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: 001-42366

UPSTREAM BIO, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**38-4187694**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
890 Winter Street, Suite 200 Waltham, MA	**02451**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (781) 208-2466

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, par value $0.001 per share	UPB	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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of November 5, 2024, the registrant had 53,596,601 shares of common stock, $0.0001 par value per share, outstanding.

Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q ("Quarterly Report") contains express or implied forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this Quarterly Report include, but are not limited to, statements about:

- the initiation, timing, progress, and results of our planned and future clinical trials for verekitug, including our ongoing Phase 2 clinical trials in severe asthma and chronic rhinosinusitis with nasal polyps ("CRSwNP") and the planned initiation of an additional development program in chronic obstructive pulmonary disease ("COPD");
- our ability to replicate positive results from earlier preclinical studies or clinical trials conducted by us or third parties in current or future clinical trials;
- our ability to demonstrate that verekitug and any potential future product candidates are safe and effective for their proposed indications and our expectations around their beneficial characteristics and therapeutic effects;
- our ability to advance verekitug and any potential future product candidates through applicable regulatory approval processes, including timing of Investigational New Drug ("IND") applications and final U.S. Food and Drug Administration ("FDA") approval of verekitug or any future product candidate;
- our estimates of the number of patients that we will enroll and our ability to initiate, recruit and enroll patients in and conduct and successfully complete our clinical trials at the pace we project;
- the implementation of our business model and strategic plans;
- our ability to rely on third-party manufacturers and successfully manufacture verekitug for preclinical use, for clinical trials and on a larger scale for commercial use, if approved;
- our ability to commercialize verekitug, if approved, and obtain favorable pricing and reimbursement;
- the size and growth potential of the markets for verekitug and our ability to serve those markets;
- our ability to realize the benefits of collaborations for the development and commercialization of verekitug or any other potential future product candidates;
- our ability to maintain, expand and protect our intellectual property;
- developments relating to our competitors and our industry;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- general economic, industry, and market conditions, including rising interest rates and inflation;
- our ability to attract, hire, and retain our key personnel and additional qualified personnel;
- our anticipated use of our existing cash, cash equivalents and short-term investments;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and
- other risks and uncertainties, including those listed under the caption "Risk Factors."

In some cases, forward-looking statements can be identified by terminology such as “may,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue,” or the negative of these terms or other comparable terminology. These statements are only predictions. Investors should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from those implied or projected by forward-looking statements include, among other things, those listed under the section titled “Risk Factors” and elsewhere in this Quarterly Report. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. Investors should read this Quarterly Report, the documents that we reference in this Quarterly Report and the other documents that we file with the Securities and Exchange Commission (“SEC”) with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

While we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. Investors should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report.

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 while 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 an exhaustive 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.

Risk Factors Summary

Our business is subject to numerous risks and uncertainties, which include, but are not limited to, the following:

- We are a clinical-stage biopharmaceutical company with a limited operating history, which may make it difficult to evaluate our current business and predict our future success and viability. We have incurred significant financial losses since our inception and anticipate that we will continue to incur significant financial losses for the foreseeable future.
- We will require additional funding in order to finance operations. If we are unable to raise capital when needed, or on acceptable terms, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.
- Verekitug is our only product candidate, and we are dependent on a third party having accurately generated, collected and reported data from certain preclinical studies that were previously conducted for verekitug.
- If we are unable to advance verekitug in clinical development for one or more of the indications that we are pursuing, obtain regulatory approval and ultimately commercialize verekitug, or experience significant delays in doing so, our business will be materially harmed.
- The successful development of pharmaceutical products involves a lengthy and expensive process and is highly uncertain.
- The regulatory approval processes of the FDA, the European Medicines Agency, and the European Commission and other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for verekitug or any other potential future product candidates, our business will be substantially harmed.
- Verekitug represents a novel approach to the treatment of inflammatory diseases, which makes it difficult to predict its likelihood of success and the timing and cost of development and obtaining regulatory approval.
- If our clinical trials fail to replicate positive results from earlier preclinical studies or clinical trials conducted by us or third parties, we may be unable to successfully develop, obtain regulatory approval for or commercialize verekitug or any other potential future product candidates.
- We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of verekitug or any other potential future product candidates, which could prevent us from achieving our projected development and commercialization goals in the timeframes we announce and expect, and harm our business and results of operations. Many of the factors that cause or lead to a delay in the initiation or completion of clinical trials may also lead to the denial of regulatory approval or limit market acceptance of verekitug or any other potential future product candidates.
- Verekitug or any other potential future product candidates may cause undesirable side effects or have other properties that could delay or prevent regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if obtained.
- Even if verekitug or any other potential future product candidates receive regulatory approval, such product candidate may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable.
- Competitive products may reduce or eliminate the commercial opportunity for verekitug or any other potential future product candidates, if approved. If our competitors develop technologies or product candidates more rapidly than we do, or their technologies or product candidates are more effective or safer than ours, our ability to develop and successfully commercialize verekitug or any other potential future product candidates may be adversely affected. Our competitors may

have significantly greater financial resources and expertise such that they may be more successful than us in obtaining regulatory approval and achieving widespread market acceptance.

- We expect to expand our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

- Our ability to develop verekitug or any other potential future product candidates and our future growth depends on attracting, hiring and retaining our key personnel and recruiting additional qualified personnel.

- We currently rely, and plan to rely in the future, on third parties to conduct and support our clinical trials. If they do not perform satisfactorily, we may not be able to obtain regulatory approval or commercialize verekitug or any other potential future product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed.

- Our use of third parties to manufacture verekitug or any other potential future product candidates may increase the risk that we will not have sufficient quantities of verekitug or any other potential future product candidates, raw materials, active pharmaceutical ingredients or drug products when needed or at an acceptable cost.

- Our success is largely based upon our intellectual property and proprietary technologies, and we may be unable to protect and/or enforce our intellectual property.

The summary risk factors described above should be read together with the text of the full risk factors in the section titled “Risk Factors” and the other information set forth in this Quarterly Report, as well as in other documents that we file with the SEC. The risks summarized above or described in full elsewhere in this Quarterly Report are not the only risks that we face. Additional risks and uncertainties not presently known to us, or that we currently deem to be immaterial, may also materially adversely affect our business, financial condition, results of operations, and future growth prospects.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Upstream Bio, Inc.
Condensed consolidated balance sheets
(Amounts in thousands, except share and per share amounts)
(Unaudited)

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 32,948	$ 25,833
Short-term investments	187,711	83,977
Accounts receivable - related party	607	98
Prepaid expenses and other current assets	6,007	7,088
Total current assets	227,273	116,996
Property and equipment, net	578	159
Operating lease right-of-use assets	1,914	43
Deferred offering costs	2,741	—
Restricted cash	194	—
Total assets	$ 232,700	$ 117,198
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 4,899	$ 1,990
Accrued expenses and other current liabilities	5,297	4,480
Operating lease liabilities, current portion	678	45
Total current liabilities	10,874	6,515
Operating lease liabilities, net of current portion	1,263	—
Preferred stock tranche right liability	—	2,874
Total liabilities	12,137	9,389
Commitments and contingencies (Note 13)		
Redeemable convertible preferred stock (Series A, B), $0.001 par value; 31,764,693 shares authorized at September 30, 2024 and December 31, 2023; 31,764,693 shares and 22,941,170 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively; aggregate liquidation preference of $430,759 and $267,718 at September 30, 2024 and December 31, 2023, respectively	380,874	230,935
Stockholders' deficit:		
Common stock, $0.001 par value; 40,684,346 shares and 40,664,346 shares authorized at September 30, 2024 and December 31, 2023, respectively; 3,025,452 and 2,992,479 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	3	3
Additional paid-in capital	8,873	4,824
Accumulated other comprehensive income	351	21
Accumulated deficit	(169,538)	(127,974)
Total stockholders' deficit	(160,311)	(123,126)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 232,700	$ 117,198

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

Upstream Bio, Inc.
Condensed consolidated statements of operations and comprehensive loss
(Amounts in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Collaboration revenue - related party	$ 607	$ 621	$ 1,757	$ 1,930
Operating expenses:				
Research and development	15,433	7,788	41,193	20,245
General and administrative	4,067	2,219	12,010	7,469
Total operating expenses	19,500	10,007	53,203	27,714
Loss from operations	(18,893)	(9,386)	(51,446)	(25,784)
Other income (expense):				
Change in fair value of preferred stock tranche right liabilities	—	4,773	2,859	14,542
Interest income	2,904	1,527	7,047	2,646
Other expense, net	(3)	(16)	(24)	(108)
Total other income, net	2,901	6,284	9,882	17,080
Net loss	$ (15,992)	$ (3,102)	$ (41,564)	$ (8,704)
Redeemable convertible preferred stock cumulative dividends	(5,041)	(3,151)	(13,041)	(14,567)
Net loss attributable to common stockholders	$ (21,033)	$ (6,253)	$ (54,605)	$ (23,271)
Net loss per share attributable to common stockholders, basic and diluted	$ (6.96)	$ (2.11)	$ (18.15)	$ (7.90)
Weighted-average common shares outstanding, basic and diluted	3,023,155	2,958,727	3,009,234	2,944,804
Comprehensive loss:				
Net loss	$ (15,992)	$ (3,102)	$ (41,564)	$ (8,704)
Unrealized gain (loss) on investments, net of tax	406	(19)	330	(77)
Comprehensive loss	$ (15,586)	$ (3,121)	$ (41,234)	$ (8,781)

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

Upstream Bio, Inc.
Condensed consolidated statements of redeemable convertible preferred stock and stockholders' deficit
(Amounts in thousands, except share amounts)
(Unaudited)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	Deficit
Balances at December 31, 2022	12,000,000	$ 112,823	2,937,197	$ 3	$ 1,279	$ (107,437)	$ —	$ (106,155)
Issuance of Series A redeemable convertible preferred stock in connection with the settlement of the tranche right liability	8,000,000	80,320	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	1,304	—	—	1,304
Net loss	—	—	—	—	—	(3,062)	—	(3,062)
Balances at March 31, 2023	20,000,000	193,143	2,937,197	3	2,583	(110,499)	—	(107,913)
Issuance of Series B redeemable convertible preferred stock, net of preferred stock tranche right liability of $11,774 and issuance costs of $385	2,941,170	37,842	—	—	—	—	—	—
Exercise of stock options, net of tax withholding	—	—	5,245	—	18	—	—	18
Stock-based compensation expense	—	—	—	—	627	—	—	627
Unrealized loss on available-for-sale securities, net of tax	—	—	—	—	—	—	(58)	(58)
Net loss	—	—	—	—	—	(2,540)	—	(2,540)
Balances at June 30, 2023	22,941,170	230,985	2,942,442	3	3,228	(113,039)	(58)	(109,866)
Series B redeemable convertible preferred stock issuance costs	—	(50)	—	—	—	—	—	—
Exercise of stock options, net of tax withholding	—	—	29,057	—	100	—	—	100
Stock-based compensation expense	—	—	—	—	683	—	—	683
Unrealized loss on available-for-sale securities, net of tax	—	—	—	—	—	—	(19)	(19)
Net loss	—	—	—	—	—	(3,102)	—	(3,102)
Balances at September 30, 2023	22,941,170	$ 230,935	2,971,499	$ 3	$ 4,011	$ (116,141)	$ (77)	$ (112,204)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	Deficit
Balances at December 31, 2023	22,941,170	$ 230,935	2,992,479	$ 3	$ 4,824	$ (127,974)	$ 21	$ (123,126)
Exercise of stock options, net of tax withholding	—	—	3,563	—	12	—	—	12
Stock-based compensation expense	—	—	—	—	643	—	—	643
Unrealized loss on available-for-sale securities, net of tax	—	—	—	—	—	—	(42)	(42)
Net loss	—	—	—	—	—	(10,894)	—	(10,894)
Balances at March 31, 2024	22,941,170	230,935	2,996,042	3	5,479	(138,868)	(21)	(133,407)
Issuance of Series B redeemable convertible preferred stock in connection with the settlement of the tranche right liability, net of issuance costs of $75	8,823,523	149,939	—	—	—	—	—	—
Exercise of stock options, net of tax withholding	—	—	24,504	—	100	—	—	100
Stock-based compensation expense	—	—	—	—	1,412	—	—	1,412
Unrealized loss on available-for-sale securities, net of tax	—	—	—	—	—	—	(34)	(34)
Net loss	—	—	—	—	—	(14,678)	—	(14,678)
Balances at June 30, 2024	31,764,693	380,874	3,020,546	3	6,991	(153,546)	(55)	(146,607)
Exercise of stock options, net of tax withholding	—	—	4,906	—	19	—	—	19
Stock-based compensation expense	—	—	—	—	1,863	—	—	1,863
Unrealized gain on available-for-sale securities, net of tax	—	—	—	—	—	—	406	406
Net loss	—	—	—	—	—	(15,992)	—	(15,992)
Balances at September 30, 2024	31,764,693	$ 380,874	3,025,452	$ 3	$ 8,873	$ (169,538)	$ 351	$ (160,311)

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

Upstream Bio, Inc.
Condensed consolidated statements of cash flows
(Amounts in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (41,564)	$ (8,704)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	40	46
Stock-based compensation expense	3,918	2,614
Change in fair value of preferred stock tranche right liabilities	(2,859)	(14,542)
Net amortization of premiums and accretion of discounts on short-term investments	(2,337)	(1,012)
Non-cash lease expense	51	59
Changes in operating assets and liabilities:		
Accounts receivable - related party	(509)	147
Prepaid expenses and other assets	1,081	(282)
Accounts payable	2,888	(479)
Accrued expenses and other current liabilities	(243)	(217)
Deferred revenue - related party	—	616
Operating lease liabilities	(26)	(62)
Net cash used in operating activities	(39,560)	(21,816)
Cash flows from investing activities:		
Purchases of short-term investments	(248,400)	(94,194)
Maturities of short-term investments	147,333	16,738
Purchases of property and equipment	(326)	(144)
Net cash used in investing activities	(101,393)	(77,600)
Cash flows from financing activities:		
Proceeds from the issuance of Series A redeemable convertible preferred stock[(1)]	—	80,000
Proceeds from the issuance of Series B redeemable convertible preferred stock including tranche right, net of issuance costs paid	149,924	49,565
Proceeds from exercises of stock options	131	118
Payments of deferred offering costs	(1,793)	—
Net cash provided by financing activities	148,262	129,683
Net increase in cash, cash equivalents and restricted cash	7,309	30,267
Cash, cash equivalents and restricted cash at beginning of period	25,833	17,051
Cash, cash equivalents and restricted cash at end of period	$ 33,142	$ 47,318
Cash, cash equivalents and restricted cash at end of period:		
Cash and cash equivalents	$ 32,948	$ 47,318
Restricted cash	194	—
Total cash, cash equivalents and restricted cash at end of period	$ 33,142	$ 47,318
Supplemental cash flow information:		
Right-of-use asset obtained in exchange for operating lease liability	$ 1,922	$ 33
Supplemental disclosure of non-cash investing and financing activities:		
Settlement of Series A preferred stock tranche right liability	$ —	$ 320
Settlement of Series B preferred stock tranche right liability	$ 15	$ —
Deferred offering costs included in accounts payable and accrued expenses	$ 948	$ —
Purchases of property and equipment included in accounts payable and accrued expenses	$ 133	$ —

(1) Includes related party amount of $10.0 million for the nine months ended September 30, 2023 (Note 16).

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

1. Nature of the business and basis of presentation

Upstream Bio, Inc. was incorporated in April 2021, under the laws of the State of Delaware, and along with its consolidated subsidiary (collectively, the "Company" or "Upstream"), is focused on developing treatments for inflammatory diseases, with an initial focus on severe respiratory disorders. Since its inception, the Company has devoted substantially all of its efforts to raising capital and incurring research and development expenses related to advancing verekitug, a clinical-stage monoclonal antibody that targets and inhibits the Thymic Stromal Lymphopoietin receptor.

Risks and uncertainties

The global economy has experienced extreme volatility and disruptions due to the military conflict between Russia and Ukraine and the war between Israel and Hamas. These conditions have impacted, and may continue to impact, the capital and credit markets, which may reduce the Company's ability to raise additional capital through equity, equity-linked instruments or debt financings which could negatively impact the Company's short-term and long-term liquidity. Additionally, the Company's results of operations could be adversely affected by general conditions in the global economy and financial markets. A severe or prolonged economic downturn could result in a variety of risks to the Company's business, including a reduced ability to raise additional capital when needed on favorable terms, if at all. The Federal Reserve raised the federal funds interest rates during 2022 and 2023 in order to mitigate persistent inflation. During September 2024, the Federal Reserve effected a reduction to the federal funds interest rate, the impact of which is not yet clear. Higher interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending. Any of the foregoing could harm the Company's business, and it cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact its ability to raise capital, business, results of operations and financial condition.

The Company is subject to risks and uncertainties common to early-stage companies in the biopharmaceutical industry, including, but not limited to, the successful development of verekitug, the development of new technological innovations by competitors, dependence on key personnel, the ability to attract and retain qualified employees, protection of proprietary technology, compliance with governmental regulations and the ability to secure additional capital to fund operations and commercial success of verekitug. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be maintained, that any therapeutic products developed will obtain required regulatory approval or that any approved or consumer products will be commercially viable. Even if the Company's development efforts are successful, it is uncertain when, if ever, the Company will generate significant product sales.

