of Series A Preferred equal to $0.0001 per share prior and in preference to any declaration or payment of any dividend on common stock during the same calendar year, other than dividends on shares of common stock payable in shares of common stock. Any declared but unpaid dividends on Series A Preferred are required to be paid in full prior to any asset distributions in the event of a liquidation.

We do not anticipate paying cash dividends for the foreseeable future, and therefore investors should not buy our stock if they wish to receive cash dividends.

You should not rely on an investment in our common stock to provide dividend income. We have never declared or paid any cash dividends or distributions on our common stock. We currently intend to retain our future earnings to support operations and to finance expansion and, therefore, we do not anticipate paying any cash dividends on our common stock in the foreseeable future. In addition, any future credit facility may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock.

Our existing directors and executive officers and related entities hold a significant portion of our common stock and will be able to exert significant control over matters subject to stockholder approval.

As of September 30, 2024, our executive officers and directors and related entities beneficially owned a significant portion of our outstanding voting stock. These stockholders, acting together, may be able to impact matters requiring stockholder approval. For example, they may be able to impact the elections of directors, amendments to our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholder and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq.

If Nasdaq delists our shares of common stock from trading on its exchange for failure to meet Nasdaq's listing standards, we and our stockholders could face significant material adverse consequences including: a limited availability of market quotations for our securities; reduced liquidity for our securities; a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities; a limited amount of new and analyst coverage; and a decreased ability to issue additional securities or obtain additional financing in the future.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

There are provisions in our amended and restated certificate of incorporation and amended and restated bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change in control was considered favorable by you and other stockholders. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue shares of convertible preferred stock, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in our control;
- provide that the authorized number of directors may be changed only by resolution of the board of directors, subject to the rights of any holders of convertible preferred stock;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and also meet specific requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a plurality of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of our stockholders may be called only by the board of directors, the chairman of the board of directors, our chief executive officer or president (in the absence of a chief executive officer); and

- provide that stockholders will be permitted to amend certain provisions of our bylaws only upon receiving at least two-thirds of the votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and bylaws could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another state court in Delaware or the federal district court for the District of Delaware) is the exclusive forum for the following (except for any claim as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within 10 days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than such court or for which such court does not have subject matter jurisdiction):

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of fiduciary duty;
- any action asserting a claim against us arising under the Delaware General Corporation Law, our certificate of incorporation or our bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

Our amended and restated bylaws further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction. The enforceability of similar exclusive federal forum provisions in other companies' organizational documents has been challenged in legal proceedings, and while the Delaware Supreme Court has ruled that this type of exclusive federal forum provision is facially valid under Delaware law, there is uncertainty as to whether other courts would enforce such provisions and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

These exclusive forum provisions may (i) increase the costs for an investor and/or (ii) limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find either exclusive forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could have a material adverse effect on our business, financial condition, and results of operations.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our certificate of incorporation and bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. In addition, as permitted by Section 145 of the Delaware General Corporation Law, our bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.

- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.

- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.

- We are not obligated pursuant to our bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.

- The rights conferred in our bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.

- We may not retroactively amend our bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

To the extent that a claim for indemnification is brought by any of our directors or officers, it would reduce the amount of funds available for use in our business.

General Risk Factors

If equities or industry analysts do not publish research or reports about our company, or if they issue adverse or misleading opinions regarding us or our stock, our stock price and trading volume could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. If such coverage is not maintained, the market price for our stock may be adversely affected. Our stock price also may decline if any analyst who covers us issues an adverse or erroneous opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet analysts' expectations. If one or more analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline and possibly adversely affect our ability to engage in future financings.

Failure to establish and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business and if investors lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline significantly.

As a public company, we are required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which requires management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of controls over financial reporting. Additionally, due to our loss of emerging growth company status as of December 31, 2023, our independent registered public accounting firm was required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 as of December 31, 2023.

We do not currently have any internal audit function. To achieve compliance with Section 404 within the prescribed period, we have engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, including through hiring additional financial and accounting personnel, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts.

Testing and maintaining internal control can divert our management's attention from other matters that are important to the operation of our business. Additionally, when evaluating our internal control over financial reporting, we may identify material weaknesses that we may not be able to remediate in time to meet the applicable deadline imposed upon us for compliance with the requirements of Section 404. If we identify any material weaknesses in our internal control over financial reporting or are unable to comply with the requirements of Section 404 in a timely manner or assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC or other regulatory authorities, which could require additional financial and management resources. In addition, if we fail to remedy any material weakness, our financial statements could be inaccurate, and we could face restricted access to capital markets.

If a restatement of our financial statements were to occur, our stockholders' confidence in our financial reporting in the future may be affected, which could in turn have a material adverse effect on our business and stock price.

If any material weaknesses in our internal control over financial reporting are discovered or occur in the future, our consolidated financial statements may contain material misstatements, and we could be required to further restate our financial results. In addition, if we are unable to successfully remediate any future material weaknesses in our internal controls or if we are unable to produce accurate and timely financial statements, our stock price may be adversely affected, and we may be unable to maintain compliance with applicable stock exchange listing requirements.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Unfavorable global economic conditions, including adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our business, financial condition, results of operations, or prospects.

Our business, financial condition, results of operations or prospects could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn, or additional global financial crises, could result in a variety of risks to our business, including weakened demand for our product candidates, if approved, or our inability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

In addition, actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems.

Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all.

Our operations are vulnerable to business disruptions, including events beyond our control, which could seriously harm operations and financial condition and increase our costs and expenses.

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

We incur significant costs as a result of being a public company, which may adversely affect our business, financial condition, results of operations, prospects, and the price of our common stock.

We incur costs associated with corporate governance requirements that are applicable to us as a public company, including rules and regulations of the SEC, under the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (the Dodd-Frank Act), and the Exchange Act, as well as the rules of Nasdaq. These rules and regulations can significantly increase our accounting, legal, insurance, financial compliance and other costs and make some activities more time consuming. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas, such as “say on pay” and proxy access. Stockholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

The Exchange Act requires us to file annual, quarterly and current reports with respect to our business and financial condition within specified time periods and to prepare a proxy statement with respect to our annual meeting of stockholders. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal controls over financial reporting. Upon the loss of our status as an emerging growth company as of December 31, 2023, we are no longer exempt from the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, and our independent registered public accounting firm will evaluate and report on the effectiveness of internal control over financial reporting, as required. Nasdaq requires that we comply with various corporate governance requirements. To maintain and improve the effectiveness of our disclosure controls and procedures and internal controls over financial reporting and comply with the Exchange Act and Nasdaq requirements, significant resources and management oversight will be required. This may divert management’s attention from other business concerns and lead to significant costs associated with compliance, which could have a material adverse effect on us and the price of our common stock.

The expenses incurred by public companies generally for reporting and corporate governance purposes have been increasing. We expect these laws and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly, although we are currently unable to estimate these costs with any degree of certainty. These laws and regulations could also make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or its committees or as our executive officers. Advocacy efforts by stockholders and third parties may also prompt even more changes in governance and reporting requirements. We cannot predict or estimate the amount of costs we may incur or the timing of these costs. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions and other regulatory action and potentially civil litigation. Accordingly, increases in costs incurred as a result of becoming a publicly traded company may adversely affect our business, financial condition, results of operations, and prospects.

We are, and may in the future become, subject to securities litigation, which is expensive and could divert management attention.

Following periods of volatility in the market price of a company’s securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we have been, and may in the future again become, the target

of securities litigation. Securities litigation against us could result in substantial costs and divert our management's attention and resources from our business, which could seriously harm our business. See Note 5, "Commitments and Contingencies," in the notes to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for more information regarding the putative securities class action complaint filed against us on March 1, 2024. We intend to defend against the claims set forth in the complaint vigorously. Regardless, failure by us to obtain a favorable resolution of such claims could require us to pay damage awards or otherwise enter into settlement arrangements for which our insurance coverage may be insufficient. Any such damage awards or settlement arrangements in current or future litigation could have a material adverse effect on our business, operating results or financial condition. Even if plaintiffs' claims are not successful, defending against securities litigation is expensive and could divert management's attention and resources, all of which could have a material adverse effect on our financial condition and operations, operating results and financial condition and negatively affect the price of our common stock. In addition, such lawsuits may make it more difficult for us to finance our operations in the future.

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

There were no sales of unregistered securities by us during the quarter ended September 30, 2024 that were not previously reported in current reports on Form 8-K filed with the SEC.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not Applicable.

Item 5. Other Information.

Consulting Agreement Amendment

As previously disclosed on the Company's Current Report on Form 8-K, filed on April 5, 2024, the Company entered into a Consulting Agreement with Christopher Krueger on April 5, 2024. On September 10, 2024, the Company entered into Amendment No. 1 to Consulting Agreement with Mr. Krueger to extend the term of the Consulting Agreement an additional six months for Mr. Krueger to continue to provide certain transition services to the Company.

Securities Trading Plans of Directors and Executive Officers

No officers or directors, as defined in Rule 16a-1(f), adopted or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," as defined in Regulation S-K Item 408, during the last fiscal quarter.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as amended June 9, 2023 (incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q, dated August 10, 2023).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, dated December 12, 2022).
3.3	Certificate of Designations of Preferences, Rights and Limitations of Series A Non-Voting Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, dated September 23, 2024).
10.1	Securities Purchase Agreement, dated September 23, 2024, by and between the Registrant and Aventis Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, dated September 23, 2024).
10.2+*	Separation and Release Agreement, dated August 30, 2024, by and between the Registrant and Martin Auster.
10.3+*	Offer Letter, dated December 1, 2022, by and between the Registrant and Roy Gonzales.
10.4+*	Offer Letter, dated July 2, 2024, by and between the Registrant and Mark Forman.
10.5+*	Consulting Agreement by and between the Registrant and Christopher Krueger, dated April 5, 2024, as amended by Amendment No. 1 to Consulting Agreement, dated September 10, 2024.
31.1*	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.
31.2*	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.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema with Embedded Linkbase documents
104	Cover page formatted as Inline XBRL and contained in Exhibit 101

* Filed herewith.

+ Indicates management contract or compensatory plan.

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Ventyx Biosciences, Inc.

Date: November 7, 2024

By: /s/ Roy Gonzales

Roy Gonzales, C.P.A., M.B.A.
Senior Vice President, Finance
(Interim Principal Financial and Accounting Officer and duly authorized to sign on behalf of the registrant)

Exhibit 10.2

SEPARATION AGREEMENT AND RELEASE

This Separation Agreement and Release ("Agreement") is made by and between Martin D. Auster, M.D. ("Executive") and Ventyx Biosciences, Inc. (the "Company") (jointly referred to as the "Parties" or individually referred to as a "Party").