Stock split

On October 4, 2024, the Company effected a 1.049-for-one stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios of each series of the Company's preferred stock (see Notes 8 and 17). Accordingly, all share and per share amounts for all periods presented in the accompanying condensed consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this stock split and adjustment of the preferred stock conversion ratios.

Liquidity

The Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year from the issuance of these condensed consolidated financial statements.

The accompanying condensed consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. The Company has historically financed its operations principally through the issuance and sale of Series A redeemable convertible preferred stock ("Series A Preferred Stock") and Series B redeemable convertible preferred stock ("Series B Preferred Stock"), which are collectively referred to as the "Preferred Stock." The Company has incurred recurring losses and negative cash flows from operations since its inception and expects to continue to incur losses and negative cash flows for the foreseeable future as it continues the research and development of verekitug. The Company incurred net losses of $41.6 million and $8.7 million for the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, the Company had an accumulated deficit of $169.5 million.

In October 2024, the Company completed its initial public offering ("IPO") of its common stock. In connection with its IPO, the Company issued and sold 17,250,000 shares of common stock, including 2,250,000 shares pursuant to the full exercise of the

underwriters' option to purchase additional shares, at a price to the public of $17.00 per share. As a result of the IPO, the Company received approximately $268.7 million in net proceeds, after deducting $20.5 million in underwriting discounts and commissions, and approximately $4.0 million in other offering costs.

The Company expects its cash, cash equivalents and short-term investments will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next twelve months from the date of issuance of these condensed consolidated financial statements. The Company will need additional financing to support its continuing operations and pursue its growth strategy. Until such time as the Company can generate significant product revenue, if ever, the Company expects to fund its operations through equity offerings or debt financings, credit or loan facilities, potentially other capital resources, or a combination of one or more of these funding sources. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. The Company's failure to raise capital as and when needed could have a negative impact on its financial condition and its ability to pursue its business strategies. If adequate funds are not available to the Company, the Company may be required to delay, reduce or eliminate clinical programs, obtain funds through arrangements with collaborators on terms unfavorable to the Company or pursue merger or acquisition strategies. There can be no assurances the Company will be able to obtain additional funding. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

Basis of presentation

The accompanying unaudited condensed consolidated financial statements reflect the operations of the Company. Intercompany balances and transactions have been eliminated in consolidation. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial reporting and as required by Regulation S-X, Rule 10-01. Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

The condensed consolidated interim financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of the Company's financial position as of September 30, 2024 and the results of operations for the three and nine month interim periods ended September 30, 2024 and 2023. The condensed balance sheet as of December 31, 2023 was derived from audited annual financial statements but does not include all disclosures required by U.S. GAAP. The results of operations for the interim periods are not necessarily indicative of results to be expected for the year ending December 31, 2024, any other interim periods, or any future year or period.

2. Summary of Significant Accounting Policies

Other than policies noted below, there have been no significant changes from the significant accounting policies and estimates disclosed in Note 2 of the "Notes to Consolidated Financial Statements" in our audited annual financial statements included in the Company's IPO final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the Securities and Exchange Commission (the "SEC") on October 11, 2024.

Use of estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and the disclosure of contingent assets and liabilities as of and during the reporting period. The Company bases estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. The Company assesses estimates on an ongoing basis; however, actual results could materially differ from those estimates. Significant estimates and assumptions reflected within these condensed consolidated financial statements include, but are not limited to, prepaid and accrued research and development expenses, including those related to contract research organizations ("CROs"), contract manufacturing organizations ("CMOs") and other third-party vendors, the valuation of the Company's common stock and stock-based awards and the valuation of the preferred stock tranche right liabilities. Changes in estimates are recorded in the period in which they become known.

Concentration of credit risk and of significant suppliers

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash, cash equivalents and short-term investments. The Company deposits its cash and cash equivalents in financial institutions in amounts that may exceed federally insured limits, and has not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships. The Company's short-term investments consist of U.S. treasury bills and U.S. government agency bonds which the Company believes represent minimal credit risk.

The Company is dependent on third-party manufacturers to supply products for research and development activities related to verekitug, including preclinical and clinical studies and testing. In particular, the Company relies and expects to continue to rely on a small number of manufacturers for the supply of verekitug. The Company's preclinical and clinical studies and testing could be adversely affected by a significant interruption in the supply.

Cash and cash equivalents

The Company considers all short-term, highly liquid investments, with an original maturity of three months or less, to be cash equivalents, and includes amounts held in money market funds in the amount of $32.5 million and $23.3 million as of September 30, 2024 and December 31, 2023, respectively.

Restricted cash

Restricted cash consisted of a letter of credit totaling $0.2 million as of September 30, 2024, that is required to be maintained in connection with the Company's lease arrangements. The letter of credit is in the name of the Company's landlord and is required to fulfill lease requirements in the event the Company should default on its lease obligations. As of September 30, 2024, the Company classified its restricted cash as non-current assets on the condensed consolidated balance sheet based on the release date of the restriction. The Company did not hold a letter of credit as of December 31, 2023.

Short-term investments

Available-for-sale securities consist of investments with original maturities greater than 90 days at acquisition date. The Company classifies any investments with maturities beyond one year as short term, based on their highly liquid nature and because such available-for-sale securities represent the investment of cash that is available for current operations.

The Company's debt security investments are classified as available-for-sale and are carried at fair value, with the unrealized gains and losses reported as a component of accumulated other comprehensive income (loss) in stockholders' deficit. Realized gains and losses and declines in fair value due to credit-related factors are based on the specific identification method and are included as other expense, net in the condensed consolidated statements of operations and comprehensive loss. The Company recorded interest income on available-for-sale investments of $2.9 million and $7.0 million, and $1.5 million and $2.6 million for the three and nine months ended September 30, 2024 and the three and nine months ended September 30, 2023, respectively, which is classified as interest income in the condensed consolidated statements of operations and comprehensive loss.

At each balance sheet date, the Company assesses available-for-sale debt securities in an unrealized loss position to determine whether the unrealized loss or any potential credit losses should be recognized in other expense, net. The Company evaluates whether it intends to sell, or it is more likely than not that it will be required to sell, the security before recovery of its amortized cost basis. The Company also evaluates whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers the severity of the impairment, any changes in interest rates, changes to the underlying credit ratings and forecasted recovery, among other factors. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in other expense, net. The portion that is not credit-related is treated in accordance with other unrealized losses as a component of accumulated other comprehensive income (loss) in stockholders' deficit. There have been no impairment or credit losses recognized during any of the periods presented.

Deferred offering costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these

costs are recorded as a reduction of the proceeds from the offering, either as a reduction of the carrying value of the Preferred Stock or in stockholders' deficit as a reduction of additional paid-in-capital generated as a result of the offering. Should the planned equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the condensed consolidated statements of operations and comprehensive loss. The Company recorded deferred offering costs of $2.7 million and $0 as of September 30, 2024 and December 31, 2023, respectively.

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* ("ASU 2023-07"). ASU 2023-07 expands public entities' segment disclosures by requiring disclosure of significant segment expenses that are regularly provided to the chief operating decision maker 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. All disclosure requirements under ASU 2023-07 are also required for public entities with a single reportable segment. ASU 2023-07 is effective for public business entities with fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. The Company is currently evaluating the impact of adopting ASU 2023-07 on its consolidated financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures* ("ASU 2023-09"). ASU 2023-09 requires entities to disclose additional information in specified categories with respect to the reconciliation of the effective tax rate to the statutory rate (the rate reconciliation) for federal, state, and foreign income taxes. It also requires greater detail about individual reconciling items in the rate reconciliation to the extent the impact of those items exceeds a specified threshold (if the effect of those reconciling items is equal to or greater than 5% of the amount computed by multiplying pretax income or loss by the applicable statutory income tax rate). In addition to new disclosures associated with the rate reconciliation, ASU 2023-09 requires information pertaining to taxes paid (net of refunds received) to be disaggregated for federal, state, and foreign taxes and further disaggregated for specific jurisdictions to the extent the related amounts exceed a quantitative threshold. The amendments are effective for public business entities for annual periods beginning after December 15, 2024. For entities other than public business entities, the amendments are effective for annual periods beginning after December 15, 2025. Early adoption is permitted. The Company is currently evaluating the timing and impact of adopting ASU 2023-09 on its consolidated financial statements and related disclosures.

In November 2024, the FASB issued an ASU to require more detailed information about specified categories of expenses (purchases of inventory, employee compensation, depreciation, amortization, and depletion) included in certain expense captions presented on the face of the income statement. This ASU is effective for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The amendments may be applied either (1) prospectively to financial statements issued for reporting periods after the effective date of this ASU or (2) retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the impact of adopting this ASU on its consolidated financial statements and related disclosures.

3. Fair value measurements

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

	Fair Value Measurements at September 30, 2024 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 32,492	$ —	$ —	$ 32,492
Short-term investments:				
U.S. treasury bills	—	93,275	—	93,275
U.S. government agency bonds	—	94,436	—	94,436
	$ 32,492	$ 187,711	$ —	$ 220,203

	Fair Value Measurements at December 31, 2023 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 23,314	$ —	$ —	$ 23,314
Short-term investments:				
U.S. treasury bills	—	45,864	—	45,864
U.S. government agency bonds	—	38,113	—	38,113
	$ 23,314	$ 83,977	$ —	$ 107,291
Liabilities:				
Preferred stock tranche right liability (Series B)	$ —	$ —	$ 2,874	$ 2,874

For the three and nine months ended September 30, 2024 and for the year ended December 31, 2023, there were no transfers between Level 1, Level 2 and Level 3.

The Company classifies its U.S. treasury bills and U.S. government agency bonds as short-term based on each instrument's availability for use in current operations. The fair value of the Company's U.S. treasury bills and U.S. government agency bonds are classified as Level 2 because they are valued using observable inputs to quoted market prices, benchmark yields, reported trades, broker/dealer quotes or alternative pricing sources with reasonable levels of price transparency.

Short-term investments consisted of the following (in thousands):

	September 30, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Short-term investments:				
U.S. treasury bills	$ 93,201	$ 81	$ (7)	$ 93,275
U.S. government agency bonds	94,160	276	—	94,436
Total short-term investments:	$ 187,361	$ 357	$ (7)	$ 187,711

	December 31, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Short-term investments:				
U.S. treasury bills	$ 45,863	$ 9	$ (8)	$ 45,864
U.S. government agency bonds	38,093	23	(3)	38,113
Total short-term investments:	$ 83,956	$ 32	$ (11)	$ 83,977

The contractual maturities of the Company's short-term investments in available-for-sale securities held were as follows (in thousands):

	September 30, 2024	December 31, 2023
Due within one year	$ 157,861	$ 83,977
Due after one year through two years	29,850	—
Total available-for-sale securities	$ 187,711	$ 83,977

Valuation of preferred stock tranche right liabilities

As of December 31, 2023, the preferred stock tranche right liability in the table above is composed of the fair value of the obligation to issue Series B Preferred Stock (Note 8). The fair value of the preferred stock tranche right liabilities was based on significant inputs not observable in the market, which represented a Level 3 measurement within the fair value hierarchy.

Series A preferred stock tranche right liability

In February 2023, upon satisfaction of certain conditions, the second closing of the Series A Preferred Stock was completed. The Company issued and sold 8,000,000 shares of Series A Preferred Stock at a price of $10.00 per share, which resulted in the settlement of the associated Series A preferred stock tranche right liability. The fair value of Series A Preferred Stock was $10.04 per share upon the second closing.

Series B preferred stock tranche right liability

The fair value of the Series B preferred stock tranche right liability was determined using an option pricing model as it represents an option for the Series B Option Shares (as defined in Note 8). The valuation considered as inputs the estimated fair value of the Series B Preferred Stock as of each valuation date, the risk-free interest rate, volatility, expected dividends, and estimated time to the tranche closing.

The most significant assumption in the valuation model impacting the fair value of the preferred stock tranche right liability is the fair value of the Company's Series B Preferred Stock as of each measurement date. The Company determined the fair value per share of the underlying Series B Preferred Stock by taking into consideration the most recent sales of its Series B Preferred Stock, results obtained from third-party valuations and additional factors the Company deemed relevant. In June 2023, the initial tranche of the Series B Preferred Stock closed with a fair value of $13.00 per share. As of December 31, 2023, the fair value of Series B Preferred Stock was $15.86 per share. In April 2024, upon satisfaction of certain conditions, the Company issued and sold 8,823,523 shares of Series B Preferred Stock at a price of $17.00 per share, which resulted in the settlement of the associated Series B preferred stock tranche right liability. The fair value of Series B Preferred Stock was $17.002 per share upon the closing. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining estimated time to the tranche closing. The volatility is based on the historical volatility of publicly traded peer companies adjusted for the seniority of the Series B Preferred Stock. The expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future. Changes in these inputs can have a significant impact on the fair value of the preferred stock tranche right liability.

The following table presents the assumptions used in the option-pricing model to determine the fair value of the Series B preferred stock tranche right liability during the periods presented:

	2023		
	June *(Issuance Date)*	June 30,	December 31,
Expected volatility	51.0%	36.2%	21.2%
Expected dividends	0.0%	0.0%	0.0%
Expected term (in years)	0.80	0.75	0.25
Risk-free rate	5.3%	5.4%	5.4%

The following table presents a roll-forward of the fair value of the Series B preferred stock tranche right liability during the nine months ended September 30, 2024, for which fair value is determined using Level 3 inputs (in thousands):

	Series B Preferred Stock Tranche Right Liability
Fair value at December 31, 2023	$ 2,874
Change in fair value of Series B preferred stock tranche right liability	(2,859)
Final settlement of Series B preferred stock tranche right liability	(15)
Fair value at September 30, 2024	$ -

The following table presents a roll-forward of the fair value of the Series A and Series B preferred stock tranche right liabilities during the nine months ended September 30, 2023, for which fair value is determined using Level 3 inputs (in thousands):

	Preferred Stock Tranche Right Liability	
	Series A	Series B
Fair value at December 31, 2022	$ 6,947	$ —
Fair value of Series B preferred stock tranche right liability at issuance	—	11,774
Change in fair value of preferred stock tranche right liabilities	(6,627)	(7,915)
Final settlement of Series A preferred stock tranche right liability	(320)	—
Fair value at September 30, 2023	$ —	$ 3,859

4. Prepaid expenses and other current assets

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

	September 30, 2024	December 31, 2023
Prepaid research and development expense	$ 5,076	$ 6,436
Interest receivable	485	138
Prepaid employee-related costs	58	123
Other	388	391
	$ 6,007	$ 7,088

5. Property and equipment, net

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

	September 30, 2024	December 31, 2023
Office equipment	$ 163	$ 163
Computer equipment	141	36
Leasehold improvements	59	27
Construction in progress	322	—
	685	226
Less: Accumulated depreciation and amortization	(107)	(67)
Property and equipment, net	$ 578	$ 159

Depreciation and amortization expense related to property and equipment, net was less than $0.1 million for each of the three and nine months ended September 30, 2024 and 2023.

6. Accrued expenses and other current liabilities

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

	September 30, 2024	December 31, 2023
Accrued employee compensation and benefits	$ 1,999	$ 2,168
Accrued external research and development expenses	1,764	1,437
Accrued consultant and professional fees	747	875
Accrued offering costs	669	—
Other	118	—
	$ 5,297	$ 4,480

7. Leases

As of December 31, 2023, the Company was a party to a lease related to commercial real estate under a non-cancelable lease term and a short-term lease related to commercial real estate.

In July 2024, the Company entered into an operating lease agreement for office space located at 890 Winter Street in Waltham, Massachusetts. The lease commenced in September 2024 and the Company began paying monthly rent starting one month after the lease commenced. The Company occupies approximately 16,801 square feet of space under a three-year agreement expiring in October 2027. Initial base rent is approximately $0.7 million for the first year and approximately $0.8 million for the second and third year.

The Company previously had an operating lease for office space at 460 Totten Pond Road, Waltham, Massachusetts, for which it provided notice of termination in July 2024. This notice became effective on October 9, 2024, after which the Company's rights and obligations under this lease ceased. The lease expired on June 30, 2024, after which the Company continued to pay rent on a month-to-month basis until October 9, 2024.

8. Redeemable convertible preferred stock

The Company has issued Series A Preferred Stock and Series B Preferred Stock, which are collectively referred to as the Preferred Stock. As of September 30, 2024 and December 31, 2023, the Company authorized the issuance of 31,764,693 shares of Preferred Stock, par value of $0.001 per share, of which 20,000,000 have been designated Series A Preferred Stock and 11,764,693 have been designated Series B Preferred Stock.

Immediately prior to the closing of the Company's IPO on October 15, 2024, pursuant to the stock split and a proportional adjustment to the existing conversion ratios of each series of the Company's Preferred Stock as discussed further below, all of the Company's outstanding shares of convertible preferred stock were converted into an aggregate of 33,321,149 shares of common stock.

Issuance and sale of Series A redeemable convertible preferred stock

In October 2021, the Company issued and sold 11,000,000 shares of Series A Preferred Stock at $10.00 per share. Pursuant to the Series A Preferred Stock Purchase Agreement (the "Series A Agreement"), the Company was obligated to issue and the Series A investors were obligated to purchase an additional 9,000,000 shares of Series A Preferred Stock ("Milestone Shares") at the same purchase price of $10.00 per share (the "Series A preferred stock tranche right"), after the initial closing and upon the satisfaction of certain conditions at a date which would occur at the earlier of (i) immediately prior to the Company's first underwritten public offering of its common stock under the Securities Act; (ii) the resolution of the board of directors that the pharmacokinetics, pharmacodynamics, immunogenicity and safety profile of verekitug (formerly referred to as ASP7266), when administered as multiple ascending doses, supports further clinical development ("Second Closing Milestone") has been achieved; or (iii) the written consent of the purchasers holding a majority of the Series A Preferred Stock that the Second Closing Milestone has been waived (collectively, the "Second Closing").

The board of directors may determine at any time prior to the Second Closing to issue and sell up to 1,000,000 of the Milestone Shares at a price of $10.00 per share for gross cash proceeds of $10.0 million ("Interim Second Closing") and the number of Milestone Shares to be issued in the Second Closing will be reduced accordingly. In October 2022, the Interim Second Closing was completed and 1,000,000 of the Milestone Shares on a pro-rata basis to the purchasers of the Series A Preferred Stock were issued at a price of $10.00 per share.

In February 2023, upon the satisfaction of the Second Closing Milestone, the remaining 8,000,000 of the Milestone Shares on a pro-rata basis to the purchasers of the Series A Preferred Stock were issued at a price of $10.00 per share, which resulted in gross cash proceeds of $80.0 million. As a result of this issuance, the Series A preferred stock tranche right liability of $0.3 million was settled and the Series A Preferred Stock was recorded at its fair value of $80.3 million.

Issuance and sale of Series B redeemable convertible preferred stock

In June 2023, the Company executed the Series B Stock Preferred Purchase Agreement (the "Series B Agreement") to issue and sell up to 11,764,693 shares of Series B Preferred Stock at a price of $17.00 per share. In the initial closing in June 2023, the Company issued 2,941,170 shares of Series B Preferred Stock resulting in gross cash proceeds of $50.0 million and incurred $0.6 million of issuance costs, of which $0.1 million was allocated to the preferred stock tranche right liability and recognized in the condensed consolidated statement of operations and comprehensive loss as general and administrative expense. Pursuant to the Series B Agreement, the Company has the right ("Series B Option") to issue and sell an additional 8,823,523 shares of Series B

Preferred Stock ("Series B Option Shares") at the same price of $17.00 per share after the initial closing but prior to March 31, 2024 upon approval of at least six (6) board of directors of which at least one (1) has to be appointed by the holders of Series B Preferred Stock. If the Company does not exercise the Series B Option prior or at a date which would occur at the earlier of (i) March 31, 2024 or (ii) the closing of an acquisition agreement signed prior to March 31, 2024, the holders of Series B Preferred Stock will have the right but not obligation to require the Company to issue and sell the Series B Option Shares at the same purchase price of $17.00 per share (the "Series B preferred stock tranche right"). Upon the initial closing of the Series B Preferred Stock, the Company recorded a preferred stock tranche right liability of $11.8 million and a corresponding reduction to the carrying value of the Series B Preferred Stock. The fair value of the Series B preferred stock tranche right was allocated from the gross cash proceeds of $50.0 million of the Series B Preferred Stock issuance, and the residual value was then allocated to the Series B Preferred Stock.

In April 2024, pursuant to the satisfaction of the Series B Option contemplated in the Series B Agreement, the Company issued and sold 8,823,523 shares of Series B Preferred Stock at a price of $17.00 per share, which resulted in gross cash proceeds of $150.0

million. As a result of this issuance, the Series B preferred stock tranche right liability of less than $0.1 million was settled and the Series B Preferred Stock was recorded at its fair value of $150.0 million. The Company incurred less than $0.1 million of issuance costs in connection with the Series B Option closing.

Upon issuance of the Preferred Stock, the Company assessed the embedded conversion and liquidation features of the securities and determined that such features did not require the Company to separately account for these features.

Preferred Stock consisted of the following (dollar amounts in thousands):

	September 30, 2024				
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A Preferred Stock	20,000,000	20,000,000	$ 193,143	$ 223,800	20,980,000
Series B Preferred Stock	11,764,693	11,764,693	187,731	206,959	12,341,149
	31,764,693	31,764,693	$ 380,874	$ 430,759	33,321,149

	December 31, 2023				
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A Preferred Stock	20,000,000	20,000,000	$ 193,143	$ 216,293	20,980,000
Series B Preferred Stock	11,764,693	2,941,170	37,792	51,425	3,085,280
	31,764,693	22,941,170	$ 230,935	$ 267,718	24,065,280

The holders of the Preferred Stock have the following rights and preferences:

Dividends

The holders of Preferred Stock are entitled to a cumulative dividend from and after the date of the share issuance at the rate per annum of 5% of the Original Issue Price (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Preferred Stock), provided that the total accrued amount will not exceed 15% of the Original Issue Price in aggregate (the "Accruing Dividend"). Such dividends shall be accrued, whether or not declared.

In the event of any dividend being payable to common stockholders, the holders of Preferred Stock shall be entitled to receive, prior to any such dividend being paid to the common stockholders, the greater of (i) the Accruing Dividend then accrued and not previously paid, and (ii) the amount of any dividend being paid to the common stockholders (determined on an as-converted basis with respect to the holders of Preferred Stock).

Voting rights

The holders of the Preferred Stock are entitled to vote together with all other classes and series of stock as a single class on all matters, except those matters requiring a separate class vote, and are entitled to the number of votes equal to the number of shares of common stock into which each share of the applicable series of Preferred Stock is then convertible. The holders of Series A Preferred Stock as a separate class are entitled to elect four (4) board of directors, and the holders of Series B Preferred Stock as a separate class are entitled to elect two (2) board of directors.

Liquidation preference

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or in the event of a Deemed Liquidation Event ("DLE") which is defined as a merger or consolidation in which the Company issues shares of its capital stock (other than one in which stockholders of the Company own a majority by voting power of the outstanding shares of the surviving or acquiring corporation), and the sale, lease, transfer, exclusive license or other disposition of substantially all of the Company's assets,

the holders of shares of Preferred Stock then outstanding shall be entitled to be paid out of the assets of the Company available for distribution to its shareholders or consideration payable to stockholders in such DLE or out of the available proceeds as follows:

- Before any payment is made to the holders of Series A Preferred Stock and common stock, an amount equal to any Accruing Dividends on the Series B Preferred Stock accrued but unpaid, whether or not declared, together with any other dividends that are declared but unpaid ("Series B Dividend Payment");
- If the assets available are not sufficient for the Company to pay the Series B Dividend Payment to the holders of Series B Preferred Stock in full, holders of Series B Preferred Stock will share ratably in the assets available for distribution;
- After the Series B Dividend Payment is paid in full, holders of Preferred Stock will be entitled to be paid out of the assets of the Company available for distribution to its stockholders before any payment is made to the holders of common stock, on a pari passu basis, an amount per share equal to (i) with respect to the Series A Preferred Stock, the greater of (a) the Original Issue Price, plus any Accruing Dividends on the Series A Preferred Stock accrued but unpaid, whether or not declared, together with any other dividends declared but unpaid, or (b) such amount per share as would have been payable had all shares of Series A Preferred Stock been converted in common stock, and (ii) with respect to the Series B Preferred Stock, (1) the greater of (a) the Original Issue Price, plus any Accruing Dividends on the Series B Preferred Stock accrued but unpaid, whether or not declared, together with any other dividends declared but unpaid thereon, or (b) such amount per share as would have been payable had all shares of Series B Preferred Stock been converted in common stock, less (2) Series B Dividend Payment that was paid. ("Liquidation Amount");
- If the assets available are not sufficient for the Company to pay holders of Preferred Stock the Liquidation Amount in full, holders of Preferred Stock will share ratably in the assets available for distribution;
- After payment of Liquidation Amounts is paid in full to the holders of Preferred Stock, the remaining assets of the Company available for distribution to its stockholders, or in the case of a DLE, the consideration not payable to the holders of shares of Preferred Stock or the remaining available proceeds, will be distributed among the holders of the shares of common stock on a pro rata basis.

The "Original Issue Price" is defined as (i) with respect to the Series A Preferred Stock, $10.00 per share, and (ii) with respect to the Series B Preferred Stock, $17.00 per share.

Conversion

Optional conversion

Each share of Preferred Stock is convertible at the option of the holder and at any time into common stock as determined by dividing the Preferred Stock Original Issue Price by the Preferred Stock Conversion Price. "Conversion Price" is defined as initially the applicable Original Issue Price for the applicable series of Preferred Stock, subject to certain adjustments in the event of any down round, stock dividend, stock split, combination or other similar recapitalization.

Mandatory conversion

Each share of Preferred Stock will automatically be converted into shares of common stock, at the conversion ratio of dividing the Original Issue Price by the Preferred Stock Conversion Price, upon either (a) the closing of the sale of shares of common stock to the public at a price of at least $21.07 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the common stock) in a firm commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least $100.0 million of gross proceeds to the Company and after which the common stock is listed on the Nasdaq Global Market, the Nasdaq Global Select Market or the New York Stock Exchange or (b) the date and time, or the occurrence of an event specified by vote or written consent of the Requisite Holders (which is defined as at least a majority of the outstanding shares of Preferred Stock, voting together as a single class on an as converted to common stock basis, which majority must include holders of at least a majority of the outstanding shares of Series B Preferred Stock) voting together as a single class on an as converted to common stock basis, then all outstanding shares of Preferred Stock will automatically be converted into shares of common stock, at the then effective conversion rate and such shares of Preferred Stock may not be reissued by the Company.

Special mandatory conversion

Pursuant to the terms of the Series A Agreement, if a Series A Preferred Shareholder fails to purchase all of the Milestone Shares allocated to such shareholder at or prior to the Second Closing Milestone or breaches its obligations set forth in the Series A Agreement, then such investor will be deemed a Defaulting Purchaser. As of December 31, 2023, all of the Milestone Shares had been issued without triggering the special mandatory conversion provision under the Series A Agreement.

Pursuant to the terms of the Series B Agreement, if a Series B Preferred Shareholder fails to purchase all of the Series B Option Shares allocated to such shareholder at or prior to the closing of the Series B Option or breaches its obligations set forth in the Series B Agreement, then such investor will be deemed a Defaulting Purchaser. Each ten shares of Preferred Stock held by the Defaulting Purchaser will automatically, and without any further action on the part of such holder, be converted into one share of common stock. In April 2024, all of the Series B Option Shares had been issued without triggering the special mandatory conversion provision under the Series B Agreement.

Modification to Series A preferred stock

In June 2023, in connection with the issuance of the Company's Series B Preferred Stock, the rights of the Company's Series A Preferred Stock were amended to entitle holders to a cumulative dividend from and after the date of the share issuance at the rate per annum of 5% of the Original Issue Price (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Preferred Stock), provided that the total accrued amount will not exceed 15% of the Original Issue Price in aggregate. The dividend replaced the original accrued return definition within the liquidation preference terms of the Series A Preferred Stock. Previously, holders were entitled to a liquidation preference per share equal to the greater of (a) the Original Issue Price, plus an accrued return of 5% of the Original Issue Price per annum, provided that the total of such accrued return shall not exceed 15% of the Original Issue Price in the aggregate, or (b) such amount per share as would have been payable had all shares of Series A Preferred Stock been converted in common stock.

The changes to the rights of the Company's Series A Preferred Stock were not considered to be a significant change to the contractual terms of the Company's Series A Preferred Stock because the accrued return of the liquidation preference and the cumulative dividend definitions will result in the same amount to be received in a liquidation event, and accordingly, the Company accounted for the change as a modification.

9. Common stock

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any, subject to the preferential dividend rights of the Preferred Stock. When dividends are declared on shares of common stock, the Company must declare at the same time a dividend payable to the holders of Preferred Stock equivalent to the dividend amount they would receive if each share of Preferred Stock were converted into common stock. The Company may not pay dividends to common stockholders until all dividends accrued or declared but unpaid on the Preferred Stock have been paid in full. As of September 30, 2024 and December 31, 2023, no dividends were declared.

As of September 30, 2024 and December 31, 2023, the Company's amended and restated certificate of incorporation authorized the issuance of 40,684,346 and 40,664,346 shares, respectively, of $0.001 par value common stock. As of September 30, 2024 and December 31, 2023, there were 3,025,452 shares and 2,992,479 shares of common stock issued and outstanding, respectively.

As of September 30, 2024 and December 31, 2023, the Company had reserved 39,614,500 and 38,051,952 shares of common stock, respectively, for the conversion of shares of Preferred Stock into common stock (including committed but unissued shares under future tranche obligations for the Preferred Stock as of December 31, 2023), the exercise of outstanding stock options for common stock, and the issuance of common stock options remaining available for grant under its equity incentive plan.

On October 4, 2024, the Company's stockholders approved the third amended and restated certificate of incorporation, which was filed immediately prior to the closing of the IPO on October 15, 2024 and which, among other things, increased the number of shares of common stock authorized for issuance from 40,684,346 to 500,000,000 shares of common stock.

In October 2024, the Company completed its IPO of its common stock. In connection with its IPO, the Company issued and sold 17,250,000 shares of common stock, including 2,250,000 shares sold pursuant to the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $17.00 per share. As a result of the IPO, the Company received approximately

$268.7 million in net proceeds, after deducting $20.5 million in underwriting discounts and commissions, and approximately $4.0 million in other offering costs.

10. Stock-based compensation

Stock incentive plan

The Company's 2021 Stock Option and Grant Plan (the "2021 Plan") provides for the Company to grant incentive stock options, nonqualified stock options, restricted stock awards, unrestricted stock awards and restricted stock units (collectively, the "Awards") to among others, members of the board of directors, employees, consultants and other key persons to the Company and its affiliates. The 2021 Plan is administered by the board of directors, or at the discretion of the board of directors, by a committee of the board.

As of September 30, 2024 and December 31, 2023, the total number of shares of common stock reserved for issuance under the 2021 Plan was 6,360,626 shares and 4,765,105 shares, respectively. In April 2024, upon the satisfaction of the Series B Option contemplated in the Series B Agreement, the Company's board of directors increased the number of shares of common stock reserved for issuance under the plan from 4,765,105 to 6,360,626 shares. As of September 30, 2024 and December 31, 2023, 55,379 shares and 564,696 shares remain available for future grants, respectively. Shares of unused common stock underlying any Awards that are forfeited, canceled or reacquired by the Company prior to vesting will again be available for the grant of awards under the 2021 Plan. Shares underlying any awards that are forfeited, canceled, or reacquired by the Company prior to vesting, satisfied without the issuance of stock or otherwise terminated and shares that are withheld upon exercise of an option of settlement of an award to cover the exercise price or tax withholding shall be added back to the shares available for issuance under the 2021 Plan.

2024 Stock option and incentive plan

On August 19, 2024, the Company's board of directors adopted, and on October 4, 2024 its stockholders approved, the 2024 Stock Option and Incentive Plan (the "2024 Plan"), which became effective upon the date immediately preceding the date on which the IPO registration statement was declared effective by the SEC. The 2024 Plan allows the Company to make equity-based and cash-based incentive awards to its officers, employees, directors, and consultants. The 2024 Plan provides for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock units, restricted shares of common stock and other stock-based awards. The number of shares initially reserved for issuance under the 2024 Plan is 3,180,000 shares. The number of shares reserved under the 2024 Plan is subject to adjustment in the event of a stock split, stock dividend or other change in the Company's capitalization. In addition, the number of shares reserved and available for issuance under the 2024 Plan will automatically increase on January 1, 2025 and each January 1 thereafter, by five percent of the outstanding number of shares of its common stock on the immediately preceding December 31 or such lesser number of shares as determined by the Company's compensation committee.

The shares of common stock underlying any awards under the 2024 Plan and the 2021 Plan that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of stock, expire or are otherwise terminated (other than by exercise) will be added back to the shares of common stock available for issuance under the 2024 Plan.

2024 Employee stock purchase plan

On August 19, 2024, the Company's board of directors adopted, and on October 4, 2024 its stockholders approved, the 2024 Employee Stock Purchase Plan (the "2024 ESPP"), which became effective on the date immediately preceding the date on which the IPO registration statement was declared effective by the SEC. A total of 488,467 shares of common stock were initially reserved for issuance to participating employees under this plan. The 2024 ESPP provides that the number of shares reserved and available for issuance will automatically increase on January 1, 2025 and each January 1 thereafter through January 1, 2034, by the least of (i) 976,934 shares of common stock, (ii) one percent of the outstanding number of shares of common stock on the immediately preceding December 31, or (iii) such lesser number of shares of common stock as determined by the administrator of the 2024 ESPP. The number of shares reserved under the 2024 ESPP is subject to adjustment in the event of a stock split, stock dividend or other change in the Company's capitalization.

Fair value inputs

The following table presents, on a weighted-average basis, the assumptions used in the Black-Scholes option-pricing model to determine the fair value of stock options granted:

	Nine Months Ended September 30,	
	2024	2023
Per share fair value of common stock	$ 6.19	$ 4.52
Expected volatility	78.0%	77.0%
Expected dividends	0%	0%
Expected term (in years)	6.3	6.3
Risk-free rate	3.35%	1.94%

Stock options

The Company generally grants stock-based awards with service-based vesting. During the nine months ended September 30, 2024, the Company granted performance-based stock options to certain employees and directors for the purchase of an aggregate 1,206,249 shares of common stock with a vesting commencement date contingent upon the achievement of the Series B Option closing, which was achieved in April 2024. The Company determined that it met all the conditions to establish a grant date for these performance-based stock options at the original issuance date and that the performance condition was deemed probable of achievement, as the board of directors had approved the Series B Option closing prior to the grant date. The vesting of the performance-based stock options is also subject to the grantees' continued service until the fourth anniversary of the Series B Option closing.