RECITALS

WHEREAS, Executive was employed by the Company;

WHEREAS, Executive signed a confirmatory employment letter with the Company dated October 7, 2021 (the "Offer Letter");

WHEREAS, Executive signed an At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement with the Company on May 3, 2021 (the "Confidentiality Agreement");

WHEREAS, Executive signed an Indemnification Agreement with the Company dated October 20, 2021 (the "Indemnification Agreement");

WHEREAS, Executive signed an Executive Change in Control and Severance Plan Participation Agreement with the Company on May 8, 2022 (the "Severance Plan Participation Agreement");

WHEREAS, the Company granted Executive restricted stock units, restricted stock awards and options to purchase shares of the Company's common stock as set forth on Exhibit A (collectively, the "Equity Awards") pursuant to the terms and conditions of either the Company's 2019 Equity Incentive Plan or the Company's 2021 Equity Incentive Plan and the applicable award agreements thereunder between the Company and Executive (collectively the "Equity Agreements");

WHEREAS, Executive employment with the Company will terminate effective as of August 30, 2024 (the "Separation Date"); and

WHEREAS, the Parties wish to resolve any and all disputes, claims, complaints, grievances, charges, actions, petitions and demands that the Executive may have against the Company and any of the Releasees as defined below, including, but not limited to, any and all claims arising out of or in any way related to Executive's employment with or separation from the Company.

NOW, THEREFORE, in consideration of the mutual promises made herein, the Company and Executive hereby agree as follows:

COVENANTS

1. Consideration. In consideration of Executive's execution of this Agreement and Executive's fulfillment of all of its terms and conditions, and provided that Executive does not revoke the Agreement, the Company agrees as follows:

a. *Payment*. The Company shall pay Executive a total of $356,826.60, at the rate of $39,647.40 per month, less applicable withholdings, for nine months starting on the first regular payroll date following the Effective Date, in accordance with the Company's regular payroll practices.

b. *Continued Medical Benefits*. The Company shall reimburse Executive for the payments Executive makes for COBRA coverage through the first nine full calendar months beginning as of the month following the month in which the Effective Date occurs, or until Executive has secured health insurance coverage through another employer, whichever occurs first, provided that Executive timely elects and pays for continuation coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), within the time period prescribed pursuant to COBRA. COBRA reimbursements shall be made by the Company to Executive consistent with the Company's normal expense reimbursement policy, provided that Executive submits documentation to the Company substantiating Executive's payments for COBRA coverage.

c. *Acceleration of Equity Awards.* The unvested shares subject to the Equity Awards that would have vested had Executive's employment with the Company continued through November 30, 2024, the date that is three months following the Separation Date, will accelerate and fully vest.

d. *Acknowledgement*. Executive acknowledges that without this Agreement, Executive is otherwise not entitled to the consideration listed in this Section 1.

2. Equity. The Parties agree that for purposes of determining the number of shares of the Company's common stock that Executive is entitled to purchase or receive from the Company pursuant to the exercise or settlement (as applicable) of outstanding Equity Awards, Executive will be considered to have vested only up to the Separation Date (including, for the avoidance of doubt, any vesting acceleration pursuant to Section 1(c) of the Agreement), as set forth in Exhibit A. All unvested shares subject to outstanding Equity Awards as of the Separation Date will terminate on the Separation Date. Other than as amended pursuant to Section 1(c) of this Agreement, the Equity Awards shall continue to be governed by the terms and conditions of the applicable Equity Agreements.

3. Benefits. Executive's health insurance benefits shall cease on August 31, 2024, subject to Executive's right to continue Executive's health insurance under COBRA. Executive's participation in all benefits and incidents of employment, including, but not limited to, the accrual of bonuses, vacation and paid time off, ceased as of the Separation Date.

4. Payment of Compensation and Receipt of All Benefits. Executive acknowledges and represents that, other than the consideration set forth in this Agreement, the Company has paid or provided all salary, wages, bonuses, accrued vacation/paid time off, premiums, leaves, housing allowances, relocation costs, interest, severance, outplacement costs, fees, reimbursable expenses, commissions, stock, stock options, vesting and any and all other benefits and compensation due to Executive.

5. Release of Claims. Executive agrees that the foregoing consideration represents settlement in full of all outstanding obligations owed to Executive by the Company and its current and former: officers, directors, employees, agents, investors, attorneys, shareholders, administrators, affiliates, benefit plans, plan administrators, professional employer organization or co-employer, insurers, trustees, divisions, subsidiaries, predecessor and successor corporations and assigns (collectively, the "Releasees"). Executive, on Executive's own behalf and on behalf of Executive's respective heirs, family members, executors, agents and assigns, hereby and forever releases the Releasees from, and agrees not to sue concerning, or in any manner to institute, prosecute or pursue, any claim, complaint, charge, duty, obligation, demand or cause of action relating to any matters of any kind, whether presently known or unknown, suspected or unsuspected, that Executive may possess against any of the Releasees arising from any omissions, acts, facts or damages that have occurred up until and including the date Executive signs this Agreement, including, without limitation:

a. any and all claims relating to or arising from Executive's employment relationship with the Company and the termination of that relationship;

b. any and all claims relating to, or arising from, Executive's right to purchase, or actual purchase of shares of stock of the Company, including, without limitation, any claims for fraud, misrepresentation, breach of fiduciary duty, breach of duty under applicable state corporate law, and securities fraud under any state or federal law;

c. any and all claims for wrongful discharge of employment, termination in violation of public policy, discrimination, harassment, retaliation, breach of contract (both express and implied), breach of covenant of good faith and fair dealing (both express and implied), promissory estoppel, negligent or intentional infliction of emotional distress, fraud, negligent or intentional misrepresentation, negligent or intentional interference with contract or prospective economic advantage, unfair business practices, defamation, libel, slander, negligence, personal injury, assault, battery, invasion of privacy, false imprisonment, conversion and disability benefits;

d. any and all claims for violation of any federal, state or municipal statute, including, but not limited to, Title VII of the Civil Rights Act of 1964, the Civil Rights Act of 1991, the Rehabilitation Act of 1973, the Americans with Disabilities Act of 1990, the Equal Pay Act, the Fair Labor Standards Act, the Fair Credit Reporting Act, the Age Discrimination in Employment Act of 1967, the Older Workers Benefit Protection Act, the Employee Retirement Income Security Act of 1974, the Worker Adjustment and Retraining Notification Act, the Family and Medical Leave Act, the Immigration Reform and Control Act, the National Labor Relations Act, the California Family Rights Act, the California Labor Code, the California Workers' Compensation Act, the California Fair Employment and Housing Act, the Vermont Fair Employment Practices Act, the Vermont Employment of People with Disabilities Law, the Vermont Whistleblower Protection for Health Care Employees Law, the Vermont Conditions for Employment Law, the Vermont Parental and Family Leave Act, the Vermont Wage Payment Law, the Vermont Minimum Wage Law, the Vermont Drug Testing Law, Vermont Genetic Testing Law, and the Vermont Employment Rights For Reserve and National Guard Members Law;

e. any and all claims for violation of the federal or any state constitution;

f. any and all claims arising out of any other laws and regulations relating to employment or employment discrimination;

g. any claim for any loss, cost, damage or expense arising out of any dispute over the non-withholding or other tax treatment of any of the proceeds received by Executive from the Company; and

h. any and all claims for attorneys' fees and costs.

Executive agrees that the release set forth in this Section shall be and remain in effect in all respects as a complete general release as to the matters released. This release does not extend to any obligations incurred under this Agreement and does not eliminate any rights to indemnification that Executive may have under the Indemnification Agreement. This release does not release claims that cannot be released as a matter of law. Any and all disputed wage claims that are released herein shall be subject to binding arbitration in accordance with this Agreement, except as required by applicable law. This release does not extend to any right Executive may have to unemployment compensation benefits.

6. Acknowledgment of Waiver of Claims under ADEA. Executive acknowledges that Executive is waiving and releasing any rights Executive may have under the Age Discrimination in Employment Act of 1967 ("ADEA"), and that this waiver and release is knowing and voluntary. Executive agrees that this waiver and release does not apply to any rights or claims that may arise under the ADEA after the date Executive signs this Agreement. Executive acknowledges that the consideration given for this waiver and release is in addition to anything of value to which Executive was already entitled. Executive further acknowledges that Executive has been advised by this writing that: (a) Executive should consult with an attorney prior to executing this Agreement; (b) Executive has twenty-one (21) days within which to consider this Agreement; (c) Executive has seven (7) days following Executive's execution of this Agreement to revoke this Agreement; (d) this Agreement shall not be effective until after the revocation period has expired; and (e) nothing in this Agreement prevents or precludes Executive from challenging or seeking a determination in good faith of the validity of this waiver under the ADEA, nor does it impose any condition precedent, penalties, or costs for doing so, unless specifically authorized by federal law. In the event Executive signs this Agreement and returns it to the Company in less than the 21-day period identified above, Executive hereby acknowledges that Executive has knowingly and voluntarily chosen to waive the time period allotted for considering this Agreement. Executive acknowledges and understands that revocation must be accomplished by a written notification to the person executing this Agreement on the Company's behalf that is received prior to the Effective Date. The Parties agree that changes, whether material or immaterial, do not restart the running of the 21-day period.

7. No Pending or Future Lawsuits. Executive represents that Executive has no lawsuits, claims, or actions pending in Executive's name, or on behalf of any other person or entity, against the Company or any of the other Releasees. Executive also represents that Executive does not intend to bring any claims on Executive's own behalf or on behalf of any other person or entity against the Company or any of the other Releasees.

8. Application for Employment. Executive understands and agrees that, as a condition of this Agreement, Executive shall not be entitled to any employment with the Company, and Executive hereby waives any right, or alleged right, of employment or re-employment with the Company.

9. Trade Secrets and Confidential Information/Company Property. Executive acknowledges that, separate from this Agreement, Executive remains under continuing obligations to the Company under the Confidentiality Agreement, including the provisions therein regarding nondisclosure of the Company's trade secrets and confidential and proprietary information. Executive's signature below constitutes Executive's certification under penalty of perjury that Executive has returned all documents and other items provided to Executive by the Company (with the exception of a copy of the Employee Handbook and personnel documents specifically relating to Executive), developed or obtained by Executive in connection with Executive's employment with the Company, or otherwise belonging to the Company.

10. No Cooperation. Subject to the Protected Activity Not Prohibited Section, Executive agrees that Executive will not knowingly encourage, counsel or assist any attorneys or their clients in the presentation or prosecution of any disputes, differences, grievances, claims, charges or complaints by any third party against any of the Releasees, unless under a subpoena or other court order to do so or upon written request from an administrative agency or the legislature or as related directly to the ADEA waiver in this Agreement. Executive agrees both to immediately notify the Company upon receipt of any such subpoena or court order or written request from an administrative agency or the legislature, and to furnish, within three (3) business days of its receipt, a copy of such subpoena or other court order or written request from an administrative agency or the legislature. If approached by anyone for counsel or assistance in the presentation or prosecution of any disputes, differences, grievances, claims, charges or complaints against any of the Releasees, Executive shall state no more than that Executive cannot provide counsel or assistance.