The following table summarizes the activity of stock options with service-based and performance-based vesting conditions during the nine months ended September 30, 2024:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Intrinsic Value (in thousands)
Outstanding as of December 31, 2023	4,166,107	$ 3.75	8.5	4,648
Granted	3,209,120	6.19		
Exercised	(32,973)	3.99		
Forfeited or expired	(1,104,280)	3.82		
Outstanding as of September 30, 2024	6,237,974	$ 4.99	8.0	$ 35,091
Options exercisable September 30, 2024	1,861,312	$ 3.62	5.4	$ 13,028
Vested and expected to vest September 30, 2024	6,237,974	$ 4.99	8.0	$ 35,091

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the estimated fair value of the Company's common stock for those stock options that had exercise prices lower than the estimated fair value of the Company's common stock.

The weighted-average grant-date fair value of options granted during the nine months ended September 30, 2024 and 2023 was $4.36 and $3.08, respectively.

As of September 30, 2024, there was $14.1 million of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of 3.2 years.

Modification of certain stock-based compensation awards

In February 2024, the Company entered into a separation agreement with the Company's former Chief Operating Officer ("COO"), effective March 2024. Under the terms of the separation agreement, stock options for the purchase of 142,935 shares of common stock, representing all of the vested options held by the former COO as of the date of her termination, became exercisable for one year following her termination.

In March 2024, the Company entered into a separation agreement with the Company's former Chief Executive Officer ("CEO"), effective March 2024. Under the terms of the separation agreement, vesting of options for the purchase of 38,245 shares of common stock held by the former CEO were accelerated with no change to the exercise price of such options. In addition, stock options for the purchase of 532,553 shares of common stock, representing all of the vested options held by the former CEO as of the date of her termination, became exercisable for two years following her termination.

As a result of these modifications, the Company recognized $0.7 million of incremental stock-based compensation during the nine months ended September 30, 2024.

The following table illustrates the classification of stock-based compensation in the condensed consolidated statements of operations and comprehensive loss (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
General and administrative	1,553	$ 421	3,082	$ 1,801
Research and development	310	262	836	813
	$ 1,863	$ 683	$ 3,918	$ 2,614

11. Income Taxes

The Company's tax provision for interim periods is determined using an estimate of its annual effective tax rate, adjusted for discrete items, if any, that arise during the period. Each quarter, the Company updates its estimate of the annual effective tax rate and, if the estimated annual effective tax rate changes, the Company makes a cumulative adjustment in such period. No such adjustment was made as of September 30, 2024. The Company's effective federal and state tax rate for the nine months ended September 30, 2024 and 2023 was 0%, and the Company did not record any income tax expense or benefit during the nine months ended September 30, 2024 and 2023, primarily as a result of estimated net operating losses for the fiscal year to date offset by the increase in the valuation allowance against its deferred tax asset. All losses before income taxes arose in the United States.

12. Net loss per share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (dollar amounts in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Numerator:				
Net loss	$ (15,992)	$ (3,102)	$ (41,564)	$ (8,704)
Preferred Stock cumulative dividends	(5,041)	(3,151)	(13,041)	(14,567)
Net loss attributable to common stockholders	$ (21,033)	$ (6,253)	$ (54,605)	$ (23,271)
Denominator:				
Weighted-average common shares outstanding, basic and diluted	3,023,155	2,958,727	3,009,234	2,944,804
Net loss per share attributable to common stockholders, basic and diluted	$ (6.96)	$ (2.11)	$ (18.15)	$ (7.90)

Prior to June 2023, the Company's Series A Preferred Stockholders were not entitled to cumulative dividends. In connection with the Series B Agreement in June 2023, the Company modified the dividend rights for its Series A Preferred Stockholders such that they became entitled to cumulative dividends based on the original issuance dates of the respective Series A Preferred Stock (Note 8). As such for the nine months ended September 30, 2023, the Company calculated its net loss attributable to common stockholders by adjusting its net loss for the aggregate cumulative dividends that had accrued since the original issuances dates in the period in which the Preferred Stockholders became legally entitled to such dividends. For the nine months ended September 30, 2024, the Company calculated its net loss attributable to common stockholders by adjusting its net loss for the aggregate cumulative dividends that accrued during the period.

The Company's potentially dilutive securities, which include stock options to purchase common stock and Preferred Stock, have been excluded from the computation of diluted net loss per share as the effect would be anti-dilutive. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same.

The following potentially dilutive securities have been excluded from the calculation of diluted net loss per share due to their anti-dilutive effect:

	As of September 30,	
	2024	2023
Preferred Stock (as converted to common stock)[(1)]	33,321,149	24,065,280
Stock options to purchase common stock	6,237,974	4,188,618
	39,559,123	28,253,898

(1) For the nine months ended September 30, 2023, the Preferred Stock excludes 8,823,523 shares of Series B Preferred Stock (or 9,255,869 shares as converted to common stock) that were contingently issuable upon settlement of the Series B preferred stock tranche right liability (Note 8).

13. Commitments and contingencies

Legal matters

The Company is subject to contingent liabilities, such as legal proceedings and claims, that arise in the ordinary course of business activities. The Company accrues for loss contingencies when losses become probable and are reasonably estimable. If the reasonable estimate of the loss is a range and no amount within the range is a better estimate, the minimum amount of the range is recorded as a liability on the condensed consolidated balance sheets. The Company does not accrue for contingent losses that, in its judgment, are considered to be reasonably possible, but not probable; however, it discloses the range of reasonably possible losses. As of September 30, 2024 and December 31, 2023, the Company was not a party to any material legal proceedings or claims and no liabilities were recorded for loss contingencies.

Contracts

The Company enters into contracts in the normal course of business with various third parties for preclinical research studies, clinical trials, testing, manufacturing, and other services. These contracts generally provide for termination upon notice and are cancellable without significant penalty or payment, and do not contain any minimum purchase commitments.

Guarantees and indemnifications

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with all board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements that could have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its condensed consolidated financial statements as of September 30, 2024 and December 31, 2023.

14. License agreements

License agreement with Lonza

In October 2021, in connection with an asset purchase agreement entered into with Astellas Pharma, Inc. ("Astellas"), the Company and Lonza Sales AG ("Lonza") entered into a license agreement (as amended, the "Lonza License Agreement"). Pursuant to the Lonza License Agreement, the Company obtained a worldwide, non-exclusive, sublicensable (subject to Lonza's right of pre-approval with respect to any sublicense of manufacturing activities) license to certain intellectual property rights owned by Lonza. Lonza was the

originator of the master cell bank for verekitug (formerly referred to as ASP7266 and UPB-101, collectively referred to as "the Compound") developed by Astellas.

As consideration for the rights and licenses granted to the Company under the Lonza License Agreement, the Company agreed to pay Lonza certain royalties and annual payments, both payable in Swiss francs, in respect of the manufacturing and sale of the Compound, such amounts to be determined by the party manufacturing the Compound, and range from no annual payment to up to a mid-six-figure annual payment, and a less-than-one percent to a low-single-digit percentage royalty on net sales of the Compound. In accordance with the Lonza License Agreement, the Company entered into a sublicense with Wuxi Biologics (Hong Kong) Limited to manufacture the Compound, requiring the Company to pay a mid-six-figure annual fee to Lonza pursuant to this provision.

Any royalties due under the Lonza License Agreement are payable on a country-by-country basis until ten years from the first commercial sale of the Compound in that particular country.

During the nine months ended September 30, 2024 and 2023, the Company did not make any royalty payments to Lonza under the Lonza License Agreement. The Lonza agreement continues for an indefinite period of time unless otherwise terminated. The Company has the right to terminate the Lonza License Agreement at any time by providing prior written notice to Lonza.

During the nine months ended September 30, 2024 and 2023, the Company made an annual payment in the amount of $0.5 million and $0.4 million, respectively, to Lonza pursuant to the Lonza License Agreement and recognized it as research and development expense in the condensed consolidated statements of operations and comprehensive loss.

15. Revenue

Maruho agreement

In October 2021, in connection with an asset purchase agreement entered into with Astellas, the Company entered into an agreement (as amended, the "Maruho Agreement"), under which it granted Maruho an exclusive, irrevocable, perpetual, royalty-free, sublicensable (subject to its right of first negotiation) license. Pursuant to the Maruho Agreement, the Company maintains its responsibility for and controls the global research and development of the Maruho license product, including in Japan. The Company will conduct specified clinical trial activities for Japan as part of its global research and development plan. Maruho will reimburse the Company for the costs of these research and development activities, including the cost of drug supply. Maruho has the right to terminate the Maruho Agreement at any time by providing 60 days prior written notice to the Company with no substantial penalty.

The Company concluded that Maruho is a customer under the Maruho Agreement, and as such, the Maruho Agreement falls within the scope of ASC 606. The Company identified one performance obligation under the Maruho Agreement related to the performance of research and development services, which are an output of the Company's ordinary activities, in Japan. The Company determined that the transaction price of the Maruho Agreement as of September 30, 2024 consisted solely of variable consideration. The variable consideration was estimated using the expected value method based on the Company's experience and best judgment of the total reimbursable costs expected to be incurred through the period of performance.

The transaction price is being recognized as revenue over time using the cost-to-cost input method, which the Company believes best depicts the transfer of control to the customer. Under the cost-to-cost input method, the extent of progress towards completion is measured based on the ratio of actual costs incurred in Japan to the total estimated costs expected to satisfy the performance obligation. The calculation of the total estimated costs to fulfill the performance obligation includes costs associated with employees, clinical and development, manufacturing, and out-of-pocket costs expected to be paid to third parties. The estimate of the Company's measure of progress and estimate of variable consideration to be included in the transaction price will be updated at each reporting period as a change in estimate. The Company excludes disclosures related to the aggregate amount of the transaction price allocated to the performance obligation that are unsatisfied as of the end of the reporting period because the contract has an initial expected term of one year or less. The Company currently expects to continue providing research and development services to Maruho under the Maruho Agreement through the completion of its Phase 2 clinical trials, and if successful, through any Phase 3 clinical trials.

During the nine months ended September 30, 2023, the Company received a prepayment of $2.4 million from Maruho for research and development services to be provided by the Company under the Maruho Agreement. During the nine months ended September 30, 2023, the Company recognized $1.8 million of related revenue from the prepayments, resulting in $0.6 million in deferred revenue as of September 30, 2023. There was no deferred revenue as of December 31, 2022. The Company did not receive any prepayments or recognize any deferred revenue during the nine months ended September 30, 2024.

16. Related parties

In October 2021, the Company entered into the Maruho Agreement (Note 15). Maruho is considered to be a related party because it is one of the co-founders of the Company and has representation on the Company's board of directors. During the nine months ended September 30, 2024 and 2023, the Company received payments of $1.2 million and $2.7 million, respectively, in cost reimbursements from Maruho. The Company recorded related party collaboration revenue of $0.6 million during each of the three months ended September 30, 2024 and 2023. The Company recorded related party collaboration revenue of $1.8 million and $1.9 million during the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024 and 2023, there was $0.6 million and $0.3 million in related party accounts receivable, respectively, representing amounts due for qualifying reimbursable expenses related to the Maruho Agreement.

In February 2023, the Company issued 1,000,000 shares of Series A Preferred Stock to Maruho for gross proceeds of $10.0 million.

17. Subsequent events

Stock split

On October 4, 2024, the Company effected a 1.049-for-one stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios of each series of the Company's preferred stock (see Note 8). Accordingly, all share and per share amounts for all periods presented in the accompanying condensed consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this stock split and adjustment of the preferred stock conversion ratios.

In connection with the stock split, the Company's board of directors adopted, and its stockholders approved, the third amended and restated certificate of incorporation, which, among other things, increased the number of shares of common stock authorized for issuance to 500,000,000 shares of common stock.

Written consent for the conversion of preferred stock

On October 4, 2024, the Company obtained written consent from the Requisite Holders (as defined in the Company's second amended and restated certificate of incorporation) for the conversion of the preferred stock into common stock in connection with the Company's IPO (see Note 8). Upon the closing of the IPO, 31,764,693 shares of outstanding convertible preferred stock were automatically converted into 33,321,149 shares of common stock, after the effect of the 1.049-for-one stock split, with the related carrying value of $380.9 million reclassified to common stock and additional paid-in capital.

Initial public offering

In October 2024, the Company completed its IPO of its common stock. In connection with its IPO, the Company issued and sold 17,250,000 shares of its common stock, including 2,250,000 shares pursuant to the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $17.00 per share. As a result of the IPO, the Company received approximately $268.7 million in net proceeds, after deducting $20.5 million in underwriting discounts and commissions, and approximately $4.0 million in other offering costs.

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

The following discussion and analysis of our financial condition and results of operations should be read, considered and evaluated together with our audited consolidated financial statements as of and for the years ended December 31, 2023 and 2022 and the related notes included in our initial public offering final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the Securities and Exchange Commission ("SEC") on October 11, 2024 and our unaudited condensed consolidated financial statements as of September 30, 2024 and for the three and nine months ended September 30, 2024 and 2023 and the related notes included elsewhere in this Quarterly Report on Form 10-Q ("Quarterly Report"). This discussion and analysis as well as other parts of this Quarterly Report contain forward-looking statements that involve risks and uncertainties, including but not limited to, information with respect to our plans and strategy for our business. As a result of many factors, including those factors set forth in the section titled "Risk factors," our actual results could differ materially from the results described in or implied by the forward-looking statements. You should carefully read, consider and evaluate the section titled "Risk factors" to gain an understanding of the factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section titled "Special note regarding forward-looking statements" included elsewhere in this Quarterly Report. Our historical results are not necessarily indicative of the results that may be expected for any period in the future. For convenience of presentation, some of the numbers have been rounded in the text below.

Overview

We are a clinical-stage biotechnology company developing treatments for inflammatory diseases, with an initial focus on severe respiratory disorders. We are developing verekitug, the only known antagonist currently in clinical development that targets the receptor for Thymic Stromal Lymphopoietin ("TSLP"), a cytokine which is a clinically validated driver of inflammatory response positioned upstream of multiple signaling cascades that affect a variety of immune mediated diseases. Preclinical and clinical data to date demonstrate verekitug's highly potent inhibition of the TSLP receptor, which we believe will translate to a differentiated product profile, including improved clinical outcomes, substantially extended dosing intervals and the potential to treat a broad spectrum of patients. We have advanced this highly potent monoclonal antibody into separate Phase 2 trials for the treatment of severe asthma and chronic rhinosinusitis with nasal polyps ("CRSwNP") and plan to initiate development in chronic obstructive pulmonary disease ("COPD"). Our experienced team is committed to maximizing verekitug's unique attributes to address the substantial unmet needs for patients underserved by today's standard of care.

Through September 30, 2024, we have historically financed our operations principally through the issuance and sale of our Series A redeemable convertible preferred stock ("Series A Preferred Stock") and Series B redeemable convertible preferred stock ("Series B Preferred Stock"), which are collectively referred to as the "Preferred Stock." As of September 30, 2024, we have received total gross proceeds of $400.0 million from the issuance and sale of our Preferred Stock and we have also received cash of $4.7 million in connection with research and development services we provided to Maruho Co., Ltd ("Maruho"), a related party.

We have incurred significant net operating losses and negative cash flows since our inception. Since our inception, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, establishing licensing, building our proprietary platform technologies, developing verekitug, establishing our intellectual property portfolio, conducting research, preclinical studies, and clinical trials, establishing arrangements with third parties for the manufacture of verekitug and related raw materials, and providing general and administrative support for these operations. Our ability to generate product revenue sufficient to achieve profitability, if ever, will depend on the successful development, regulatory approval and eventual commercialization of verekitug and any other potential future product candidates, which we expect will take a number of years. For the three months ended September 30, 2024 and 2023, we reported net losses of $16.0 million and $3.1 million, respectively, and for the nine months ended September 30, 2024 and 2023, we reported net losses of $41.6 million and $8.7 million, respectively. Our net losses have resulted principally from costs incurred in our research and development activities. As of September 30, 2024, we had an accumulated deficit of $169.5 million, and we had cash, cash equivalents and short-term investments of $220.7 million. In October 2024, we completed our initial public offering ("IPO") in which we issued and sold 17,250,000 shares of our common stock, including 2,250,000 shares pursuant to the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $17.00 per share. As a result of the IPO, we received approximately $268.7 million in net proceeds, after deducting $20.5 million in underwriting discounts and commissions, and approximately $4.0 million in other offering costs. Based on our current operating plan, we believe that our existing cash and cash equivalents and short-term investments, including the net proceeds received in connection with our IPO, will be sufficient to fund our operating expenses and capital expenditure requirements through 2027.

We expect to continue to incur significant net operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if, and as we:

- continue to conduct our ongoing clinical trials of verekitug, including advancement into global Phase 2 clinical trials, as well as initiate and complete additional clinical trials of verekitug in new indications or patient populations;

- conduct larger-scale clinical trials for verekitug or any potential future product candidates;
- manufacture, or have manufactured, clinical and commercial supplies of verekitug;
- seek regulatory approvals, prepare for and, if approved, proceed to commercialization for verekitug in current or new indications or any potential future product candidates;
- attract, hire and retain additional clinical, scientific, and management personnel;
- implement operational, financial, and management information systems;
- add quality control, quality assurance, legal, compliance, and other groups to support our operations;
- obtain, maintain, protect, expand and enforce our intellectual property portfolio, including intellectual property obtained through license agreements;
- defend against any claims by third parties that we have infringed, misappropriated or otherwise violated any intellectual property of any such third party;
- make royalty, milestone or other payments under current, and any future, license or collaboration agreements;
- establish a sales, marketing and distribution infrastructure, either ourselves or in partnership with others, to commercialize verekitug, if approved;
- potentially experience any delays, challenges, or other issues associated with the clinical development of verekitug and any potential future product candidates, including with respect to our regulatory strategies; and
- incur additional legal, accounting, investor relations and other general and administrative expenses associated with operating as a public company.

Our net operating losses may fluctuate significantly from period to period, depending upon the timing of our expenditures on research and development activities. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our accounts payable and accrued expenses and other current liabilities.

As a result, we will need additional financing to support our continuing operations. To date, we have funded our operations primarily with the proceeds from our IPO and the sale of our Preferred Stock. We do not have any products approved for sale and have not generated any revenue from product sales since our inception. We do not expect to generate revenue from any product candidates that we develop until we obtain regulatory approval for one or more of such product candidates and commercialize our products or enter into collaboration arrangements with third parties. Until we can generate sufficient product revenue to finance our cash requirements, if ever, we expect to fund our operations through equity offerings or debt financings, credit or loan facilities, potentially other capital resources, or a combination of one or more of these funding sources. We may be unable to raise additional funds or enter into other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back, or discontinue the development or commercialization of verekitug and one or more potential future product candidates, which could have a material adverse effect on our business, results of operations or financial condition.

Because of the numerous risks and uncertainties associated with research and development of product candidates, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenue from product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

Asset purchase and license agreements

Below is a summary of the key terms for certain of our asset purchase and license agreements. For a more detailed description of these agreements, see the section titled “Business—Asset purchase and license agreements” included in our IPO final prospectus filed on October 11, 2024.

Asset purchase agreement with Astellas and related letter agreement with Astellas and Regeneron

In October 2021, we entered into an asset purchase agreement (the “Astellas Asset Purchase Agreement”) with Astellas Pharma, Inc. (“Astellas”). Pursuant to the Astellas Asset Purchase Agreement, we purchased from Astellas the compound designated by Astellas as

ASP7266 (the "Compound," which was subsequently renamed by us as verekitug). There are no future payments owed to Astellas under the Astellas Asset Purchase Agreement.

In connection with the Astellas Asset Purchase Agreement, we concurrently entered into a letter agreement (the "Regeneron Letter Agreement") with Astellas and Regeneron Pharmaceuticals, Inc. ("Regeneron").

The Regeneron Letter Agreement relates to a prior Non-Exclusive License and Material Transfer Agreement (the "Terminated Regeneron License Agreement") that Regeneron and Astellas entered into in March 2007, as amended in July 2010 and subsequently terminated in June 2018, subject to certain surviving rights and obligations of both Regeneron and Astellas. Under the Terminated Regeneron License Agreement, Astellas utilized Regeneron's human antibody technology in its internal research programs to discover certain product candidates, including the Compound, which it sold to us under the Astellas Asset Purchase Agreement.

Under the Regeneron Letter Agreement, Astellas assigned and transferred to us and we assumed and accepted certain of Astellas' surviving rights and obligations under the Terminated Regeneron License Agreement, including Astellas' royalty payment, reporting and indemnification obligations in connection with activities conducted by us or on our behalf with respect to the Compound. By assuming and accepting Astellas' surviving obligations under the Terminated Regeneron License Agreement, we are required to pay Regeneron mid-single-digit percentage royalties on aggregate worldwide net sales of any product developed by or on behalf of us that contains the Compound as an ingredient or component of the materials sold (a "Royalty Product") during the royalty term. The royalties are determined on a product-by-product and country-by-country basis and expire on the later of (i) a specified number of years after the launch of a given Royalty Product in a given country and (ii) the expiration of the last valid claim of royalty bearing company patent rights claiming or covering such Royalty Product in such country. To date, we have not made any royalty payments to Regeneron under the Regeneron Letter Agreement.

Exclusive license agreement with Maruho

In October 2021, we entered into a license agreement with Maruho (as amended, the "Maruho License Agreement"), under which we granted Maruho an exclusive, irrevocable, perpetual, royalty-free, sublicensable (subject to our right of first negotiation) license. Under the Maruho License Agreement, Maruho is responsible for and controls, at its sole expense, (i) the preparation, filing, prosecution, obtaining and maintaining all regulatory approvals in Japan and (ii) the promotion, marketing, sale and commercialization in Japan.

Pursuant to the Maruho License Agreement, we maintain our responsibility for and control the global research and development of the Maruho license product, including in Japan. We will conduct specified clinical trial activities for Japan as part of our global research and development plan. Maruho will reimburse us for the costs of these research and development activities, including the cost of drug supply. Apart from reimbursement of qualifying research and development expenses, Maruho is not obligated to make any future payments under the Maruho License Agreement.

During the year ended December 31, 2023, we received payments from Maruho in the amount of $2.7 million which was received during the nine months ended September 30, 2023. During the year ended December 31, 2022, we received payments from Maruho in the amount of $0.8 million. During the nine months ended September 30, 2024, we received payments from Maruho in the amount of $1.2 million.

License agreement with Lonza

In October 2021, in connection with the Astellas Asset Purchase Agreement, we entered into a license agreement with Lonza Sales AG ("Lonza") (as amended, the "Lonza License Agreement"). Pursuant to the Lonza License Agreement, we obtained a worldwide, non-exclusive, sublicensable (subject to Lonza's right of pre-approval with respect to any sublicense of manufacturing activities) license to certain intellectual property rights owned by Lonza. Lonza was the originator of the master cell bank for the Compound developed by Astellas. As consideration for the rights and licenses granted to us under the Lonza License Agreement, we agreed to pay Lonza certain royalties and annual payments, both payable in Swiss francs, in respect of the manufacturing and sale of the Compound, such amounts to be determined by the party manufacturing the Compound, and range from no annual payment to up to a mid-six figure annual payment, and a less-than-one percent to a low-single-digit percentage royalty on net sales of the Compound. In accordance with the Lonza License Agreement, we entered into a sublicense with Wuxi Biologics (Hong Kong) Limited to manufacture the Compound, requiring us to pay a mid-six-figure annual fee to Lonza pursuant to this provision. Any royalties due under the Lonza License Agreement are payable on a country-by-country basis until ten years from the first commercial sale of the Compound in that particular country. The Lonza agreement continues for an indefinite period of time unless otherwise terminated. We have the right to terminate the Lonza License Agreement at any time by providing prior written notice to Lonza. During the year ended December 31, 2023, we made an annual payment to Lonza in the amount of $0.4 million, which was paid during the nine months ended June 30, 2023. During the year ended December 31, 2022, we made an annual payment to Lonza in the amount of $0.4

million. During the nine months ended September 30, 2024, we made an annual payment to Lonza in the amount of $0.5 million. These payments are recognized as research and development expense in the consolidated statements of operations and comprehensive loss. To date, we have not made any royalty payments to Lonza under the Lonza License Agreement.

Components of our results of operations

Collaboration revenue—related party

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from product sales in the foreseeable future. All of our collaboration revenue has been derived from the Maruho License Agreement. If our development efforts for verekitug or any potential future product candidates are successful and result in regulatory approval, or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from product sales, royalties or payments from such collaboration or license agreements, or a combination of product sales and payments from such agreements.

Operating expenses

Research and development expenses

Research and development expenses consist primarily of costs incurred for our preclinical research and clinical development of verekitug, which include:

- expenses incurred under agreements with third parties, including contract research organizations ("CROs"), contract manufacturing organizations ("CMOs"), and investigative sites that conduct clinical trials on our behalf, and costs related to the Maruho License Agreement;
- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions and costs related to the Maruho License Agreement;
- costs of outside consultants, including their fees and related travel expenses; and
- costs associated with license agreements to support the development of our technology.

We expense all research and development expenses in the periods in which they are incurred. Our direct research and development expenses are tracked on an indication-by-indication basis and consist of costs that include CROs and investigative sites that conduct clinical trials on our behalf, third party vendors that conduct research and preclinical studies on our behalf and outside consulting costs directly allocable to an indication. We do not allocate costs related to CMOs that manufacture verekitug for use in our preclinical studies and clinical trials as they are not distinguishable by indication but support all current and potential indications under our verekitug program. Additionally, we do not allocate costs for employee costs, including stock-based compensation, consulting, or other indirect costs that cannot be directly allocated to a specific indication.

We expect that our research and development expenses will increase in the future as we advance verekitug through clinical trials and any potential future product candidates that we may develop through preclinical studies and clinical trials, in pursuit of regulatory approval. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials.

At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of verekitug and any potential future product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales or licensing of verekitug or any potential future product candidates. This is due to the numerous risks and uncertainties associated with drug development, including the uncertainty of:

- the scope, timing, progress, costs and results of the ongoing development of verekitug as well as for potential discovery, preclinical development and clinical trials for other potential future product candidates;
- the number of clinical trials required for regulatory approval of verekitug or our potential future product candidates;
- the costs, timing and outcome of regulatory review of verekitug or our potential future product candidates;
- the costs associated with acquiring or licensing additional product candidates, technologies or assets, including the timing and amount of any milestones, royalties or other payments due in connection with our acquisitions and licenses;
- the cost of manufacturing clinical supplies of verekitug or our potential future product candidates;
- the costs associated with hiring additional clinical, quality control, medical, scientific and other technical personnel to support the ongoing development of verekitug;

- the costs associated with increasing our headcount as we expand our research and development organization and market development and pre-commercial planning activities;
- the effectiveness of our approach to identifying target patient populations;
- our ability to maintain existing, and establish new, strategic collaborations or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement prior to regulatory approval;
- the effect of macroeconomic trends including inflation and rising interest rates; and
- addressing any potential supply chain interruptions or delays.

A change in the outcome of any of these factors or underlying variables with respect to the development of a product candidate could significantly change the costs and timing associated with the development of that product candidate.

General and administrative expenses

General and administrative expenses consist primarily of salaries and benefits, including stock-based compensation expense, for personnel in executive, finance, accounting, legal, human resources, business development, information technology, and other administrative functions. General and administrative expenses also include legal fees relating to patents and corporate matters; professional fees for accounting, auditing, tax, and consulting services; insurance costs; travel expenses; and facility-related expenses, which include depreciation costs and expenses for rent and maintenance of facilities and other operating costs.

We expect that our general and administrative expenses will increase in the future as we increase our headcount and expand our infrastructure to support the continued research and development of our programs and the growth of our business. We also expect to incur increased expenses associated with operating as a public company, including costs of accounting, audit, legal, regulatory, tax-related services, compliance with SEC rules and regulations and listing requirements, director and officer insurance premiums and investor relations costs.

Other income (expense)

Change in fair value of preferred stock tranche right liability

In connection with our Preferred Stock financings, we issued shares under stock purchase agreements that provided an obligation for us to issue additional Preferred Stock in subsequent closings upon the satisfaction of certain conditions. The Series A and Series B tranche right liabilities were settled in February 2023 and April 2024, respectively, upon the satisfaction of relevant conditions. We classified the preferred stock tranche rights as liabilities on our consolidated balance sheets and initially recorded them at fair value upon the issuance date of the rights. We remeasured the tranche right liabilities to fair value at each reporting date and immediately prior to being settled, and recognized changes in the fair value of the preferred stock tranche right liability as a component of other income (expense) in our consolidated statements of operations and comprehensive loss. Upon settlement of the tranche rights, we derecognized the related liability, and stopped recognizing changes in the fair value of the preferred stock tranche right liability.

Interest income

Interest income consists of interest earned on money market funds, U.S. treasury bills and U.S. government agency bond investments.

Other income (expense), net

Other income (expense), net consists of miscellaneous income and expense unrelated to our core operations.

Income taxes

We recorded a full valuation allowance of our deferred tax asset position as of September 30, 2024 and December 31, 2023 and 2022 as we believe it was more likely than not that we would not be able to utilize our deferred tax assets.

As of December 31, 2023, we had federal and state net operating losses (“NOLs”) carryforwards of $25.0 million and $27.6 million, respectively. The federal NOLs are not subject to expiration and are limited in utilization to 80% of taxable income and the state NOLs begin to expire in 2041. As of December 31, 2023, we had federal and state research and development credits of $0.8 million which will begin to expire in 2043 and 2037, respectively.

Results of operations

Comparison of the three months ended September 30, 2024 and 2023

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

	Three Months Ended September 30,		
	2024	2023	Change
		(in thousands)	
Collaboration revenue - related party	$ 607	$ 621	$ (14)
Operating expenses:			
Research and development	15,433	7,788	7,645
General and administrative	4,067	2,219	1,848
Total operating expenses	19,500	10,007	9,493
Loss from operations	(18,893)	(9,386)	(9,507)
Other income (expense):			
Change in fair value of preferred stock tranche right liabilities	—	4,773	(4,773)
Interest income	2,904	1,527	1,377
Other expense, net	(3)	(16)	13
Total other income, net	2,901	6,284	(3,383)
Net loss	$ (15,992)	$ (3,102)	$ (12,890)

Collaboration revenue—related party

Related party collaboration revenue was $0.6 million for the three months ended September 30, 2024 compared to $0.6 million for the three months ended September 30, 2023. Revenue during the three months ended September 30, 2024 was primarily related to the work performed associated with our Phase 2 clinical trial in patients with severe asthma and the revenue during the three months ended September 30, 2023 was related to the work performed associated with our Phase 1 and Phase 2 clinical trials in patients with severe asthma under the Maruho License Agreement.

Research and development expenses

	Three Months Ended September 30,		
	2024	2023	Change
		(in thousands)	
Direct research and development expenses by program:			
Verekitug program:			
Asthma indication	$ 7,073	$ 3,866	$ 3,207
CRSwNP indication	2,365	981	1,384
COPD indication	80	—	80
Unallocated research and development expense:			
Personnel expenses (including stock-based compensation)	2,503	2,003	500
Manufacturing costs	2,179	269	1,910
Professional fees	418	238	180
Other unallocated expenses	815	431	384
Total research and development expense	$ 15,433	$ 7,788	$ 7,645

Research and development expenses were $15.4 million for the three months ended September 30, 2024 compared to $7.8 million for the three months ended September 30, 2023. The increase of $7.6 million was primarily driven by an increase of $4.6 million in expenses directly related to our verekitug program and $3.0 million of unallocated research and development expenses.

The increase in direct costs of $3.2 million and $1.4 million related to the asthma indication and CRSwNP indication, respectively, were primarily due to continued progress associated with our Phase 2 clinical trials during the three months ended September 30, 2024 compared to the same period in 2023.

The increase in personnel expenses of $0.5 million was primarily due to increased headcount in our research and development function. Personnel expenses for each of the three months ended September 30, 2024 and 2023 included stock-based compensation expense of $0.3 million. The increase in manufacturing costs of $1.9 million was primarily attributable to an increase in CMO costs for the development of Phase 3 clinical trial material during the three months ended September 30, 2024 for which there was no

comparable expense during the same period in 2023. The increase of $0.2 million in professional fees was related to preclinical consulting services to support our verekitug program. The increase in other unallocated expenses of $0.4 million was primarily driven by an increase in preclinical studies to support our verekitug clinical trials.

General and administrative expenses

	Three Months Ended September 30,		
	2024	2023	Change
		(in thousands)	
Personnel expenses (including stock-based compensation)	$ 2,839	$ 1,367	$ 1,472
Professional fees	880	637	243
Other	348	215	133
Total general and administrative expense	$ 4,067	$ 2,219	$ 1,848

General and administrative expenses were $4.1 million for the three months ended September 30, 2024 compared to $2.2 million for the three months ended September 30, 2023. The increase of $1.8 million was primarily driven by an increase in personnel expenses of $1.5 million due to increased headcount in our general and administrative functions. Personnel expenses for the three months ended September 30, 2024 and 2023 included stock-based compensation expense of $1.6 million and $0.4 million, respectively. Additionally, there was an increase of $0.2 million of professional fees including increased consulting and audit fees. Other expenses increased by $0.1 million primarily due to an increase in software licenses.

Other income (expense)

Change in fair value of preferred stock tranche right liabilities

We recorded other income for the change in the fair value of the preferred stock tranche right liabilities of $4.8 million for the three months ended September 30, 2023 related to the Series B preferred stock tranche right liability, for which there was no comparable income during the three months ended September 30, 2024 as the Series B was settled in April 2024. The change in fair value of the Series B preferred stock tranche right liability was due to changes in the assumptions used in the valuation model during the period, including the estimated fair value of the Series B Preferred Stock, volatility and estimated time to the tranche closing.

Interest income

Interest income was $2.9 million and $1.5 million for the three months ended September 30, 2024 and 2023, respectively, representing an increase of $1.4 million. The increase in interest income was due to increased balances in our money market funds, U.S. treasury bills and U.S. government agency bonds held during the three months ended September 30, 2024, as compared to the three months ended September 30, 2023.

Comparison of the nine months ended September 30, 2024 and 2023

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

	Nine Months Ended September 30,		
	2024	2023	Change
		(in thousands)	
Collaboration revenue - related party	$ 1,757	$ 1,930	$ (173)
Operating expenses:			
Research and development	41,193	20,245	20,948
General and administrative	12,010	7,469	4,541
Total operating expenses	53,203	27,714	25,489
Loss from operations	(51,446)	(25,784)	(25,662)
Other income (expense):			
Change in fair value of preferred stock tranche right liabilities	2,859	14,542	(11,683)
Interest income	7,047	2,646	4,401
Other expense, net	(24)	(108)	84
Total other income, net	9,882	17,080	(7,198)
Net loss	$ (41,564)	$ (8,704)	$ (32,860)

Collaboration revenue—related party

Related party collaboration revenue was $1.8 million for the nine months ended September 30, 2024 compared to $1.9 million for the nine months ended September 30, 2023. Revenue during the nine months ended September 30, 2024 was primarily related to the work performed associated with our Phase 2 clinical trial in patients with severe asthma and the revenue during the nine months ended September 30, 2023 was primarily related to the work performed associated with our Phase 1 clinical trial in patients with severe asthma under the Maruho License Agreement.