11. Cooperation with the Company. Executive agrees that Executive shall provide reasonable cooperation and assistance to the Company in the resolution of any matters in which Executive was involved during the course of Executive employment or about which Executive has knowledge in the defense or prosecution of any investigations, audits, claims or actions now in existence or which may be brought or threatened in the future against or on behalf of the Company, including any investigations, audits, claims or actions involving or against its officers, directors and employees. Executive's cooperation with such matters shall include, without limitation, being available to consult with the Company regarding such matters; to reasonably assist the Company in preparing for any proceeding (including, without limitation, depositions, mediations, hearings, settlement negotiations, discovery conferences, arbitration, or trial); to provide affidavits reflecting truthful written testimony; to assist with any audit, inspection, proceeding or other inquiry; and to act as a witness to provide truthful testimony in connection with any investigation, audit, mediation, litigation or other legal proceeding affecting the Company. Executive agrees to keep the Company's Human Resources department apprised of Executive's current contact information, including telephone numbers, work address, home address, and email address(es), and to promptly respond to communications from the Company in connection with this Cooperation with Company section. Executive understands and agrees that this provision requires his cooperation with the Company but is not intended to have any influence whatsoever on any specific outcome in any matter and Executive is expected at all times to provide truthful testimony and responses in connection with any matter. Executive understands and agrees that Executive is not otherwise entitled to any additional compensation for such transition assistance, beyond the payments and consideration provided under this Agreement.

12. Protected Activity Not Prohibited. Executive understands that nothing in this Agreement shall in any way limit or prohibit Executive from engaging in any Protected Activity. Protected Activity includes: (i) filing and/or pursuing a charge, complaint or report with, or otherwise communicating, cooperating or participating in any investigation or proceeding that may be conducted by any federal, state or local government agency or commission, including the Securities and Exchange Commission, the Equal Employment Opportunity Commission, the Occupational Safety and Health Administration, and the National Labor Relations Board ("Government Agencies"); and/or (ii) discussing or disclosing information about unlawful acts in the workplace, such as harassment or discrimination or any other conduct that Executive has reason to believe is unlawful. Executive understands that in connection with such Protected Activity, Executive is permitted to disclose documents or other information as permitted by law, without giving notice to, or receiving authorization from, the Company. Notwithstanding the foregoing, Executive agrees to take all reasonable precautions to prevent any unauthorized use or disclosure of any Company trade secrets, proprietary information or confidential information that does not involve unlawful acts in the workplace or the activity otherwise protected herein. Executive further understands that Protected Activity does not include the disclosure of any Company attorney-client privileged communications or attorney work product.

13. Non-disparagement. Subject to the Protected Activity Not Prohibited Section, Executive agrees to refrain from any disparagement, defamation, libel or slander of any of the Releasees, and agrees to refrain from any tortious interference with the contracts and relationships of any of the Releasees. The Company agrees to refrain from making any disparagement statements about Executive. Executive understands that the Company's obligations under this Section extend only to the Company's current C-suite executive officers and members of its Board of Directors as of the Effective Date and only for so long as each officer or member is an officer or Director of the Company. Executive shall direct any inquiries by potential future employers to the Company's human resources department, which shall use its best efforts to provide only the Executive's last position and dates of employment.

14. Breach. In addition to the rights provided in the "Attorneys' Fees" Section below, Executive acknowledges and agrees that any breach of this Agreement, unless such breach constitutes a legal action by Executive challenging or seeking a determination in good faith of the validity of the waiver herein under the ADEA, or of any provision of the Confidentiality Agreement, shall entitle the Company immediately to recover and/or cease providing the consideration provided to Executive under this Agreement and to obtain damages, except as provided by law.

15. No Admission of Liability. Executive understands and acknowledges that with respect to all claims released herein, this Agreement constitutes a compromise and settlement of any and all actual or potential disputed claims by Executive, unless such claims were explicitly not released by the release in this Agreement. No action taken by the Company hereto, either previously or in connection with this Agreement, shall be deemed or construed to be (a) an admission of the truth or falsity of any actual or potential claims or (b) an acknowledgment or admission by the Company of any fault or liability whatsoever to Executive or to any third party.

16. Costs. The Parties shall each bear their own costs, attorneys' fees and other fees incurred in connection with the preparation of this Agreement.

17. ARBITRATION. THE PARTIES AGREE THAT ANY AND ALL DISPUTES ARISING OUT OF THE TERMS OF THIS AGREEMENT, THEIR INTERPRETATION, AND ANY OF THE MATTERS HEREIN RELEASED, SHALL BE SUBJECT TO ARBITRATION UNDER THE FEDERAL ARBITRATION ACT (THE "FAA") AND THAT THE FAA SHALL GOVERN AND

APPLY TO THIS ARBITRATION AGREEMENT WITH FULL FORCE AND EFFECT; HOWEVER, WITHOUT LIMITING ANY PROVISIONS OF THE FAA, A MOTION OR PETITION OR ACTION TO COMPEL ARBITRATION MAY ALSO BE BROUGHT IN STATE COURT UNDER THE PROCEDURAL PROVISIONS OF SUCH STATE'S LAWS RELATING TO MOTIONS OR PETITIONS OR ACTIONS TO COMPEL ARBITRATION. THE ARBITRATION SHALL BE BEFORE A SINGLE ARBITRATOR WHO SHALL BE A FORMER FEDERAL OR STATE COURT JUDGE. EXECUTIVE AGREES THAT EXECUTIVE MAY ONLY BRING ANY SUCH ARBITRATION IN EXECUTIVE'S INDIVIDUAL CAPACITY. SUCH ARBITRATION WILL OCCUR IN THE COUNTY IN VERMONT IN WHICH EXECUTIE RESIDES AS OF THE SEPARATION DATE, OR SUCH OTHER LOCATION TO WHICH THE PARTIES MUTUALLY AGREEMENT, BEFORE JAMS UNDER ITS APPLICABLE RULES AND PROCEDURES ("JAMS RULES") AND VERMONT LAW. THE ARBITRATOR MAY GRANT INJUNCTIONS AND OTHER RELIEF IN SUCH DISPUTES. THE ARBITRATOR SHALL ADMINISTER AND CONDUCT ANY ARBITRATION IN ACCORDANCE WITH VERMONT LAW, AND THE ARBITRATOR SHALL APPLY SUBSTANTIVE VERMONT LAW AND THE FEDERAL RULES OF CIVIL PROCEDURE TO ANY DISPUTE OR CLAIM, WITHOUT REFERENCE TO ANY CONFLICT-OF-LAW PROVISIONS OF ANY JURISDICTION. TO THE EXTENT THAT THE JAMS RULES CONFLICT WITH VERMONT LAW, VERMONT LAW SHALL TAKE PRECEDENCE. THE DECISION OF THE ARBITRATOR SHALL BE WRITTEN, FINAL, AND BINDING ON THE PARTIES TO THE ARBITRATION. THE PARTIES AGREE THAT THE PREVAILING PARTY IN ANY ARBITRATION SHALL BE ENTITLED TO INJUNCTIVE RELIEF IN ANY COURT OF COMPETENT JURISDICTION TO ENFORCE THE ARBITRATION AWARD. THE PARTIES TO THE ARBITRATION SHALL EACH PAY HALF THE COSTS AND EXPENSES OF SUCH ARBITRATION, AND EACH PARTY SHALL SEPARATELY PAY FOR ITS RESPECTIVE COUNSEL FEES AND EXPENSES; PROVIDED, HOWEVER, THAT THE ARBITRATOR SHALL AWARD ATTORNEYS' FEES AND COSTS TO THE PREVAILING PARTY, EXCEPT AS PROHIBITED BY LAW. IN THE EVENT THAT JAMS FAILS, REFUSES, OR OTHERWISE DOES NOT ENFORCE THE AFOREMENTIONED ARBITRATION COSTS SHARING PROVISION, EITHER PARTY MAY COMMENCE AN ACTION TO RECOVER SUCH AMOUNTS AGAINST THE NON-PAYING PARTY IN COURT AND THE NON-PAYING PARTY SHALL REIMBURSE THE MOVING PARTY FOR THE ATTORNEYS' FEES AND COSTS INCURRED IN CONNECTION WITH SUCH ACTION. THE PARTIES AGREE THAT PUNITIVE DAMAGES SHALL BE UNAVAILABLE IN ARBITRATION. THE PARTIES HEREBY AGREE TO WAIVE THEIR RIGHT TO HAVE ANY DISPUTE BETWEEN THEM RESOLVED IN A COURT OF LAW BY A JUDGE OR JURY. NOTWITHSTANDING THE FOREGOING, THIS SECTION WILL NOT PREVENT EITHER PARTY FROM SEEKING INJUNCTIVE RELIEF (OR ANY OTHER PROVISIONAL REMEDY) FROM ANY COURT HAVING JURISDICTION OVER THE PARTIES AND THE SUBJECT MATTER OF THEIR DISPUTE RELATING TO THIS AGREEMENT AND THE AGREEMENTS INCORPORATED HEREIN BY REFERENCE. SHOULD ANY PART OF THE ARBITRATION AGREEMENT CONTAINED IN THIS SECTION CONFLICT WITH ANY OTHER ARBITRATION AGREEMENT BETWEEN THE PARTIES, THE PARTIES AGREE THAT THIS ARBITRATION AGREEMENT SHALL GOVERN.

18. Tax Consequences. The Company makes no representations or warranties with respect to the tax consequences of the payments and any other consideration provided to Executive or made on Executive's behalf under the terms of this Agreement. Executive agrees and understands that Executive is responsible for payment, if any, of local, state and/or federal taxes on the payments and any other consideration provided hereunder by the Company and any penalties or assessments thereon. Executive further agrees to indemnify and hold the Releasees harmless from any claims, demands, deficiencies, penalties, interest, assessments, executions, judgments or recoveries by any government agency against the Company for any amounts claimed due on account of (a) Executive's failure to pay or delayed payment of federal or state taxes or (b) damages sustained by the Company by reason of any such claims, including attorneys' fees and costs. The Parties agree and acknowledge that the payments made pursuant to Section 1 of this Agreement are not related to sexual harassment or sexual abuse and not intended to fall within the scope of 26 U.S.C. Section 162(q).

19. Section 409A. It is intended that this Agreement comply with, or be exempt from, Code Section 409A and the final regulations and official guidance thereunder ("Section 409A") and any ambiguities herein will be interpreted to so comply and/or be exempt from Section 409A. Each payment and benefit to be paid or provided under this Agreement is intended to constitute a series of separate payments for purposes of Section 1.409A-2(b)(2) of the Treasury Regulations. The Company and Executive will work together in good faith to consider either (i) amendments to this Agreement; or (ii) revisions to this Agreement with respect to the payment of any awards, which are necessary or appropriate to avoid imposition of any additional tax or income recognition prior to the actual payment to Executive under Section 409A. In no event will the Releasees reimburse Executive for any taxes that may be imposed on Executive as a result of Section 409A.

20. Authority. The Company represents and warrants that the undersigned has the authority to act on behalf of the Company and to bind the Company and all who may claim through it to the terms and conditions of this Agreement. Executive represents and warrants that Executive has the capacity to act on Executive's own behalf and on behalf of all who might claim through Executive to bind them to the

terms and conditions of this Agreement. Each Party warrants and represents that there are no liens or claims of lien or assignments in law or equity or otherwise of or against any of the claims or causes of action released herein.