Research and development expenses

	Nine Months Ended September 30,		
	2024	2023	Change
		(in thousands)	
Direct research and development expenses by program:			
Verekitug program:			
Asthma indication	$ 20,175	$ 8,369	$ 11,806
CRSwNP indication	6,000	1,268	4,732
COPD indication	82	—	82
Unallocated research and development expense:			
Personnel expenses (including stock-based compensation)	7,343	5,467	1,876
Manufacturing costs	3,820	3,060	760
Professional fees	1,438	977	461
Other unallocated expenses	2,335	1,104	1,231
Total research and development expense	$ 41,193	$ 20,245	$ 20,948

Research and development expenses were $41.2 million for the nine months ended September 30, 2024 compared to $20.2 million for the nine months ended September 30, 2023. The increase of $21.0 million was primarily driven by an increase of $16.6 million in expenses directly related to our verekitug program and $4.3 million of unallocated research and development expenses.

The increase in direct costs of $11.8 million and $4.7 million related to the asthma indication and CRSwNP indication, respectively, were primarily due to continued progress associated with our Phase 2 clinical trials during the nine months ended September 30, 2024 compared to the same period in 2023.

The increase in personnel expenses of $1.9 million was primarily due to increased headcount in our research and development function. Personnel expenses for each of the nine months ended September 30, 2024 and 2023 included stock-based compensation expense of $0.8 million. The increase of $0.5 million in professional fees was related to manufacturing, regulatory and quality services to support our verekitug program. The increase in other unallocated expenses of $1.2 million was primarily driven by an increase in preclinical studies to support our verekitug clinical trials. The increase in manufacturing costs of $0.8 million was attributable to an increase of $2.7 million in CMO costs for the development of Phase 3 clinical material during the nine months ended September 30, 2024 for which there was no comparable expense during the same period in 2023, offset by a decrease of $1.9 million in CMO costs for the development of Phase 2 clinical trial material during the nine months ended September 30, 2024 compared to the same period in 2023.

We begin to separately track program expenses at development candidate nomination. Through September 30, 2024, we have incurred approximately $44.9 million, $9.4 million and $0.1 million in direct external expenses for the development of verekitug for severe asthma, CRSwNP and COPD, respectively, since their development candidate nominations.

General and administrative expenses

	Nine Months Ended September 30,		
	2024	2023	Change
		(in thousands)	
Personnel expenses (including stock-based compensation)	$ 7,529	$ 4,670	$ 2,859
Professional fees	3,340	2,091	1,249
Other	1,141	708	433
Total general and administrative expense	$ 12,010	$ 7,469	$ 4,541

General and administrative expenses were $12.0 million for the nine months ended September 30, 2024 compared to $7.5 million for the nine months ended September 30, 2023. The increase of $4.5 million was primarily driven by an increase in personnel expenses of $2.9 million due to increased headcount in our general and administrative functions. Personnel expenses for the nine months ended September 30, 2024 and 2023 included stock-based compensation expense of $3.1 million and $1.8 million, respectively. Additionally, there was an increase of $1.2 million of professional fees including increased consulting and audit fees. Other expenses increased by $0.4 million primarily due to an increase in software licenses and franchise taxes.

Other income (expense)

Change in fair value of preferred stock tranche right liabilities

We recorded other income for the change in the fair value of the preferred stock tranche right liabilities of $2.9 million for the nine months ended September 30, 2024, related to the Series B preferred stock tranche right liability, as compared to other income of $14.5 million for the nine months ended September 30, 2023, including $6.6 million related to the Series A preferred stock tranche right liability and $7.9 million related to the Series B preferred stock tranche right liability. The change in the fair value of the Series A preferred stock tranche right liability was due to changes in the assumptions used in the valuation model during the periods, including the expected fair value of the Series A Preferred Stock and the probability and expected timing of achieving certain milestone events. The change in fair value of the Series B preferred stock tranche right liability was due to changes in the assumptions used in the valuation model during the periods, including the estimated fair value of the Series B Preferred Stock, volatility and estimated time to the tranche closing. The Series A and Series B tranche right liabilities were settled in February 2023 and April 2024, respectively, upon the satisfaction of relevant conditions.

Interest income

Interest income was $7.0 million and $2.6 million for the nine months ended September 30, 2024 and 2023, respectively, representing an increase of $4.4 million. The increase in interest income was due to increased balances in our money market funds, U.S. treasury bills and U.S. government agency bonds held during the nine months ended September 30, 2024, as compared to the nine months ended September 30, 2023.

Liquidity and capital resources

Since our inception, we have incurred significant operating losses. We have not yet commercialized verekitug and we do not expect to generate revenue from product sales of verekitug for the next several years, if at all. To date, we have funded our operations primarily with proceeds from our IPO and the sale of our Preferred Stock. Through September 30, 2024, we have received gross proceeds of $400.0 million from sales of our Preferred Stock and received $4.7 million in connection with our research and development arrangement with Maruho. As of September 30, 2024, we had cash, cash equivalents and short-term investments of $220.7 million. In October 2024, we completed our IPO and as a result, we received approximately $268.7 million in net proceeds.

Cash flows

The following table summarizes our sources and uses of cash for each of the periods presented:

	Nine Months Ended September 30,	
	2024	2023
	(in thousands)	
Net cash used in operating activities	$ (39,560)	$ (21,816)
Net cash used in investing activities	(101,393)	(77,600)
Net cash provided by financing activities	148,262	129,683
Net increase in cash, cash equivalents and restricted cash	$ 7,309	$ 30,267

Operating activities

During the nine months ended September 30, 2024, operating activities used $39.6 million of cash, resulting primarily from our net loss of $41.6 million, non-cash changes in fair value of the preferred stock tranche right liability of $2.9 million, and non-cash amortization of premiums and accretion of discounts on short-term investments of $2.3 million, partially offset by changes in operating assets and liabilities of $3.2 million and non-cash stock-based compensation expense of $3.9 million. Net cash provided by changes in operating assets and liabilities was primarily driven by a $2.9 million increase in accounts payable and a $1.1 million decrease in prepaid expenses and other current assets, partially offset by a $0.2 million decrease in accrued expenses and other current liabilities and a $0.5 million increase in related party accounts receivable. The increase in related party accounts receivable resulted

primarily from the timing of revenue recognition compared to the timing of payments from Maruho for qualifying reimbursable expenses related to the Maruho License Agreement.

During the nine months ended September 30, 2023, operating activities used $21.8 million of cash, resulting primarily from our net loss of $8.7 million, non-cash changes in fair value of the preferred stock tranche right liability of $14.5 million, non-cash amortization of premiums and accretion of discounts on short-term investments of $1.0 million and changes in operating assets and liabilities of $0.3 million, partially offset by non-cash stock-based compensation expense of $2.6 million. Net cash used in changes in operating assets and liabilities was driven by a $0.3 million increase in prepaid expenses and other current assets and a $0.2 million decrease in accrued expenses and other current liabilities, partially offset by a $0.6 million increase in related party deferred revenue and a $0.1 million decrease in related party accounts receivable. The increase in related party deferred revenue and decrease in related party accounts receivable resulted primarily from the timing of revenue recognition compared to the timing of payments from Maruho for qualifying reimbursable expenses related to the Maruho License Agreement.

For all periods presented, changes in prepaid expenses and other assets, accounts payable and accrued expenses and other current liabilities not described above were generally due to the growth in our business, the advancement of our clinical programs, and the timing of vendor invoicing and payments.

Investing activities

During the nine months ended September 30, 2024, net cash used in investing activities was $101.4 million, consisting primarily of purchases of short-term investments of $248.4 million, net of maturities of short-term investments of $147.3 million and purchases of property and equipment of $0.3 million.

During the nine months ended September 30, 2023, net cash used in investing activities was $77.6 million, consisting primarily of purchases of short-term investments of $94.2 million, net of maturities of short-term investments of $16.7 million and purchases of property and equipment of $0.1 million.

Financing activities

During the nine months ended September 30, 2024, net cash provided by financing activities was $148.3 million, consisting of $149.9 million in net proceeds from the issuance of Series B Preferred Stock and $0.1 million in net proceeds from the exercise of stock options, partially offset by $1.8 million in payments of deferred offering costs.

During the nine months ended September 30, 2023, net cash provided by financing activities was $129.7 million, consisting of $80.0 million in proceeds from the issuance of Series A Preferred Stock and $49.6 million in net proceeds from the issuance of Series B Preferred Stock, including the Series B preferred stock tranche right liability and $0.1 million in net proceeds from the exercise of stock options.

Funding requirements

We expect our research and development and general and administrative expenses and our operating losses will increase in the future as we advance verekitug through clinical trials and any potential future product candidates that we may develop through preclinical studies and clinical trials, in pursuit of regulatory approval. Due to the numerous risks and uncertainties associated with research, development and commercialization of product candidates, changes in the outcome of any factors with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. In addition, we expect to incur increased expenses associated with operating as a public company.

Our business plans may change in the future and we will continue to require additional capital to meet the needs of our operating expenses. See the section titled “Risk factors—Risks related to our limited operating history, financial condition and need for additional capital” included elsewhere in this Quarterly Report.

We believe our existing cash and cash equivalents and short-term investments, including the net proceeds received in connection with our IPO, will be sufficient to fund our operating expenses and capital expenditure requirements through 2027. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. 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 of these securities may include liquidation or other preferences that adversely affect your rights as a common

stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, 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 or other arrangements when needed, we would be required to delay, scale back or discontinue our research, product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual obligations and other commitments

Asset acquisition from Astellas and related letter agreement with Astellas and Regeneron

In October 2021, we entered into the Astellas Asset Purchase Agreement with Astellas, and concurrently entered into the Regeneron Letter Agreement with Astellas and Regeneron.

Under the Regeneron Letter Agreement, Astellas assigned and transferred to us and we assumed and accepted certain of Astellas' surviving rights and obligations under the Terminated Regeneron License Agreement. By assuming and accepting Astellas' surviving obligations under the Terminated Regeneron License Agreement, we are required to pay Regeneron mid-single-digit percentage royalties on aggregate worldwide net sales of a Royalty Product during the royalty term.

The royalties are determined on a product-by-product and country-by-country basis and expire on the later of (i) a specified number of years after the launch of a given Royalty Product in a given country and (ii) the expiration of the last valid claim of royalty bearing company patent rights claiming or covering such Royalty Product in such country.

To date, we have not made any royalty payments to Regeneron under the Regeneron Letter Agreement.

License agreement with Lonza

As consideration for the rights and licenses granted to us under the Lonza License Agreement, we agreed to pay Lonza certain royalties and annual payments, both payable in Swiss francs, in respect of the manufacturing and sale of the Compound, such amounts to be determined by the party manufacturing the Compound, and range from no annual payment to up to a mid-six figure annual payment, and a less-than-one percent to a low-single-digit percentage royalty on net sales of the Compound. In accordance with the Lonza License Agreement, we entered into a sublicense with Wuxi Biologics (Hong Kong) Limited to manufacture the Compound, requiring us to pay a mid-six-figure annual fee to Lonza pursuant to this provision.

Any royalties due under the Lonza License Agreement are payable on a country-by-country basis until ten years from the first commercial sale of the Compound in that particular country.

During the year ended December 31, 2023, we made an annual payment to Lonza in the amount of $0.4 million, which was paid during the nine months ended September 30, 2023. During the year ended December 31, 2022, we made an annual payment to Lonza in the amount of $0.4 million. During the nine months ended September 30, 2024, we made an annual payment to Lonza in the amount of $0.5 million. These payments were recognized as research and development expense in the condensed consolidated statements of operations and comprehensive loss. To date, we have not made any royalty payments to Lonza under the Lonza License Agreement.

Lease agreement

On July 3, 2024, we entered into a three-year agreement for office space located at 890 Winter Street in Waltham, Massachusetts. We began paying monthly rent starting one month after lease commencement.

Initial base rent is approximately $0.7 million for the first year and approximately $0.8 million for the second and third year. The lease commenced in September 2024.

On July 8, 2024, we provided notice of termination of our current operating lease and sublease of office space at 460 Totten Pond Road, Waltham, Massachusetts. This notice became effective on October 9, 2024, after which our rights and obligations under this lease and sublease ceased.

Research and development

We enter into contracts in the normal course of business with CROs and investigator sites that conduct clinical trials on our behalf, CMOs that manufacture product candidates for use in our preclinical studies and clinical trials, and third-party vendors, including CROs, that conduct research and preclinical studies on our behalf. Prepayments under these arrangements can generally be repurposed or the services themselves cancelable upon prior written notice, though cancellation fees are likely. Payments due upon cancellation consist only of payments for services provided and expenses incurred up to the date of cancellation.

Critical accounting estimates and significant judgments

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosures of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses incurred during the reporting periods. We base our estimates on historical experience, known trends and events, and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities recorded revenues and expenses that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Actual results may differ from these estimates.

During the nine months ended September 30, 2024, there were no material changes to our critical accounting policies and significant judgements described under Management's Discussion and Analysis of Critical Accounting Policies and Significant Judgments which are included in our IPO final prospectus dated October 11, 2024.

Recently issued and adopted accounting pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements included in our IPO final prospectus dated October 11, 2024.

Emerging growth company and smaller reporting company status

The Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different effective dates for public and private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until the earlier of the date that we (i) are no longer an emerging growth company or (ii) irrevocably elect to "opt out" of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for non-public companies.

We are also a "smaller reporting company," meaning that the market value of our common stock and non-voting common stock held by non-affiliates is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our common stock and non-voting common stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our common stock and non-voting common stock held by non-affiliates is less than $700.0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

Item 4. Controls and Procedures.

Management's evaluation of disclosure controls and procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in the reports we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating the disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. As required by Rule 13a-15(b) or Rule 15d-15(b) promulgated by the SEC under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer (our Chief Executive Officer) and principal financial officer (our Chief Financial and Operating Officer), of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report. Based on the foregoing, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Quarterly Report at the reasonable assurance level.

Changes in internal control over financial reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 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.

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors.

Our business involves significant risks. Investors should carefully consider the risks and uncertainties described below, as well as the other information in this Quarterly Report on Form 10-Q ("Quarterly Report") and in the other documents that we file with the Securities and Exchange Commission ("SEC"). The risks described below are not the only ones facing us. The following risks, or additional risks and uncertainties not presently known to us or that we currently believe to be immaterial, could materially and adversely affect our business, financial condition, results of operations and growth prospects. In such an event, the trading price of our common stock could decline, and investors could lose all or part of their investment.

This Quarterly Report also contains forward-looking statements and estimates that involve risks and uncertainties not presently known to us or that we currently deem immaterial, which also may impair our business operations. See "Special Note Regarding Forward-Looking Statements" elsewhere in this Quarterly Report for more information. Our actual results could differ materially from those anticipated in our forward-looking statements as a result of specific factors, including the risks and uncertainties described below.

Risks related to our limited operating history, financial condition and need for additional capital

We are a clinical-stage biopharmaceutical company with a limited operating history, which may make it difficult to evaluate our current business and predict our future success and viability. We have incurred significant financial losses since our inception and anticipate that we will continue to incur significant financial losses for the foreseeable future.

We are a clinical-stage biopharmaceutical company with a limited operating history. We were formed in April 2021 and our operations to date have been limited to pre-commercial activities. We have not yet demonstrated an ability to generate revenues, obtain regulatory approvals, manufacture any product on a commercial scale or arrange for a third party to do so on our behalf or conduct sales and marketing activities necessary for successful product commercialization. Our limited operating history as a company makes any assessment of our future success and viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields, and we have not yet demonstrated an ability to successfully overcome such risks and difficulties. If we do not address these risks and difficulties successfully, our business will suffer.

We have no products approved for commercial sale and have not generated any revenue from product sales to date. Verekitug is currently our only product candidate. We will continue to incur significant research and development and other expenses related to our preclinical and clinical development of verekitug and ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' deficit and working capital. Our net losses totaled $20.5 million and $23.9 million for the years ended December 31, 2023 and 2022, respectively, and $41.6 million and $8.7 million for the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, we had an accumulated deficit of $169.5 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, verekitug in multiple indications.

We anticipate that our expenses will increase substantially if, and as, we:

- advance verekitug through clinical development;
- seek regulatory approvals for verekitug in indications for which clinical trials are successful;
- hire additional clinical, quality control, medical, scientific and other technical personnel to support the ongoing development of verekitug;
- experience an increase in headcount as we expand our research and development organization and market development and pre-commercial planning activities;

- undertake any pre-commercial or commercial activities required to establish sales, marketing and distribution capabilities;
- seek to identify, acquire and develop additional product candidates, including through business development efforts to invest in or in-license other technologies or product candidates;
- maintain, expand and protect our intellectual property portfolio;
- make milestone, royalty or other payments due under our license agreements and any potential future in-license or collaboration agreements; and
- make milestone, royalty, interest or other payments due under any potential future financing or other arrangements with third parties.