21. Severability. In the event that any provision or any portion of any provision hereof or any surviving agreement made a part hereof becomes or is declared by a court of competent jurisdiction or arbitrator to be illegal, unenforceable or void, this Agreement shall continue in full force and effect without said provision or portion of provision.

22. Attorneys' Fees. Except with regard to a legal action challenging or seeking a determination in good faith of the validity of the waiver herein under the ADEA, in the event that either Party brings an action to enforce or effect its rights under this Agreement, the prevailing Party shall be entitled to recover its costs and expenses, including the costs of mediation, arbitration, litigation, court fees and reasonable attorneys' fees incurred in connection with such an action.

23. Effect of Termination. As of the Separation Date, Executive shall no longer be an employee or officer of the Company or any of its subsidiaries. In furtherance of the foregoing, Executive hereby resigns from all positions and titles with the Company and its subsidiaries, effective as of the Separation Date.

24. Entire Agreement. This Agreement represents the entire agreement and understanding between the Company and Executive concerning the subject matter of this Agreement and Executive's employment with and separation from the Company and the events leading thereto and associated therewith, and supersedes and replaces any and all prior agreements and understandings concerning the subject matter of this Agreement and Executive's relationship with the Company (including, but not limited to, the Severance Plan Participation Agreement), with the exception of the Indemnification Agreement, Confidentiality Agreement, and the Equity Agreements, except as otherwise modified or superseded herein.

25. No Oral Modification. This Agreement may only be amended in a writing signed by Executive and an executive officer of the Company.

26. Governing Law. This Agreement shall be governed by the laws of the State of Vermont, without regard for choice-of-law provisions, except that any dispute regarding the enforceability of the arbitration section of this Agreement shall be governed by the FAA.

27. Effective Date. Executive understands that Executive cannot execute this Agreement prior to the Separation Date and that this Agreement shall be null and void if not executed by Executive within twenty-one (21) days. Each Party has seven (7) days after that Party signs this Agreement to revoke it. This Agreement will become effective on the eighth (8^{th}) day after Executive signed this Agreement, so long as it has been signed by the Parties and has not been revoked by either Party before that date (the "Effective Date").

28. Counterparts. This Agreement may be executed in counterparts and each counterpart shall be deemed an original and all of which counterparts taken together shall have the same force and effect as an original and shall constitute an effective, binding agreement on the part of each of the undersigned. The counterparts of this Agreement may be executed and delivered by facsimile, photo, email PDF, or other electronic transmission or signature.

[THE REMAINDER OF THIS PAGE IS INTENTIONALLY LEFT BLANK;

SIGNATURE PAGE FOLLOWS]

29. Voluntary Execution of Agreement. Executive understands and agrees that Executive cannot sign this Agreement prior to the Separation Date and that Executive executed this Agreement voluntarily and without any duress or undue influence on the part or behalf of the Company or any third party, with the full intent of releasing all of Executive's claims against the Company and any of the other Releasees. Executive acknowledges that:

(a) Executive has read this Agreement;

(b) Executive has a right to consult with an attorney regarding this Agreement, and has been represented in the preparation, negotiation and execution of this Agreement by an attorney of Executive's own choice or has elected not to retain an attorney;

(c) Executive understands the terms and consequences of this Agreement and of the releases it contains;

(d) Executive is fully aware of the legal and binding effect of this Agreement; and

(e) Executive has not relied upon any representations or statements made by the Company that are not specifically set forth in this Agreement.

IN WITNESS WHEREOF, the Parties have executed this Agreement on the respective dates set forth below.

MARTIN D. AUSTER, M.D., an individual

Dated: August 31, 2024

/s/ Martin D. Auster

VENTYX BIOSCIENCES, INC.

Dated: September 4, 2024

By /s/ Raju Mohan
Raju Mohan
Chief Executive Officer

EXHIBIT A

EQUITY AWARDS

Outstanding Option Awards

Grant Date	Exercise Price	Vesting	Shares	Vesting Commencement Date	Shares Vested as of Separation Date*
May 6, 2021	$3.45	(1)	381,184^	May 3, 2021	219,184
September 18, 2021	$8.04	(2)	56,883	September 17, 2021	45,032
February 4, 2022	$12.21	(3)	145,000	February 3, 2022	99,687
January 17, 2023	$33.84	(3)	108,750	January 17, 2023	49,843
December 18, 2023	$2.14	(3)	181,250	December 18, 2023	41,536
January 2, 2024	$2.49	(4)	125,000	January 2, 2024	0

^ 50,000 shares were exercised on December 2, 2022; 21,000 shares were exercised on April 4, 2023; 7,000 shares were exercised on April 17, 2023; 28,000 shares were exercised on April 25, 2023; 28,000 shares were exercised on June 6, 2023; 28,000 shares were exercised on July 25, 2023.
*Includes acceleration pursuant to Section 1(c) of the Agreement.

(1) One third (1/3rd) of the shares subject to the option shall vest on the one year anniversary of the Vesting Commencement date, and, thereafter, one twenty-fourth (1/24th) of the remaining shares subject to the option shall vest each month on the same day of the month as the Vesting Commencement Date (and if there is no corresponding day, on the last day of the month).

(2) Twenty-five percent (25%) of the shares subject to the option shall vest on the one year anniversary of the Vesting Commencement date, and, thereafter, one thirty-sixth (1/36th) of the remaining shares subject to the option shall vest each month on the same day of the month as the Vesting Commencement Date (and if there is no corresponding day, on the last day of the month).

(3) One forty-eighth (1/48th) of the total shares subject to the option shall vest each month following the Vesting Commencement Date on the same day of the month as the Vesting Commencement Date (and if there is no corresponding day, on the last day of the month).

(4) 100% of the total shares subject to the Option shall vest on the one-year anniversary of January 2, 2024.

Outstanding Restricted Stock Units

Grant Date	Vesting	Shares	RSU Vesting Commencement Date	Shares Vested as of Separation Date*
January 17, 2023	(1)	18,125	March 28, 2023	4,531

*Includes acceleration pursuant to Section 1(c) of the Agreement.

(1) Twenty-five percent (25%) of the restricted stock units subject to the RSU Award shall vest on the one (1) year anniversary of the RSU Vesting Commencement Date, and twenty-five percent (25%) of the total restricted stock units subject to the RSU Award shall vest each year thereafter on each annual anniversary of the RSU Vesting Commencement Date (and if there is no corresponding day, on the last day of the month), subject to the reporting person continuing to be a Service Provider (as defined in the Plan) through each such date.

Restricted Stock

Grant Date	Vesting	Shares	Vesting Commencement Date	Shares Vested as of Separation Date
May 6, 2021	(1)	95,296#	May 3, 2021	95,296#

Reflects a reverse stock split of 1-for-9.5644.

(1) One-third of the Shares subject to the Grant shall vest on the one-year anniversary of the Vesting Commencement Date, and thereafter, the remaining Shares shall vest each month on the same day of the month as the Vesting Commencement Date in twenty-four (24) equal monthly installments, subject to Optionee continuing to be a Service Provider through each such date.

Exhibit 10.3

December 1, 2022

Roy Gonzales
[***]

Dear Roy,

On behalf of Ventyx Biosciences, Inc. (the "Company"), I am pleased to set forth the terms of your employment with the Company, should you accept our offer:

1. You will serve as Vice President of Accounting of the Company. You will be responsible for performing such duties and responsibilities as are customary for your position, as well as such other duties and responsibilities as assigned to you by the Company. You shall report to the Chief Financial Officer of the Company.

2. You will be classified as an exempt employee. You will receive a monthly salary equal to $23,750, less applicable withholdings. Your salary will be paid bi-weekly in accordance with the Company's regular payroll practices. You should note that the Company may modify job titles, salaries and benefits from time to time as it deems necessary.

3. You will commence employment on January 19, 2023 (the "Start Date") or such other date mutually acceptable to you and the Company's Chief Financial Officer.

4. Unless you have the prior, written permission of the Company's Chief Executive Officer, during the term of your employment with the Company, you may not engage in any other employment, occupation, consulting or other business activity directly related to the business in which the Company or any of its subsidiaries is now involved or becomes involved during the term of your employment, nor will you engage in any other activities that conflict with your obligations to the Company or any of its subsidiaries.

5. Following the end of each fiscal year and subject to the approval of the Company's Board of Directors or its authorized committee (in either case, the "Committee"), you will be eligible for a cash bonus with a target amount of 30% of your actual base salary then in effect, based on your individual performance and the Company's performance during the applicable fiscal year, as determined by the Committee, in its sole discretion. You must be an active employee of the Company on the date any bonus is paid to be eligible for and to earn and receive a bonus. A bonus (if any) earned under this Section 5 shall be paid in accordance with the Company's bonus or incentive plan then in effect, but in no event, later than March 15th following the calendar year in which the bonus is earned.

6. Subject to the terms and conditions thereof and all eligibility requirements, you may participate in all benefit programs that the Company establishes and makes available to its employees from time to time. You will also be eligible for paid time off ("PTO") in accordance with the Company's PTO policy. The Company may change the benefit programs made available by the Company, and the rules, terms and conditions for participation in such benefit programs, at any time.

7. The Company is committed to complying with federal, state and local law on employee vaccinations. Ventyx promotes and encourages full vaccination status.

8. Subject to the approval of the Committee, the Company will grant you a stock option (the "Option Grant") under the Company's 2021 Equity Incentive Plan (the "Stock Plan") to purchase 70,000 shares of common stock of the Company at a price per share equal to the fair market value on the date of grant. The Option Grant will be evidenced by and subject to the terms of the Stock Plan and a stock option agreement thereunder provided by the Company (together, with the Stock Plan the "Equity Documents"). Unless otherwise provided by the Committee, 25% of the shares subject to the Option Grant will vest on the one year anniversary of the vesting commencement date, and 1/48th of the shares subject to the Option Grant will vest each month thereafter, in each case subject to your continued status as a Service Provider (as defined in the Stock Plan) through the applicable vesting date.

9. The Company intends that all payments and benefits provided under this letter or otherwise are exempt from, or comply with, the requirements of Section 409A of the Internal Revenue Code of 1986, as amended, and any final regulations and guidance thereunder and any applicable state law equivalent, as each may be amended or promulgated from time to time so that none of the payments or benefits will be subject to the additional tax imposed under Section 409A, and any ambiguities will be interpreted to

so be exempt or comply. Each payment and benefit payable under this letter is intended to constitute a separate payment for purposes of Section 1.409A-2(b)(2) of the Treasury Regulations.

10. You will be required to execute the Company's standard form of At-Will Employment, Confidential Information, Invention Assignment and Arbitration Agreement (the "At-Will Employment Agreement") as a condition of your employment with the Company. Among other provisions, the At-Will Employment Agreement provides for the assignment of patent rights to any invention made during your employment at the Company, and non-disclosure of Company proprietary information. We must receive your signed At-Will Employment Agreement before your first day of employment.

11. You must disclose to the Company all agreements relating to your prior employment or other engagements that may affect your eligibility to be employed by the Company or limit the way you may be employed. It is the Company's understanding that any such agreements will not prevent you from performing the duties of your position, and you represent that such is the case. Similarly, you agree not to bring any third party confidential information to the Company, including that of your former employer, and that in performing your duties for the Company you will not in any way utilize any such confidential information.

12. As a Company employee, you will be expected to abide by the Company's rules and standards. Specifically, you will be required to sign an acknowledgment that you have read and that you understand the Company's rules of conduct, which are included in the Company's Employee Handbook.

13. You are required to provide to the Company documentation of your identity and eligibility for employment in the United States, as required by the Immigration Reform and Control Act of 1986, within three business days of your date of hire. If you do not provide this information, our employment relationship with you may be terminated.

14. The Company reserves the right to conduct background investigations and/or reference checks on all its potential employees. Your job offer, therefore, is contingent upon a clearance of such a background investigation and/or reference check, if any.

15. The Company is excited about your joining and looks forward to a beneficial and productive relationship. Nevertheless, you should be aware that your employment with the Company is for no specified period and constitutes at-will employment. This means the Company may terminate your employment at any time for any reason (or no reason) with or without notice. Likewise, you may terminate your employment at any time for any reason (or no reason) with or without notice. We request that, in the event of resignation, you give the Company at least two weeks' notice. This letter shall not be construed as an agreement, either expressed or implied, to employ you for any stated term.

16. This letter, along with the At-Will Employment Agreement and the Equity Documents, sets forth the terms of your employment with the Company and supersede any prior representations or agreements, as well as any representations made during your recruitment, interviews or pre-employment negotiations, whether written or oral. This letter, including, but not limited to, the at-will employment provision, may not be modified or amended, except by a written agreement signed by an executive officer of the Company and you.

If you agree with the employment provisions of this letter, please sign this letter in the space provided below and return it to the Company.

Very Truly Yours,

/s/ Christopher W. Krueger

Name: Christopher W. Krueger
Title: Chief Business Officer

I acknowledge and agree that this offer letter correctly sets forth the terms of my at-will employment by Ventyx Biosciences, Inc. I am not relying on any representations other than those set forth above.

By: /s/ Roy Gonzales
Name: Roy Gonzales

Date: December 4, 2022

Exhibit 10.4

July 2, 2024

Mark Forman, MD, PhD
[***]

Via electronic mail

Re: Employment Letter

Dear Mark,

This employment letter agreement (the "Agreement") is entered into between you and Ventyx Biosciences, Inc. (the "Company" or "we"), to set forth the terms and conditions of your employment with the Company.

1. Title; Position. Effective as of August 15, 2024 (the "Effective Date"), you will serve as the Company's Chief Medical Officer, reporting to the Company's President and Chief Executive Officer, and will perform the duties and responsibilities customary for such position and such other related duties as are reasonably assigned by the Company's President and Chief Executive Officer. The period of your employment under this Agreement is referred to herein as the "Employment Term." While you render services to the Company, you will not engage in any other employment, consulting or other business activity (whether full time or part-time) that would create a conflict of interest with the Company, except as approved by the Company's Board of Directors (the "Board") or its authorized committee ("Committee"). By signing this Agreement, you reconfirm to the Company that you have no contractual commitments or other legal obligations that would prohibit you from performing your duties for the Company. Similarly, you agree not to bring any third-party confidential information to the Company, including that of your former employer, and that in performing your duties for the Company you will not in any way utilize any such confidential information.

2. Location. You will perform your duties during the Employment Term from your home office located in Wynnewood, PA, subject to customary travel as reasonably required by the Company and necessary to perform your job duties. Business travel including travel to the Company's office in San Diego, CA will be reimbursed in accordance with the Company's travel and expense policy.

3. Base Salary. Commencing on the Effective Date and during the Employment Term, your annual base salary will be $482,000 ("Salary"), which will be payable, less any applicable withholdings, in accordance with the Company's normal payroll practices. Your Salary will be subject to review and adjustment from time to time by our Board or its Compensation Committee (the "Committee"), as applicable, in its sole discretion.

4. Annual Bonus. During the Employment Term, your target fiscal year annual cash bonus target will be 40% of your annual base salary earned during the fiscal year (the "Bonus Opportunity"), based on achieving performance objectives established by the Board or the Committee, as applicable, in its sole discretion and payable upon achievement of those objectives as determined by the Committee. The annual bonus for 2024 will not be prorated based on date of hire. Unless determined otherwise by the Board or Committee, as applicable, the payment of the achieved portion of such Bonus Opportunity will be subject to your continued employment through and until the date of payment. Any such bonus amounts paid will be subject to any applicable withholdings. Your annual Bonus Opportunity and the applicable terms and conditions may be adjusted from time to time by our Board or the Committee, as applicable, in its sole discretion.

5. Equity Awards. On the Effective Date, subject to the approval of the Board or Committee, you will be granted an option to purchase 350,000 shares of the Company's common stock pursuant to the Company's 2021 Equity Incentive Plan and a form of option agreement thereunder (such documents, together with the documents for any prior equity awards granted to you by the Company, collectively, the "Equity Documents") at an exercise price per share equal to the fair market value of the stock on the date of the grant, which will be the closing price of the Company's common stock as reported on The Nasdaq Global Select Market on the Effective Date (the "Option"). The Option will be granted to you only if you remain an employee of the Company through the grant date. The shares subject to the Option will vest as follows, subject to your continued service through the applicable vesting date: 25% of the shares subject to the Option

will vest on the one-year anniversary of the Effective Date, and 1/48th of the shares subject to the option will vest ratably each month thereafter, in each case subject to your continued service with the Company through the applicable vesting date. Additionally, during the Employment Term, you will be eligible to receive awards of stock options or other equity awards pursuant to any plans or arrangements the Company may have in effect from time to time. The Board or Committee, as applicable, will determine in its sole discretion whether you will be granted any such equity awards and the terms of any such award in accordance with the terms of any applicable plan or arrangement that may be in effect from time to time. No right to any stock is earned or accrued until such time that vesting occurs, nor does the grant confer any right to continue vesting or employment.

6. Employee Benefits. Commencing on the Effective Date and during the Employment Term, you will be eligible to participate in the benefit plans and programs established by the Company for its employees from time to time, subject to their applicable terms and conditions, including, without limitation, any eligibility requirements. The Company will reimburse you for reasonable travel or other expenses incurred by you in the furtherance of or in connection with the performance of your duties under this Agreement, pursuant to the terms of the Company's expense reimbursement policy as may be in effect from time to time. The Company reserves the right to modify, amend, suspend or terminate the benefit plans, programs, and arrangements it offers to its employees at any time.

7. Severance. You will be eligible for the Company's Executive Change in Control and Severance Plan (the "Severance Plan") based on your position within the Company. Your Participation Agreement under the Severance Plan will specify the severance payments and benefits you could be eligible to receive in connection with certain terminations of your employment with the Company. These protections will supersede all other severance or change in control payments and benefits you would otherwise currently be eligible for to, or would become eligible for in the future, under any plan, program or policy that the Company may have in effect from time to time.

8. Confidential Information and Inventions Assignment. You will be required to execute the Company's standard form of At-Will Employment, Confidential Information, Invention Assignment and Arbitration Agreement (the "At-Will Employment Agreement") as a condition of your employment with the Company. Among other provisions, the At-Will Employment Agreement provides for the assignment of patent rights to any invention made during your employment at the Company, and non-disclosure of Company proprietary information. We must receive your signed At-Will Employment Agreement before your first day of employment.

9. At-Will Employment. This Agreement does not imply any right to your continued employment for any period with the Company or any parent, subsidiary, or affiliate of the Company. Your employment with the Company is and will continue to be at-will, as defined under applicable law. This Agreement and any provisions under it will not interfere with or limit in any way your or the Company's right to terminate your employment relationship with the Company at any time, with or without cause or notice, to the extent permitted by applicable laws. We request that, in the event of resignation, you give the Company at least two weeks' notice. This letter shall not be construed as an agreement, either expressed or implied, to employ you for any stated term.

10. Miscellaneous. The Company reserves the right to conduct background investigations and/or reference checks on all its potential employees. Your employment, therefore, is contingent upon the timely and successful completion of the Company's background check in advance of the Effective Date. In the event we allow you to start employment before we receive the results of the background check, you understand and agree that your employment is contingent upon our receipt of results of the background check, satisfactory to us, within 30 days after the Effective Date. For purposes of federal immigration law, you will be required to provide to the Company documentary evidence of your identity and eligibility for employment in the United States. Such documentation must be provided to us within three (3) business days of your date of hire, or our employment relationship with you may be terminated. As a Company employee, you will be expected to abide by the Company's rules and standards. Specifically, you will be required to sign an acknowledgment that you have read and that you understand the Company's rules of conduct, which are included in the Company's Employee Handbook. This Agreement, together with the At-Will Employment Agreement, the Equity Documents and the Severance Plan, constitute the entire agreement between you and the Company regarding the material terms and conditions of your employment, and they supersede and replace all prior negotiations, representations or agreements between you and the Company, whether written or oral. This Agreement will be governed by the laws of the State of Pennsylvania but without regard to the conflict of law provision. This Agreement may be modified only by a written agreement signed by a duly authorized officer of the Company (other than yourself) and you.

[Signature page follows]

If you agree with the employment provisions of this letter, please sign this letter in the space provided below and return it to the Company.

Sincerely,

VENTYX BIOSCIENCES, INC.

By: /s/ Raju Mohan
Name: Raju Mohan
Title: Chief Executive Officer

Date: **July 7, 2024**

I acknowledge and agree that this offer letter correctly sets forth the terms of my at-will employment by Ventyx Biosciences, Inc. I am not relying on any representations other than those set forth above.

Agreed to and accepted:

/s/ Mark Forman

Date: **July 4, 2024**

Exhibit 10.5

CONSULTING AGREEMENT

This Consulting Agreement (this "***Agreement***") is made and entered into as of April 5, 2024, by and between **Ventyx Biosciences, Inc.**, a corporation organized under the laws of Delaware, having a principal place of business at 12790 El Camino Real, Suite 200, San Diego, CA 92130 (the "***Company***"), and **Christopher W. Krueger**, an individual with an address at [***] ("***Consultant***") (each herein referred to individually as a "***Party***," or collectively as the "***Parties***"). This Agreement will be effective as of April 15, 2024 (the "***Effective Date***").

The Company desires to retain Consultant as an independent contractor to perform consulting services for the Company and/or its Affiliates that are outside the usual course of the Company's business. "Affiliate" means any corporation or other entity which controls, is controlled by, or is under common control with, a Party. A corporation or other entity will be regarded as in control of another corporation or entity if it owns or directly or indirectly controls more than 50% of the voting securities or other ownership interest of the other corporation or entity, or if it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the corporation or other entity. Consultant is customarily engaged in an independently established trade, occupation, or business of the same nature of the services to be performed, and Consultant is willing to perform such services, on the terms described below. In consideration of the mutual promises contained herein, the Parties agree as follows:

1. Services and Compensation

Consultant will perform the services described in Exhibit A (the "***Services***") for the Company (or its designee) in a competent and professional manner in accordance with the terms of this Agreement and all applicable laws, rules and regulations. The Company will pay Consultant the compensation described in Exhibit A for performance of the Services.