Biopharmaceutical product development entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, secure market access and reimbursement and become commercially viable, and therefore any investment in us is highly speculative. Accordingly, before making an investment in us, our prospects, factoring in the costs, uncertainties, delays and difficulties frequently encountered by companies in clinical development, especially clinical-stage biopharmaceutical companies such as ours, should be carefully considered. Any predictions about our future success or viability may not be as accurate as they would otherwise be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives.

Additionally, our expenses could increase beyond our expectations if we are required by the U.S. Food and Drug Administration ("FDA"), the European Medicines Agency ("EMA"), the European Commission, or other comparable foreign regulatory authorities to perform clinical trials in addition to those that we currently expect, or if there are any delays in establishing appropriate manufacturing arrangements for or in completing our clinical trials or the development of verekitug.

We will require additional funding in order to finance operations. If we are unable to raise capital when needed, or on acceptable terms, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

Developing biopharmaceutical products, including conducting preclinical studies and clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete. We expect our expenses to continue to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek regulatory and marketing approval for, verekitug in multiple indications. Even if verekitug or our potential future product candidates are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. To date, we have funded our operations principally through private financings and our initial public offering ("IPO"), which closed in October 2024. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the clinical development of verekitug, and commence additional clinical trials.

As of December 31, 2023 and September 30, 2024, we had cash, cash equivalents and short-term investments in the amount of $109.8 million and $220.7 million, respectively. In October 2024, we completed our IPO, in which we issued and sold 17,250,000 shares of our common stock, including 2,250,000 shares pursuant to the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $17.00 per share. As a result of the IPO, we received approximately $268.7 million in net proceeds, after deducting $20.5 million in underwriting discounts and commissions, and approximately $4.0 million in other offering costs. Based upon our current operating plan, we believe that our existing cash, cash equivalents and short-term investments, including the net proceeds received in connection with our IPO, will be sufficient to fund our operating expenses and capital expenditure requirements through 2027. We have based this estimate on assumptions that may prove to be wrong, and we could expend our available capital resources sooner than we expect. We may also raise additional financing on an opportunistic basis in the future. For example, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop verekitug. Our future capital requirements will depend on many factors, including but not limited to:

- the scope, timing, progress, costs and results of the ongoing development of verekitug as well as for potential discovery, preclinical development and clinical trials for other potential future product candidates;
- the number of clinical trials required for regulatory approval of verekitug or our potential future product candidates;
- the costs, timing and outcome of regulatory review of verekitug or our potential future product candidates;
- the costs associated with acquiring or licensing additional product candidates, technologies or assets, including the timing and amount of any milestones, royalties or other payments due in connection with our acquisitions and licenses;

- the cost of manufacturing clinical and commercial supplies of verekitug or our potential future product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- the effectiveness of our approach to identifying target patient populations;
- our ability to maintain existing, and establish new, strategic collaborations or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for verekitug or any other potential future product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of verekitug or any other potential future product candidates for which we receive marketing approval;
- expenses to attract, hire and retain skilled personnel;
- the costs of operating as a public company;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payors;
- the effect of macroeconomic trends including inflation and rising interest rates;
- addressing any potential supply chain interruptions or delays;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in business, products and technologies.

Because of the numerous risks and uncertainties associated with research and development of product candidates, we are unable to predict the timing or amount of our working capital requirements. In addition, if we obtain regulatory approval for verekitug or any other potential future product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution which make it difficult to predict when or if we will be able to achieve or maintain profitability. Furthermore, we have incurred and expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to support our continuing operations. Our ability to raise additional funds will depend on financial, economic, political and market conditions and other factors, over which we may have no or limited control. Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If we fail to obtain necessary capital when needed on acceptable terms, or at all, it could force us to delay, limit, reduce or terminate our product development programs, future commercialization efforts or other operations.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to verekitug or any other potential future product candidates.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations with our existing cash, cash equivalents and short-term investments, any future equity or debt financings and upfront and milestone and royalties payments, if any, received under any future licenses or collaborations. If we raise additional capital through the sale of equity or convertible debt securities, or issue any equity or convertible debt securities in connection with a collaboration agreement or other contractual arrangement, the ownership interests of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders. In addition, the possibility of such issuance may cause the market price of our common stock to decline. Debt financing, if available, may result in increased fixed payment obligations and involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends or acquiring, selling or licensing intellectual property rights or assets, which could adversely impact our ability to conduct our business.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, technologies, future revenue streams or verekitug or any other potential future product candidates or grant licenses on terms that may not be favorable to us. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable. Any of these occurrences may have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Risks related to our business

Verekitug is our only product candidate, and we are dependent on a third party having accurately generated, collected and reported data from certain preclinical studies that were previously conducted for verekitug.

We currently have a single product candidate, verekitug, which is in Phase 2 clinical development for the treatment of severe asthma and chronic rhinosinusitis with nasal polyps ("CRSwNP"), and we also plan to initiate development in chronic obstructive pulmonary disease ("COPD"). Our business presently depends entirely on our ability to successfully develop, obtain regulatory approval for, and commercialize verekitug for one or more of the indications that we are pursuing in a timely manner. This may make an investment in our company riskier than similar companies that have multiple product candidates in active development and may be able to better sustain the delay or failure of a lead product candidate.

In addition, our assumptions about verekitug's development potential are partially based on data generated from preclinical studies conducted by Astellas Pharma, Inc. ("Astellas"), which sold the rights to verekitug to us pursuant to an asset purchase agreement in October 2021. We are dependent on Astellas having conducted its research and development in accordance with the applicable protocols, informed consent, legal and regulatory requirements, and scientific standards; having accurately reported the results of all preclinical studies conducted with respect to verekitug and having correctly collected the data from these studies. If these activities were not compliant, accurate or correct, the clinical development, regulatory approval or commercialization of verekitug will be adversely affected. Furthermore, we may observe materially and adversely different results as we continue to conduct our clinical trials. If we are unable to develop, receive marketing approval for and successfully commercialize verekitug, or if we experience delays as a result of any of the above factors or otherwise, our business would be significantly harmed.

If we are unable to advance verekitug in clinical development for one or more of the indications that we are pursuing, obtain regulatory approval and ultimately commercialize verekitug, or experience significant delays in doing so, our business will be materially harmed.

To date, as an organization, we have not completed the development of any product candidate, and verekitug remains in clinical development. Our future success and ability to generate revenue is dependent on our ability to successfully develop, obtain regulatory approval for and commercialize verekitug or any other potential future product candidates. Verekitug and any other potential future product candidates will require substantial additional investment for clinical development, regulatory review and approval in one or more jurisdictions. If verekitug or any other potential future product candidates encounter safety or efficacy problems, development delays or regulatory issues or other problems, our development plans and business would be materially harmed.

We may not have the financial resources to continue development of verekitug or any other potential future product candidates if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, verekitug or any potential future product candidates, including:

- our inability to demonstrate to the satisfaction of the FDA, EMA, the European Commission, or other comparable foreign regulatory authorities that verekitug is, or any other potential future product candidates are, safe and effective;
- insufficiency of our financial and other resources to complete the necessary clinical trials and preclinical studies;
- negative or inconclusive results from our clinical trials, preclinical studies or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional clinical trials or preclinical studies or abandon a program;
- product-related adverse events experienced by subjects in our clinical trials, or by individuals using drugs or therapeutic biologics similar to verekitug or any other potential future product candidates;
- delays in submitting an Investigational New Drug ("IND") application or other regulatory submission to the FDA, EMA, or other comparable foreign regulatory authorities, or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial or a suspension, termination, or hold, of a clinical trial once commenced;
- conditions imposed by the FDA, the competent authorities of individual EU Member States or other comparable foreign regulatory authorities regarding the scope or design of our clinical trials;
- poor performance of verekitug or any other potential future product candidates during clinical trials;
- better than expected performance of control arms, such as placebo groups, which could lead to negative or inconclusive results from our clinical trials;
- delays in enrolling subjects in our clinical trials;
- high drop-out rates of subjects from our clinical trials;

- inadequate supply or quality of verekitug or any other potential future product candidates or other materials necessary for the conduct of our clinical trials;
- higher than anticipated clinical trial or manufacturing costs;
- unfavorable FDA, EMA, competent authorities of individual EU Member States, or other comparable foreign regulatory authority inspection and review of our clinical trial sites;
- failure of our third-party contractors or investigators to comply with regulatory requirements or the clinical trial protocol or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policies and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our therapies in particular; or
- varying interpretations of data by the FDA, EMA, the European Commission, and other comparable foreign regulatory authorities.

We are currently conducting, and may in the future conduct, clinical trials for verekitug or any other potential future product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We are currently conducting, and may in the future conduct, clinical trials for verekitug or any other potential future product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials. We are currently conducting clinical trials outside the United States, including but not limited to in Canada, Japan, South Korea, South Africa, the United Kingdom ("UK") and countries in South America and the European Union, and we expect to continue to conduct trials internationally in the future. The acceptance of data from clinical trials conducted outside the United States or another jurisdiction by the FDA or any other comparable foreign regulatory authorities may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless the data are applicable to the U.S. population and U.S. medical practice, the trials were performed by clinical investigators of recognized competence and pursuant to Good Clinical Practice ("GCP") regulations, and the FDA can validate the data through on-site inspections or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements, including in relation to the use of data from clinical trials conducted in foreign jurisdictions. In addition, such foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in verekitug or any other potential future product candidates that we may develop being delayed or not receiving approval for commercialization in the applicable jurisdiction.

The successful development of pharmaceutical products involves a lengthy and expensive process and is highly uncertain.

Successful development of pharmaceutical products is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- clinical trial results may show product candidates to be less effective than expected (for example, a clinical trial could fail to meet its primary or key secondary endpoint(s)) or have an unacceptable safety or tolerability profile;
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals, which, among other things, may be caused by patients who fail the trial screening process, slow enrollment in clinical trials, patients dropping out of trials, patients lost to follow-up, length of time to achieve trial endpoints, additional time requirements for data analysis or a Biologics License Application ("BLA") or similar foreign application preparation, discussions with the FDA, an FDA request for additional preclinical or clinical data (such as long-term toxicology studies) or unexpected safety or manufacturing issues;
- preclinical study results may show verekitug or any other potential future product candidates to have harmful side effects;
- post-marketing approval requirements; or
- the proprietary rights of others and their competing products and technologies that may prevent verekitug or any other potential future product candidates from being commercialized.

The length of time necessary to complete clinical trials and submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one product candidate to the next and from one country or jurisdiction to the next and may be difficult to predict.

Furthermore, any product candidate we develop and the activities associated with its development and commercialization, including its design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for verekitug or any other potential future product candidates will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction, and it is possible that verekitug or any of our other potential future product candidates will not ever obtain regulatory approval.

We have no experience as an organization in submitting and supporting the applications necessary to gain marketing approvals and expect to rely on third-party contract research organizations ("CROs") or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude its obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have 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. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval that we may ultimately obtain could be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Even if we are successful in obtaining marketing approval, commercial success of any approved products will also depend in large part on the availability of coverage and adequate reimbursement from third-party payors, including government payors such as the Medicare and Medicaid programs and comparable foreign programs and managed care organizations in the United States or country-specific governmental organizations in foreign countries, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. Third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other healthcare payors were not to provide coverage and adequate reimbursement for our products once approved, market acceptance and commercial success would be reduced.

In addition, if verekitug or any other potential future product candidates receive marketing approval, we will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and registration, and will need to continue to comply (or ensure that our third-party providers comply) with current Good Manufacturing Practices ("cGMPs") and GCPs for any clinical trials that we conduct post-approval. In addition, there is always the risk that we, a regulatory authority or a third party might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any failure to comply or other issues with verekitug or any other potential future product candidates post-approval could adversely affect our business, financial condition, results of operations and growth prospects.

Certain estimates of market opportunity and forecasts may prove to be smaller than we believe.

The estimates of market opportunity and forecasts of market growth included in documents that we file with the SEC may prove to be smaller than we believe, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all. Our initial focus is on the development of verekitug for the treatment of severe respiratory disorders, including severe asthma, CRSwNP and COPD. Our projections of addressable patient populations within these indications are based on our estimates and independent market research, industry and general publications obtained from third parties. Market opportunity estimates and growth forecasts included in this Quarterly Report and the other documents that we file with the SEC are subject to significant uncertainty and are based on assumptions and estimates. These estimates, which have been derived from a variety of

sources, including scientific literature, surveys of clinics, patient foundations and market research, may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these indications. Additionally, the potentially addressable patient population may not ultimately be amenable to treatment with our product candidate if we cannot achieve our intended dosing interval. Our market opportunity may also be limited by current and future products of our competitors that are already available in the market or may enter the market for such patients. If any of our estimates prove to be inaccurate, the market opportunity for verekitug could be significantly diminished and have an adverse material impact on our business.

Due to the significant resources required for drug development and depending on our ability to access capital, we must prioritize the development of verekitug. Moreover, we may fail to expend our limited resources on the development of verekitug for the treatment of additional indications or for the development of other potential future product candidates that may have been more profitable or for which there is a greater likelihood of success.

Our product candidate, verekitug for the treatment of severe asthma and CRSwNP, is currently in Phase 2 clinical development in each of these indications, and we plan to initiate clinical development for verekitug in COPD. Our initial focus is on developing verekitug for the treatment of severe respiratory disorders.

Due to the significant resources required for the development of verekitug, we must decide which indications to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular indications may not lead to the development of viable commercial products and may divert resources away from better opportunities. If we make incorrect determinations regarding the viability or market potential of verekitug or misread trends in the pharmaceutical industry, our business, financial condition, results of operations and growth prospects could be materially and adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities verekitug or any potential future product candidates with other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to verekitug through collaboration, licensing or royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

If we successfully commercialize verekitug, our results of operations will be affected by the level of royalty payments that we are required to pay to Regeneron.

In connection with our Asset Purchase Agreement with Astellas, we also entered into a letter agreement (the "Regeneron Letter Agreement") with Astellas and Regeneron Pharmaceuticals Inc. ("Regeneron"). Under the Regeneron Letter Agreement, we assumed from Astellas an obligation to make mid-single-digit percentage royalty payments to Regeneron upon the commercialization of products developed from materials originally licensed to Astellas. The payment of royalties may have a negative effect on our results of operations and our ability to reinvest capital generated from commercialization to develop verekitug in additional indications or grow our company. Furthermore, any failure on our part to pay royalties owed to Regeneron could impact our rights to verekitug, lead to the initiation of legal proceedings against us and thereby adversely affect our business.

We may seek to grow our business through acquisitions or investments in new or complementary businesses, products or technologies, through the licensing of products or technologies from third parties or other strategic alliances. The failure to manage acquisitions, investments, licenses or other strategic alliances, or the failure to integrate them with our existing business, could have a material adverse effect on our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

Our success depends on our ability to continually enhance and broaden our product offerings in response to changing clinician and patients' needs, competitive technologies and market pressures. Accordingly, from time to time we may consider opportunities to acquire, make investments in or license other technologies, products and businesses that may enhance our capabilities, complement our existing products and technologies or expand the breadth of our markets or customer base. Potential and completed acquisitions, strategic investments, licenses and other alliances involve numerous risks, including:

- difficulty assimilating or integrating acquired or licensed technologies, products, employees or business operations;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions or strategic alliances, including the assumption of unknown or contingent liabilities and the incurrence of debt or future write-offs of intangible assets or goodwill;
- diversion of management's attention from our core business and disruption of ongoing operations;
- adverse effects on existing business relationships with suppliers, sales agents, healthcare facilities, surgeons and other healthcare professionals;

- risks associated with entering new markets in which we have limited or no experience;
- potential losses related to investments in other companies;
- potential loss of key employees of acquired businesses; and
- increased legal and accounting compliance costs.

We do not know if we will be able to identify acquisitions or strategic relationships we deem suitable, whether we will be able to successfully complete any such transactions on favorable terms, if at all, or whether we will be able to successfully integrate any acquired business, product or technology into our business or retain any key personnel, suppliers, sales agent, healthcare facilities, physicians or other healthcare providers. Our ability to successfully grow through strategic transactions depends upon our ability to identify, negotiate, complete and integrate suitable target businesses, technologies or products and to obtain any necessary financing. These efforts could be expensive and time-consuming and may disrupt our ongoing business and prevent management from focusing on our operations.

To finance any acquisitions, investments or strategic alliances, we may choose to issue shares of our common stock as consideration, which could dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may be unable to consummate any acquisitions, investments or strategic alliances using our common stock as consideration. Additional funds may not be available on terms that are favorable to us, or at all.

We, our collaborators, and our service providers are subject to a variety of stringent and evolving privacy and data security laws, regulations, and rules, contractual obligations, industry standards, policies, and other obligations related to privacy and data security. Any actual or perceived failure to comply with such obligations could expose us to significant fines or other penalties and otherwise harm our business and operations.

In the ordinary course of our business, we and the third parties upon which we rely collect, receive, store, or otherwise process personal data, including information we may collect about participants in our clinical trials. Our data processing activities subject us to numerous, evolving privacy and data security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to privacy and data security.

The legislative and regulatory framework for the processing of personal data worldwide is rapidly evolving in a manner that is increasingly stringent and, globally, this legal and regulatory framework is likely to remain uncertain for the foreseeable future. In the United States, numerous federal, state and local laws and regulations, including federal health information privacy laws, state information security and data breach notification laws, federal consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), state consumer protection and privacy laws, and other similar laws (e.g., wiretapping and communications interception laws) govern the processing of health-related and other personal data.

At the state level, numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording individuals certain rights concerning their personal data. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While existing state comprehensive privacy laws exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely.