2. Confidentiality

A. *Definition*. "***Confidential Information***" means any information that relates to the actual or anticipated business and/or products, services, research or development of the Company or its Affiliates, or to the Company's or its Affiliates' technical data, trade secrets or know-how, including, but not limited to, patents and patent applications, research, product plans or other information regarding the Company's or its Affiliates products or services and markets, customer lists, gene sequences, cell lines, samples, compounds, assays, biological materials, techniques, works of authorship, models, software, developments, inventions, processes, formulas, technology, designs, drawings, hardware configuration information, marketing, finance, and other business information disclosed by the Company, or its Affiliates, either directly or indirectly, in writing, orally or by drawings or inspection of premises, parts, equipment, or other property of the Company or subsidiaries. Notwithstanding the foregoing, Confidential Information will not include any such information which Consultant can establish (i) was publicly known or made generally available prior to the time of disclosure to Consultant; (ii) becomes publicly known or made generally available after disclosure to Consultant through no wrongful action or inaction of Consultant; or (iii) is in the rightful possession of Consultant, without confidentiality obligations, at the time of disclosure as shown by Consultant's then-contemporaneous written records; *provided, however*, that any combination of individual items of information shall not be deemed to be within any of the foregoing exceptions merely because one or more of the individual items are within such exception, unless the combination as a whole is within such exception. Nothing in this Agreement is intended to deny workers the right to disclose information pertaining to sexual harassment or any unlawful or potentially unlawful conduct, as protected by applicable law.

B. *Nonuse and Nondisclosure*. During and after the term of this Agreement, Consultant will hold in the strictest confidence, and take all reasonable precautions to prevent any unauthorized use or disclosure of Confidential Information, and Consultant will not (i) use the Confidential Information for any purpose whatsoever other than as necessary for the performance of the Services on behalf of the Company, or (ii) subject to Consultant's right to engage in Protected Activity (as defined below), disclose the Confidential Information to any third party without the prior written consent of an authorized representative of the Company, except that Consultant may disclose Confidential Information to any third party on a need-to-know basis for the purposes of Consultant performing the Services; *provided, however*, that such third party is subject to written non-use and non-disclosure obligations at least as protective of the Company and the Confidential Information as this Article 2. Consultant may also disclose Confidential Information to the extent compelled by applicable law; *provided however*, prior to such disclosure, Consultant will provide prior written notice to the Company and seek a protective order or such similar confidential protection as may be available under applicable law. No ownership of Confidential Information is conveyed to the Consultant. Without limiting the foregoing, Consultant will not use or disclose any Company property, intellectual property rights, trade secrets or other proprietary

know-how of the Company to invent, author, make, develop or design, or enable others to invent, author, make, develop or design, identical or substantially similar products or services as those being developed or commercialized by the Company for any third party. Consultant's obligations under this Section 2.B will continue after the termination of this Agreement.

C. *Other Client Confidential Information*. Consultant will not improperly use, disclose or induce the Company or its Affiliates to use any proprietary information or trade secrets of any former or concurrent employer of Consultant or other person or entity with which Consultant has an obligation to keep in confidence. Consultant will not bring onto the Company's premises or transfer onto the Company's technology systems any unpublished document, proprietary information or trade secrets belonging to any third party, unless disclosure to, and use by, the Company has been consented to in writing by such third party.

D. *Third Party Confidential Information*. Consultant recognizes that the Company and its Affiliates have received, and in the future will receive, from third parties their confidential or proprietary information subject to a duty on the Company's (or its Affiliate's) part to maintain the confidentiality of such information and to use it only for certain limited purposes. At all times during the term of this Agreement and thereafter, Consultant owes the Company, its Affiliates and such third parties a duty to hold all such confidential or proprietary information in the strictest confidence and not to use it or to disclose it to any person, firm, corporation or other third party, except as necessary in carrying out the Services for the Company consistent with the Company's agreement with such third party.

3. Ownership

A. *Assignment of Inventions*. All right, title and interest in and to any compounds, substances, biological materials, methods, protocols, processes, techniques, formula, notes, records, drawings, designs, inventions, improvements, developments, discoveries and trade secrets conceived, discovered, authored, invented, developed or reduced to practice by Consultant, solely or in collaboration with others, during the term of this Agreement and arising out of, or in connection with, performing the Services under this Agreement and any copyrights, patents, trade secrets, mask work rights or other intellectual property rights relating to the foregoing (collectively, "***Inventions***"), are the sole property of the Company. Consultant will make full written disclosure promptly to the Company of any Inventions and will deliver and assign (or cause to be assigned) and hereby irrevocably assigns fully to the Company all right, title and interest in and to the Inventions.

B. *Pre-Existing Material*s. Subject to Section 3.A, if, in the course of performing the Services, Consultant incorporates into any Invention or utilizes in the performance of the Services any pre-existing invention, discovery, original works of authorship, development, improvements, trade secret, concept or other proprietary information or intellectual property right owned by Consultant or in which Consultant has an interest ("***Prior Invention****s*"), (i) Consultant will provide the Company with prior written notice and (ii) the Company is hereby granted a nonexclusive, royalty-free, perpetual, irrevocable, transferable, worldwide license (with the right to grant sublicenses through multiple tiers of sublicense) to make, have made, use, import, offer for sale, sell, reproduce, distribute, modify, adapt, prepare derivative works of, display, perform and otherwise exploit such Prior Inventions, without restriction, including, without limitation, as part of or in connection with such Invention, and to practice any method related thereto. Consultant will not incorporate any invention, improvement, development, concept, discovery, work of authorship or other proprietary information owned by any third party into any Invention without the Company's prior written consent.

C. *Moral Rights*. Any assignment to the Company of Inventions includes all rights of attribution, paternity, integrity, modification, disclosure and withdrawal, and any other rights throughout the world that may be known as or referred to as "moral rights," "artist's rights," "droit moral," or the like (collectively, "***Moral Rights***"). To the extent that Moral Rights cannot be assigned under applicable law, Consultant hereby waives and agrees not to enforce any and all Moral Rights, including, without limitation, any limitation on subsequent modification, to the extent permitted under applicable law.

D. *Maintenance of Records*. Consultant will keep and maintain adequate, current, accurate and authentic written records of all Inventions made by Consultant (solely or jointly with others) during the term of this Agreement, and for a period of three (3) years thereafter. The records will be in the form of notes, sketches, drawings, electronic files, reports or any other format that is customary in the industry and/or otherwise specified by the Company. Such records are and remain the sole property of the Company at all times and upon Company's request, Consultant will deliver (or cause to be delivered) such records to the Company.

E. *Further Assurances*. Consultant will assist the Company, or its designee, at the Company's expense, in every proper way to secure the Company's rights in Inventions in any and all countries, including the disclosure to the Company of all pertinent information and data with respect thereto, the execution of all applications, specifications, oaths, assignments and all other instruments that the Company may deem necessary in order to apply for, register, obtain, maintain, defend and enforce such rights,

and in order to deliver, assign and convey to the Company, its successors, assigns and nominees the sole and exclusive right, title and interest in and to all Inventions and testifying in a suit or other proceeding relating to such Inventions. Consultant's obligations under this Section 3.E will continue after the termination of this Agreement.

F. *Attorney-in-Fact*. If the Company is unable because of Consultant's unavailability, dissolution, mental or physical incapacity, or for any other reason, to secure Consultant's signature with respect to any Inventions, including, without limitation, for the purpose of applying for or pursuing any application for any United States or foreign patents or mask work or copyright registrations covering the Inventions assigned to the Company in Section 3.A, then Consultant hereby irrevocably designates and appoints the Company and its duly authorized officers and agents as Consultant's agent and attorney-in-fact, to act for and on Consultant's behalf to execute and file any papers and oaths and to do all other lawfully permitted acts with respect to such Inventions to further the prosecution and issuance of patents, copyright and mask work registrations with the same legal force and effect as if executed by Consultant. This power of attorney will be deemed coupled with an interest and will be irrevocable.

4. Conflicting Obligations

Consultant represents and warrants that Consultant has no agreements, relationships or commitments to any other person or entity that conflict with the provisions of this Agreement, Consultant's obligations to the Company under this Agreement, and/or Consultant's ability to perform the Services. Consultant will not enter into any such conflicting agreement during the term of this Agreement.

5. Return of Company Materials

Upon the expiration or termination of this Agreement, or upon the Company's earlier request, Consultant will immediately deliver to the Company, and will not keep in Consultant's possession, recreate or deliver to anyone else, any and all Company property, including, but not limited to, Confidential Information, tangible embodiments of the Inventions, all devices and equipment belonging to the Company, all electronically-stored information and passwords to access such property, those records maintained pursuant to Section 3.D and any reproductions of any of the foregoing items that Consultant may have in Consultant's possession or control.

6. Reports

Consultant will periodically keep the Company advised as to Consultant's progress in performing the Services under this Agreement. Consultant will, as requested by the Company, prepare written reports with respect to such progress. The Company and Consultant agree that the reasonable time expended in preparing such written reports will be considered time devoted to the performance of the Services.

7. Term and Termination

A. *Term.* The term of this Agreement will begin on the Effective Date of this Agreement and will continue until the earliest of (i) six (6) months from the Effective Date, or (ii) termination as provided in Section 7.B.

B. *Termination.* Either Party may terminate this Agreement at any time with or without cause upon thirty (30) days prior written notice to the other Party. In addition, the Company may terminate this Agreement immediately upon written notice to Consultant (i) if Consultant refuses to or is unable to perform the Services, or (ii) if Consultant breaches this Agreement and does not fully cure the breach to the Company's satisfaction.

C. *Survival*. Upon any termination of this Agreement, all rights and duties of the Company and Consultant toward each other will cease; *provided, however*, that:

(1) Except for termination by the Company for cause, the Company will pay, within thirty (30) days after the effective date of termination, all amounts owing to Consultant for Services completed and accepted by the Company prior to the termination date and reimbursable expenses, if any, submitted in accordance with the Company's policies and in accordance with the terms of this Agreement; and

(2) Article 2 (Confidentiality), Article 3 (Ownership), Article 5 (Return of Company Materials), Section 7.C (Survival), Article 8 (Independent Contractor; Benefits), Article 9 (Disclaimer of Warranties; Limitation of Liability), Article 10 (Arbitration and Equitable Relief), and Article 11 (Miscellaneous) will survive the expiration or termination of this Agreement in accordance with their terms. Expiration or termination of this Agreement will not affect either Party's liability for any breach of this Agreement such Party may have committed before such expiration or termination.

8. Independent Contractor; Benefits

A. *Independent Contractor.* It is the express intention of the Company and Consultant that Consultant will perform the Services as an independent contractor to the Company. Nothing in this Agreement will in any way be construed to constitute Consultant as an agent, employee or representative of the Company. Without limiting the generality of the foregoing, Consultant is not authorized to bind the Company to any liability or obligation or to represent that Consultant has any such authority. Consultant will furnish (or reimburse the Company for) all tools and materials necessary to accomplish this Agreement and will incur all expenses associated with performance, except as expressly provided in Exhibit A. Consultant will report as income all compensation received by Consultant pursuant to this Agreement. Consultant will pay all self-employment and other taxes on such income.

B. *Benefits*. The Company and Consultant agree that Consultant will receive no Company-sponsored benefits from the Company where benefits include, but are not limited to, paid vacation, sick leave, medical insurance and 401k participation. If Consultant is reclassified by a state or federal agency or court as the Company's employee, Consultant will become a reclassified employee and will receive no benefits from the Company, except those mandated by state or federal law, even if by the terms of the Company's benefit plans or programs of the Company in effect at the time of such reclassification, Consultant would otherwise be eligible for such benefits.

9. Disclaimer of Warranties; Limitation of Liability

A. *Disclaimer of Warranties.* EXCEPT AS SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY TO THE OTHER PARTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF NON-INFRINGEMENT, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

B. *Limitation of Liability.* NEITHER PARTY NOR ITS AFFILIATES WILL BE LIABLE TO THE OTHER PARTY OR ITS AFFILIATES FOR ANY INDIRECT, INCIDENTAL, SPECIAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, OR ANY DAMAGES FOR LOST PROFITS OR LOSS OF BUSINESS, ARISING OUT OF OR RELATED TO THIS AGREEMENT OR ANY SERVICES PROVIDED HEREUNDER, HOWEVER CAUSED, UNDER ANY THEORY OF LIABILITY, EVEN IF SUCH PARTY WAS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. IN NO EVENT WILL THE COMPANY'S OR ITS AFFILIATES' LIABILITY ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT EXCEED THE AMOUNTS PAID BY THE COMPANY TO CONSULTANT UNDER THIS AGREEMENT FOR THE SERVICES, DELIVERABLES OR INVENTIONS GIVING RISE TO SUCH LIABILITY.

10. Arbitration and Equitable Relief

A. *Arbitration*. IN CONSIDERATION OF CONSULTANT'S CONSULTING RELATIONSHIP WITH THE COMPANY AND ITS AFFILIATES, ITS PROMISE TO ARBITRATE ALL DISPUTES RELATED TO CONSULTANT'S CONSULTING RELATIONSHIP WITH THE COMPANY AND ITS AFFILIATES AND CONSULTANT'S RECEIPT OF THE COMPENSATION AND OTHER BENEFITS PAID TO CONSULTANT BY THE COMPANY, AT PRESENT AND IN THE FUTURE, CONSULTANT AGREES THAT ANY AND ALL CONTROVERSIES, CLAIMS, OR DISPUTES WITH ANYONE (INCLUDING THE COMPANY, ITS AFFILIATES AND ANY EMPLOYEE, OFFICER, DIRECTOR, SHAREHOLDER OR BENEFIT PLAN OF THE COMPANY OR ITS AFFILIATEIN THEIR CAPACITY AS SUCH OR OTHERWISE), ARISING OUT OF, RELATING TO, OR RESULTING FROM CONSULTANT'S CONSULTING OR OTHER RELATIONSHIP WITH THE COMPANY OR THE TERMINATION OF CONSULTANT'S CONSULTING OR OTHER RELATIONSHIP WITH THE COMPANY, INCLUDING ANY BREACH OF THIS AGREEMENT, SHALL BE SUBJECT TO BINDING ARBITRATION PURSUANT TO THE FEDERAL ARBITRATION ACT (9 U.S.C. SEC. 1 ET SEQ.) (THE "***FAA***"). THE FAA'S SUBSTANTIVE AND PROCEDURAL PROVISIONS SHALL EXCLUSIVELY GOVERN AND APPLY WITH FULL FORCE AND EFFECT TO THIS ARBITRATION AGREEMENT, INCLUDING ITS ENFORCEMENT AND ANY STATE COURT OF COMPETENT JURISDICTION SHALL COMPEL ARBITRATION IN THE SAME MANNER AS A FEDERAL COURT UNDER THE FAA. CONSULTANT FURTHER AGREES THAT, TO THE FULLEST EXTENT PERMITTED BY LAW, CONSULTANT MAY BRING ANY ARBITRATION PROCEEDING ONLY IN CONSULTANT'S INDIVIDUAL CAPACITY, AND NOT AS A PLAINTIFF, REPRESENTATIVE, OR CLASS MEMBER IN ANY PURPORTED CLASS, COLLECTIVE, OR REPRESENTATIVE LAWSUIT OR PROCEEDING. CONSULTANT MAY, HOWEVER, BRING A PROCEEDING AS A PRIVATE ATTORNEY GENERAL AS PERMITTED BY LAW. **TO THE FULLEST EXTENT PERMITTED BY LAW, CONSULTANT AGREES TO ARBITRATE ANY AND ALL COMMON LAW AND/OR**

STATUTORY CLAIMS UNDER LOCAL, STATE, OR FEDERAL LAW, INCLUDING, BUT NOT LIMITED TO, CLAIMS UNDER THE LABOR LAWS OF THE STATE IN WHICH CONSULTANT PERFORMS SERVICES, CLAIMS RELATING TO EMPLOYMENT OR INDEPENDENT CONTRACTOR STATUS, CLASSIFICATION, AND RELATIONSHIP WITH THE COMPANY, AND CLAIMS OF BREACH OF CONTRACT, EXCEPT AS PROHIBITED BY LAW. CONSULTANT ALSO AGREES TO ARBITRATE ANY AND ALL DISPUTES ARISING OUT OF OR RELATING TO THE INTERPRETATION OR APPLICATION OF THIS AGREEMENT TO ARBITRATE, BUT NOT DISPUTES ABOUT THE ENFORCEABILITY, REVOCABILITY OR VALIDITY OF THIS AGREEMENT TO ARBITRATE OR THE CLASS, COLLECTIVE AND REPRESENTATIVE PROCEEDING WAIVER HEREIN. WITH RESPECT TO ALL SUCH CLAIMS AND DISPUTES THAT CONSULTANT AGREES TO ARBITRATE, CONSULTANT HEREBY EXPRESSLY AGREES TO WAIVE, AND DOES WAIVE, ANY RIGHT TO A TRIAL BY JURY. CONSULTANT FURTHER UNDERSTANDS THAT THIS AGREEMENT TO ARBITRATE ALSO APPLIES TO ANY DISPUTES THAT THE COMPANY MAY HAVE WITH CONSULTANT. CONSULTANT UNDERSTANDS THAT NOTHING IN THIS AGREEMENT REQUIRES CONSULTANT TO ARBITRATE CLAIMS THAT CANNOT BE ARBITRATED UNDER APPLICABLE LAW, SUCH AS CLAIMS UNDER THE SARBANES-OXLEY ACT OR OTHER LAW THAT EXPRESSLY PROHIBITS ARBITRATION OF A CLAIM NOTWITHSTANDING THE APPLICATION OF THE FAA.

B. *Procedure.* ANY ARBITRATION WILL BE ADMINISTERED BY JUDICIAL ARBITRATION & MEDIATION SERVICES, INC. ("***JAMS***") PURSUANT TO ITS THEN-CURRENT EMPLOYMENT ARBITRATION RULES & PROCEDURES (THE "***JAMS RULES***"), WHICH ARE AVAILABLE AT http://www.jamsadr.com/rules-employment-arbitration/. IF THE JAMS RULES CANNOT BE ENFORCED AS TO THE ARBITRATION, THEN THE PARTIES AGREE THAT THEY WILL ARBITRATE THIS DISPUTE UTILIZING JAMS COMPREHENSIVE ARBITRATION RULES AND PROCEDURES OR SUCH RULES AS THE ARBITRATOR MAY DEEM MOST APPROPRIATE FOR THE DISPUTE. CONSULTANT AGREES THAT THE USE OF THE JAMS RULES DOES NOT CHANGE CONSULTANT'S CLASSIFICATION TO THAT OF AN EMPLOYEE. TO THE CONTRARY, CONSULTANT REAFFIRMS THAT CONSULTANT IS AN INDEPENDENT CONTRACTOR. CONSULTANT AGREES THAT THE ARBITRATOR SHALL HAVE THE POWER TO DECIDE ANY MOTIONS BROUGHT BY ANY PARTY TO THE ARBITRATION, INCLUDING MOTIONS FOR SUMMARY JUDGMENT AND/OR ADJUDICATION AND MOTIONS TO DISMISS AND DEMURRERS APPLYING THE STANDARDS SET FORTH FOR SUCH MOTIONS UNDER THE RULES OF CIVIL PROCEDURE OF THE STATE IN WHICH CONSULTANT PERFORMS SERVICES. CONSULTANT AGREES THAT THE ARBITRATOR SHALL ISSUE A WRITTEN DECISION ON THE MERITS. CONSULTANT ALSO AGREES THAT THE ARBITRATOR SHALL HAVE THE POWER TO AWARD ANY REMEDIES AVAILABLE UNDER APPLICABLE LAW, AND THAT THE ARBITRATOR SHALL AWARD ATTORNEYS' FEES AND COSTS TO THE PREVAILING PARTY, WHERE PERMITTED BY APPLICABLE LAW. CONSULTANT AGREES THAT THE DECREE OR AWARD RENDERED BY THE ARBITRATOR MAY BE ENTERED AS A FINAL AND BINDING JUDGMENT IN ANY COURT HAVING JURISDICTION THEREOF. CONSULTANT AGREES THAT THE ARBITRATOR SHALL ADMINISTER AND CONDUCT ANY ARBITRATION HEARING OR PROCEEDING APPLYING SUBSTANTIVE AND DECISIONAL LAW OF THE STATE IN WHICH CONSULTANT PERFORMS SERVICES AND THE RULES OF CIVIL PROCEDURE OF THE STATE IN WHICH CONSULTANT PERFORMS SERVICES, INCLUDING THE CALIFORNIA CIVIL DISCOVERY ACT. CONSULTANT FURTHER AGREES THAT ANY ARBITRATION UNDER THIS AGREEMENT SHALL BE CONDUCTED IN SAN DIEGO, CALIFORNIA.

C. *Remedy*. FOR PURPOSES OF SEEKING PROVISIONAL REMEDIES ONLY, CONSULTANT AGREES THAT THE COMPANY AND CONSULTANT SHALL BE ENTITLED TO PURSUE ANY PROVISIONAL REMEDY PERMITTED BY THE CALIFORNIA ARBITRATION ACT (CALIFORNIA CODE CIV. PROC. § 1281.8) OR OTHERWISE PROVIDED BY THIS AGREEMENT. EXCEPT FOR SUCH PROVISIONAL RELIEF, CONSULTANT AGREES THAT ANY RELIEF OTHERWISE AVAILABLE TO THE COMPANY OR CONSULTANT UNDER APPLICABLE LAW SHALL BE PURSUED SOLELY AND EXCLUSIVELY IN ARBITRATION PURSUANT TO THE TERMS OF THIS AGREEMENT.

D. *Administrative Relief.* EXCEPT AS PERMITTED BY LAW, THIS AGREEMENT DOES NOT PROHIBIT CONSULTANT FROM PURSUING CERTAIN ADMINISTRATIVE CLAIMS WITH LOCAL, STATE OR FEDERAL ADMINISTRATIVE BODIES OR GOVERNMENT AGENCIES, SUCH AS THE DEPARTMENT OF FAIR EMPLOYMENT AND HOUSING, THE EQUAL EMPLOYMENT OPPORTUNITY COMMISSION, THE NATIONAL LABOR RELATIONS BOARD OR THE WORKERS' COMPENSATION BOARD. THIS AGREEMENT DOES, HOWEVER, PRECLUDE CONSULTANT FROM BRINGING ANY ALLEGED WAGE CLAIMS WITH THE DEPARTMENT OF LABOR STANDARDS ENFORCEMENT.

LIKEWISE, THIS AGREEMENT DOES PRECLUDE CONSULTANT FROM PURSUING COURT ACTION REGARDING ANY ADMINISTRATIVE CLAIMS, EXCEPT AS PERMITTED BY LAW.

E. *Voluntary Nature of Agreement.* CONSULTANT IS EXECUTING THIS AGREEMENT VOLUNTARILY AND WITHOUT ANY DURESS OR UNDUE INFLUENCE BY THE COMPANY OR ANYONE ELSE. CONSULTANT HAS CAREFULLY READ THIS AGREEMENT AND HAS ASKED ANY QUESTIONS NEEDED FOR CONSULTANT TO UNDERSTAND THE TERMS, CONSEQUENCES AND BINDING EFFECT OF THIS AGREEMENT AND FULLY UNDERSTAND IT, INCLUDING THAT ***CONSULTANT IS WAIVING HIS RIGHT TO A JURY TRIAL***. FINALLY, CONSULTANT HAS BEEN PROVIDED AN OPPORTUNITY TO SEEK THE ADVICE OF AN ATTORNEY OF CONSULTANT'S CHOICE BEFORE SIGNING THIS AGREEMENT. FINALLY, THIS ARBITRATION AGREEMENT IS NOT SUBJECT TO CALIFORNIA LABOR CODE SECTION 432.6.

11. Miscellaneous

A. *Governing Law; Consent to Personal Jurisdiction*. This Agreement will be governed by the laws of the State of California, without regard to the conflicts of law provisions of any jurisdiction, except that any dispute regarding the enforceability of the arbitration section of this Agreement shall be governed by the FAA. The United Nations Convention on Contracts for the International Sale of Goods will not apply to this Agreement. To the extent that any lawsuit is permitted under this Agreement, the Parties hereby expressly consent to the personal and exclusive jurisdiction and venue of the state and federal courts located in California.

B. *Assignability*. This Agreement will be binding upon Consultant's heirs, executors, assigns, administrators and other legal representatives, and will be for the benefit of the Company, its successors, and its assigns. There are no intended third-party beneficiaries to this Agreement, except as expressly stated. Except as may otherwise be provided in this Agreement, Consultant may not sell, assign or delegate any rights or obligations under this Agreement. Notwithstanding anything to the contrary herein, the Company may assign this Agreement and its rights and obligations under this Agreement to any successor to all or substantially all of the Company's relevant assets, whether by merger, consolidation, reorganization, reincorporation, sale of assets or stock, change of control or otherwise.

C. *Entire Agreement.* This Agreement constitutes the entire agreement and understanding between the Parties with respect to the subject matter herein and supersedes all prior written and oral agreements, discussions or representations between the Parties. Consultant represents and warrants that he/she is not relying on any statement or representation not contained in this Agreement. To the extent any terms set forth in any exhibit or schedule conflict with the terms set forth in this Agreement, the terms of this Agreement will control, unless otherwise expressly agreed by the Parties in such exhibit or schedule.

D. *Headings*. Headings are used in this Agreement for reference only and will not be considered when interpreting this Agreement.

E. *Severability*. If a court or other body of competent jurisdiction finds, or the Parties mutually believe, any provision of this Agreement, or portion thereof, to be invalid or unenforceable, such provision will be enforced to the maximum extent permissible so as to affect the intent of the Parties, and the remainder of this Agreement will continue in full force and effect.

F. *Notices*. Any notice or other communication required or permitted by this Agreement to be given to a Party will be in writing and will be delivered as follows with notice deemed given as indicated: (i) by personal delivery when delivered personally; (ii) by overnight courier upon written verification of receipt; (iii) by electronic mail upon acknowledgement of receipt of electronic transmission; or (iv) by certified or registered mail, return receipt requested, upon verification of receipt. Notice will be sent to the addresses set forth below or such other address as either party may specify in writing.

(1) If to the Company, to:
Ventyx Biosciences, Inc.
12790 El Camino Real, Suite 200
San Diego, California 92130
Attention: Austin A. Rutherford
Email: legalnotice@ventyxbio.com

(2) If to Consultant, to the address for notice on the signature page to this Agreement or, if no such address is provided, to the last address of Consultant provided by Consultant to the Company.

G. *Attorneys' Fees.* In any court action at law or equity that is brought by one of the Parties to this Agreement to enforce or interpret the provisions of this Agreement, the prevailing Party will be entitled to reasonable attorneys' fees, in addition to any other relief to which that Party may be entitled.

H. *Modification, Waiver.* No modification of or amendment to this Agreement, or any waiver of any rights under this Agreement, will be effective, unless it is in writing signed by both Parties. Waiver by either Party of a breach of any provision of this Agreement will not operate as a waiver of any other or subsequent breach.

I. *Counterparts.* This Agreement may be executed in two or more counterparts, each of which will be deemed to be an original, but all of which will together constitute one and the same agreement. Delivery of an executed counterpart of a signature page to this Agreement by email of a pdf or scanned copy will be effective as delivery of an original executed counterpart of this Agreement.

J. *Protected Activity Not Prohibited.* Consultant understands that nothing in this Agreement shall in any way limit or prohibit Consultant from engaging in any Protected Activity. For purposes of this Agreement, "***Protected Activity***" shall mean filing a charge, complaint, or report with, or otherwise communicating, cooperating, or participating in any investigation or proceeding that may be conducted by, any federal, state or local government agency or commission, including the Securities and Exchange Commission ("***Government Agencies***"). Consultant understands that in connection with such Protected Activity, Consultant is permitted to disclose documents or other information as permitted by law, and without giving notice to, or receiving authorization from, the Company. Notwithstanding the foregoing, Consultant agrees to take all reasonable precautions to prevent any unauthorized use or disclosure of any information that may constitute Company Confidential Information to any parties other than the Government Agencies. Consultant further understands that "***Protected Activity***" does not include the disclosure of any Company attorney-client privileged communications. Pursuant to the Defend Trade Secrets Act of 2016, Consultant is notified that an individual will not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that (i) is made in confidence to a federal, state, or local government official (directly or indirectly) or to an attorney *solely* for the purpose of reporting or investigating a suspected violation of law, or (ii) is made in a complaint or other document filed in a lawsuit or other proceeding, if (and only if) such filing is made under seal. In addition, an individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the individual's attorney and use the trade secret information in the court proceeding, if the individual files any document containing the trade secret under seal and does not disclose the trade secret, except pursuant to court order.

(*signature page follows*)

IN WITNESS WHEREOF, the Parties hereto have executed this Consulting Agreement as of the date first written above.

VENTYX BIOSCIENCES, INC.

By:	/s/ Raju Mohan
Name:	Raju Mohan
Title:	Chief Executive Officer

CHRISTOPHER W. KRUEGER

/s/ Christopher W. Krueger

EXHIBIT A

SERVICES AND COMPENSATION

1. *Services*. Consultant will advise the Company and/or its Affiliates on business strategy and corporate matters (the "***Services***").

2. *Compensation*.

A. *Fees; Invoicing.* The Company will pay Consultant $300 per hour for Services rendered to the Company. Consultant will submit invoices to the Company on a monthly basis for Services performed in the previous month, including a description of Services performed and time billed during the previous month. Payment to Consultant of undisputed fees and expenses will be due thirty (30) days following the Company's receipt of the applicable invoice for such fees and expenses. Consultant will be paid as an independent contractor. All invoices will be sent to the attention of Accounts Payable at ap@ventyxbio.com.

B. *Expenses.* The Company will reimburse Consultant, in accordance with the Company's policy, for all reasonable expenses incurred by Consultant in performing the Services pursuant to this Agreement, if Consultant receives written consent from an authorized agent of the Company prior to incurring such expenses and submits receipts for such expenses to the Company in accordance with the Company's policy.

AMENDMENT NO. 1 TO CONSULTING AGREEMENT

This **AMENDMENT NO. 1 TO CONSULTING AGREEMENT ("Amendment")**, effective September 10, 2024, is entered into by and between **VENTYX BIOSCIENCES, INC. ("Ventyx")** and **CHRISTOPHER W. KRUEGER ("Consultant")**.

WHEREAS, Ventyx and Consultant entered into that certain Consulting Agreement effective April 15, 2024 **("Agreement");**

WHEREAS, Ventyx and Consultant wish to amend the Agreement as set forth in this Amendment.

NOW, THEREFORE, in consideration of the mutual promises contained herein, the parties hereby agree as follows:

1. Section 7.A. of the Agreement is hereby deleted in its entirety and replaced with the following:

> **A. Term.** The term of this Agreement will begin on the Effective Date of this Agreement and will continue until the earlier of (i) April 15, 2025 or (ii) termination as provided in Section 7.B.

2. General. Capitalized terms used and not otherwise defined herein will have the meanings given them in the Agreement. Except as modified herein, all terms and conditions of Agreement continue in full force and effect. This Amendment may be executed in two or more counterparts, each of which will be deemed an original, but all of which will together constitute one and the same agreement. Delivery of an executed counterpart of a signature page to this Amendment by email of a scanned .pdf copy will be effective as delivery of an original executed counterpart of this Agreement.

AGREED TO AND ACCEPTED BY:

VENTYX BIOSCIENCES, INC.	**CHRISTOPHER W. KRUEGER**
By: /s/ Raju Mohan Name: Raju Mohan Title: Chief Executive Officer	By: /s/ Christopher W. Krueger

Exhibit 31.1

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, Raju Mohan, Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ventyx Biosciences, 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: November 7, 2024

By: /s/ Raju Mohan
Raju Mohan, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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, Roy Gonzales, C.P.A., M.B.A., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ventyx Biosciences, 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: November 7, 2024

By: /s/ Roy Gonzales
Roy Gonzales, C.P.A., M.B.A.
Senior Vice President, Finance
(Interim Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Ventyx Biosciences, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: November 7, 2024

By: /s/ Raju Mohan
Raju Mohan, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF 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 Quarterly Report of Ventyx Biosciences, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: November 7, 2024

By: /s/ Roy Gonzales
Roy Gonzales, C.P.A., M.B.A.
Senior Vice President, Finance
(Interim Principal Financial and Accounting Officer)