Additionally, we may be subject to new laws governing the privacy of consumer health data. These various privacy and data security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern privacy, data security, and the transfer of personal data between jurisdictions. For example, the European Union's General Data Protection Regulation ("EU GDPR") and the United Kingdom's General Data Protection Regulation ("UK GDPR", together with the EU GDPR, "GDPR") impose strict requirements for processing personal data including relating to processing of sensitive data (such as health data), ensuring there is a legal basis or condition to justify the processing of personal data, where required requirements relating to obtaining consent of individuals, disclosures about how personal data is to be used, limitations on retention of information, implementing safeguards to protect the security and confidentiality of personal data, where required providing notification of data breaches, maintaining records of processing activities and documenting data protection impact assessments where there is high risk processing and taking certain measures when engaging third-party processors. Under GDPR, companies may face temporary or definitive bans on data processing and other corrective activities, fines of up to €20 million (£17.5 million GBP) or 4% of annual global revenues, whichever is greater, and private litigation related to processing of personal data brought by classes of data subjects or consumer

protection organizations authorized at law to represent their interests. Non-compliance could also result in a material adverse effect on our business, financial position and results of operations.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area ("EEA") and the UK have significantly restricted the transfer of personal data to the United States and other countries. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework ("Framework") and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States (or other countries), or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activities activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

In addition to privacy and data security laws, we are contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by other contractual obligations related to privacy and data security, and our efforts to comply with such obligations may not be successful.

We publish privacy policies and other statements, such as compliance with certain certifications or self-regulatory principles, regarding privacy and data security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Obligations related to privacy and data security are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail in our efforts to comply with our privacy and data security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable privacy and data security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims), and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for significant statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, financial condition, results of operations and growth prospects, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

Artificial intelligence presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information, and personal data.

Issues in the development and use of artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability, or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. We may adopt and integrate generative artificial

intelligence tools into our systems for specific use cases reviewed by legal and information security. Our vendors may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If we, our vendors, or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

Risks related to the discovery and development of verekitug or any other potential future product candidates

The regulatory approval processes of the FDA, the EMA, and the European Commission and other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for verekitug or any other potential future product candidates, our business will be substantially harmed.

We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining regulatory approval from the FDA. Regulatory authorities outside of the United States impose similar requirements. The time required to obtain approval by the FDA, European Commission and other comparable foreign regulatory authorities is inherently unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including substantial discretion of the regulatory authorities. In addition, 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. For instance, jurisdictions outside of the United States, such as the European Union or Japan, may have different requirements for regulatory approval, which may require us to conduct additional clinical, nonclinical or chemistry, manufacturing and control studies. To date, we have not submitted a BLA to the FDA or similar drug approval submissions to comparable foreign regulatory authorities for any product candidate. We must complete additional preclinical studies and clinical trials to demonstrate the safety and efficacy of verekitug or any other potential future product candidates in humans before we will be able to obtain these approvals.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. The general approach for FDA approval of a new drug is dispositive data from two or more adequate and well-controlled clinical trials of the product candidate in the relevant patient population. The FDA, the EMA, the European Commission, or other comparable foreign regulatory authorities may disagree with us about whether a clinical trial is adequate and well-controlled or may request that we conduct additional clinical trials prior to regulatory approval. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. In addition, there is no assurance that the doses, endpoints and trial designs that we intend to use for our planned clinical trials, including those that we have developed based on feedback from regulatory agencies or those that have been used for the approval of similar drugs, will be acceptable for future approvals. The clinical development of verekitug or any other potential future product candidates is also susceptible to the risk of failure inherent at any stage of development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements and determination by the FDA or any comparable foreign regulatory authority that a product candidate may not continue development or is not approvable. It is possible that even if verekitug or any other potential future product candidates have a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of such product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity of, or intolerability caused by, such product candidate, or mistakenly believe that verekitug or any other potential future product candidates are toxic or not well tolerated when that is not in fact the case. Serious adverse events or other adverse events, as well as tolerability issues, could hinder or prevent market acceptance of the product candidate at issue.

Verekitug or any other potential future product candidates could fail to receive regulatory approval, or regulatory approval could be delayed, for many reasons, including the following:

- the FDA, the EMA, the competent authorities of individual EU Member States, or other comparable foreign regulatory authorities may disagree with the dosing regimen, design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, the EMA and the European Commission, or other comparable foreign regulatory authorities that a product candidate is safe and effective for any of its proposed indications;

- the results of clinical trials may not meet the level of statistical significance required by the FDA, the EMA and the European Commission, or other comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA, the EMA or the European Commission, or other comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials or preclinical studies;
- the data collected from clinical trials of verekitug or any other potential future product candidates may not be sufficient to support the submission of a BLA to the FDA or other submission or to obtain regulatory approval in the United States, the European Union or elsewhere;
- the FDA, the EMA or other comparable foreign regulatory authorities may not file or accept our BLA or marketing application for substantive review;
- the FDA, the competent authorities of individual EU Member States or other comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, the EMA and the European Commission, or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of clinical trial results may result in our failing to obtain regulatory approval to market any product candidate we develop, which would substantially harm our business, results of operations and prospects. The FDA and other comparable foreign authorities have discretion in the approval process and determining when or whether regulatory approval will be granted for verekitug or any other potential future product candidates that we develop. Even if we believe the data collected from future clinical trials verekitug or any other potential future product candidates are promising, such data may not be sufficient to support approval by the FDA, the European Commission, or any other comparable foreign regulatory authority.

In addition, even if we were to obtain approval, regulatory authorities may approve verekitug or any other potential future product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve verekitug or any other potential future product candidates with a label that does not include the labeling claims necessary or desirable for the successful commercialization. Any of the foregoing scenarios could materially harm the commercial prospects for verekitug or any other potential future product candidates.

Verekitug represents a novel approach to the treatment of inflammatory diseases, which makes it difficult to predict its likelihood of success and the timing and cost of development and obtaining regulatory approval.

We have concentrated our research and development efforts to develop the only known antagonist currently in clinical development that targets the receptor for Thymic Stromal Lymphopoietin ("TSLP") and our future success depends on the successful development of this differentiated therapeutic approach. We are in the early stages of developing verekitug and there can be no assurance that any development problems we have experienced or may experience in the future will not cause significant delays or result in unforeseen issues or unanticipated costs, or that any such development problems or issues can be overcome. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our future clinical studies or commercializing our products on a timely or profitable basis, if at all. In addition, our expectations with regard to the advantages of inhibiting the TSLP receptor relative to the approach of other therapies may not materialize or materialize to the degree we anticipate. Further, our scalability and costs of manufacturing may vary significantly as we develop verekitug and understand these critical factors.

In addition, the clinical study requirements of the FDA, the EMA and the European Commission, and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate are determined according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more complex and consequently more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. Approvals by the European Commission and FDA for existing biologic treatments for asthma, such as dupilumab and tezepelumab, as well as other pathways to approval, may not be indicative of what these regulators may require for approval of our therapy. More generally, approvals by any regulatory authority may not be indicative of what any other regulatory authority may require for approval or what such regulatory authorities may require for approval in connection with new product candidates.

Verekitug may also not perform successfully in clinical trials or may be associated with adverse events that distinguish it from previously approved therapies or those that may be approved in the future. Unexpected clinical outcomes could materially and adversely affect our business, results of operations and prospects.

If our clinical trials fail to replicate positive results from earlier preclinical studies or clinical trials conducted by us or third parties, we may be unable to successfully develop, obtain regulatory approval for or commercialize verekitug or any other potential future product candidates.

The results observed from preclinical studies or early-stage clinical trials of verekitug or any other potential future product candidates may not necessarily be predictive of the results of later-stage clinical trials that we conduct. Similarly, positive results from such preclinical studies or early-stage clinical trials may not be replicated in our subsequent preclinical studies or clinical trials. For instance, results seen in our Phase 1b multiple ascending dose ("MAD") clinical trial for verekitug in patients with asthma may not translate to similar results in our ongoing Phase 2 clinical trial in patients with severe asthma. Furthermore, verekitug or any other potential future product candidates may not be able to demonstrate similar activity or adverse event profiles as other product candidates that we believe may have similar profiles. In addition, in our planned future clinical trials, we may utilize clinical trial designs or dosing regimens that have not been tested in prior clinical trials.

There can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of verekitug or any other potential future product candidates. There is a high failure rate for drugs proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, adverse safety or efficacy observations made in clinical trials.

Additionally, we may utilize an "open-label" clinical trial design. 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 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. The results from an open-label trial may not be predictive of future clinical trial results of a product candidate when studied in a controlled environment with a placebo or active control.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA, European Commission, or comparable foreign regulatory authority approval.

We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of verekitug or any other potential future product candidates, which could prevent us from achieving our projected development and commercialization goals in the timeframes we announce and expect, and harm our business and results of operations. Many of the factors that cause or lead to a delay in the initiation or completion of clinical trials may also lead to the denial of regulatory approval or limit market acceptance of verekitug or any other potential future product candidates.

We may experience delays in completing our clinical trials or preclinical studies and initiating or completing additional clinical trials or preclinical studies, including as a result of regulators not allowing or delay in allowing clinical trials to proceed under an IND or similar foreign authorization, or not approving or delaying approval for any clinical trial grant or similar approval we need to initiate a clinical trial. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize verekitug or any other potential future product candidates we develop, including:

- regulators, institutional review boards ("IRBs"), ethics committees, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site, or provide a related positive opinion permitting such activities;
- we may not reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- we may experience challenges or delays in recruiting principal investigators or study sites to lead our clinical trials;
- the number of subjects or patients required for clinical trials of verekitug or any other potential future product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of

clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;

- our third-party contractors, including those manufacturing verekitug or any other potential future product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have to amend clinical trial protocols submitted to regulatory authorities or conduct additional studies to reflect changes in regulatory requirements or guidance, which may be required to resubmit to an IRB, ethics committee and regulatory authorities for re-examination;
- regulators or other reviewing bodies may find deficiencies with, fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for clinical and commercial supplies, or the supply or quality of any product candidate or other materials necessary to conduct clinical trials of verekitug or any other potential future product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; and
- the potential for approval policies or regulations of the FDA, the EMA, and the European Commission, or the applicable regulatory authorities to significantly change in a manner rendering our clinical data insufficient for approval.

Regulators, IRBs, or ethics committees of the institutions in which clinical trials are being conducted may suspend, limit or terminate a clinical trial, or data monitoring committees may recommend that we suspend or terminate a clinical trial, 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, the competent authorities of individual EU Member States, or other comparable foreign regulatory authorities resulting in the imposition of a clinical hold, safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Negative or inconclusive results from our clinical trials or preclinical studies could mandate repeated or additional clinical trials and, to the extent we choose to conduct clinical trials in other indications, could result in changes to or delays in clinical trials of verekitug or any other potential future product candidates in such other indications. We do not know whether any clinical trials that we conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market verekitug or any other potential future product candidates for the indications that we are pursuing. If later-stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for verekitug or any other potential future product candidates will be adversely impacted.

For planning purposes, we sometimes estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing approval or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions which, if not realized as expected, may cause the timing of achievement of the milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the FDA and other comparable foreign regulatory authorities and the timing thereof;
- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of materials used to manufacture verekitug or any other potential future product candidates;
- the efforts of our collaborators with respect to the commercialization of verekitug or any other potential future product candidates; and
- the securing of, costs related to, and timing issues associated with, product manufacturing as well as sales and marketing activities.

If we fail to achieve announced milestones in the timeframes we expect, the development and commercialization of verekitug or any other potential future product candidates may be delayed, and our business, financial condition, results of operations and growth prospects may be harmed.

Our failure to successfully initiate and complete clinical trials and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market verekitug or any other potential future product candidates would also significantly harm our business. Our development costs will also increase if we experience delays in testing or regulatory approvals and we may be required to obtain additional funds to complete clinical trials. There can be no assurance that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure or otherwise modify our trials after they have begun. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize verekitug or any other potential future product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize verekitug or any other potential future product candidates, which may harm our business, financial condition, results of operations and growth prospects. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of verekitug or any other potential future product candidates.

If we experience delays in obtaining approval or if we fail to obtain approval of verekitug or any other potential future product candidates we may develop, the commercial prospects for such product candidate may be harmed, and our ability to generate revenues will be materially impaired.

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 becomes available and are subject to audit and verification procedures that could result in material changes in the final data.

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 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 participants enrollment continues and more participants' data become available or as participants from our clinical trials continue other treatments for their disease. Adverse differences between 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 and could adversely affect 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 investors 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, verekitug or any other potential future product candidates may be harmed, which could harm our business, financial condition, results of operations and growth prospects. 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. Furthermore, if we fail to replicate the positive results from our preclinical studies or clinical trials in our future clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize verekitug or any other potential future product candidates.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with our protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. Patient enrollment is affected by many factors, including:

- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the number and location of study sites and proximity of patients to study sites;
- the design of the trial;

- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications that we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in our clinical trials will drop out of the trials before completion.

We may experience challenges in recruiting principal investigators and patients to participate in ongoing and future clinical trials for verekitug or any other potential future product candidates if we are unable to sufficiently demonstrate the potential of such product candidate. In addition, our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as verekitug or any other potential future 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. Since the number of qualified clinical investigators is limited, we may 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 in such clinical trial site. Furthermore, if significant adverse events or other side effects are observed in any of our clinical trials, we may have difficulty recruiting patients to our trials and patients may drop out of our trials.

If we are unable to enroll a sufficient number of patients for our clinical trials, it would result in significant delays or might require us to abandon one or more clinical trials or our development efforts altogether. Delays in patient enrollment may result in increased costs, affect the timing or outcome of the planned clinical trials, product candidate development and approval process and jeopardize our ability to seek and obtain the regulatory approval required to commence product sales and generate revenue, which could prevent completion of these trials, adversely affect our ability to advance the development of verekitug or any other potential future product candidates, cause the value of the company to decline and limit our ability to obtain additional financing if needed.

Verekitug or any other potential future product candidates may cause undesirable side effects or have other properties that could delay or prevent regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if obtained.

Undesirable side effects caused by verekitug or any other potential future product candidates could cause us or 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, European Commission, or other comparable foreign regulatory authorities. We may also observe additional safety or tolerability issues with verekitug or any other potential future product candidates in ongoing or future clinical trials.

Many compounds that initially showed promise in clinical or earlier-stage testing are later found to cause undesirable or unexpected side effects that prevented further development of the compound. Results of ongoing or future clinical trials of verekitug or any other potential future product candidates could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics, despite a favorable tolerability profile observed in earlier-stage testing. In addition, although we believe that verekitug's mechanism of action may differentiate it from other products that address the TSLP signaling pathway, such as tezepelumab, adverse events observed in clinical studies or postmarket use of these products may also be observed with verekitug, which could impact our ability to recruit patients to our clinical trials and our clinical development strategy.

If unacceptable side effects arise in the development of verekitug or any other potential future product candidates, we, the FDA, competent authorities of individual EU Member States, or other comparable foreign regulatory authorities, the IRBs, or independent ethics committees at the institutions in which our trials are conducted, could suspend, limit or terminate our clinical trials, or the independent safety monitoring committee could recommend that we suspend, limit or terminate our trials, or the FDA, competent authorities of individual EU Member States or other comparable foreign regulatory authorities could order us to cease clinical trials, or the FDA, the European Commission, or other comparable foreign regulatory authorities could deny approval of verekitug or any other potential future product candidates for any or all targeted indications. Treatment-emergent side effects that are deemed to be drug-related could delay recruitment of clinical trial subjects or may cause subjects that enroll in our clinical trials to discontinue participation in our clinical trials. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We may need to train medical personnel using verekitug or any other potential future product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of verekitug or any other potential future product candidates. Inadequate training in recognizing or managing the potential side effects of verekitug or any other potential future product candidates could result in harm to patients that are administered verekitug or any other potential future product candidates. Any of these occurrences may adversely affect our business, financial condition, results of operations and growth prospects significantly.

Moreover, clinical trials are conducted in carefully defined sets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects.

If we fail to expand our development of verekitug into additional indications, or discover or acquire, and subsequently develop and commercialize other product candidates, we may be unable to grow our business and our ability to achieve our strategic objectives would be impaired.

Although the development and commercialization of verekitug in severe asthma, CRSwNP and COPD are our initial focus, as part of our longer-term growth strategy, we plan to initiate and advance development of verekitug in additional indications. Expansion into new indications will require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA, the European Commission, and comparable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, there can be no assurance that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives.

Risks related to the commercialization of verekitug or any other potential future product candidates

Even if verekitug or any other potential future product candidates receive regulatory approval, such product candidate may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable.

We have never commercialized a product, and even if verekitug or any other potential future product candidate is approved by the appropriate regulatory authorities for marketing and sale, such product candidate may nonetheless fail to achieve sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Many of the indications for verekitug have well-established standards of care that physicians, patients and payors are familiar with. Even if verekitug or any other potential future product candidates are successful in registrational clinical trials, such product candidate may not be successful in displacing these current standards of care if we are unable to demonstrate superior efficacy, safety, ease of administration and/or cost-effectiveness. For example, physicians may be reluctant to take their patients off their current medications and switch their treatment regimen to verekitug or any other potential future product candidates. Further, patients often acclimate to the treatment regimen that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch due to lack of coverage and adequate reimbursement. Even if we are able to demonstrate verekitug's or any other potential future product candidates' safety and efficacy to the FDA, the European Commission, and other regulators, safety or efficacy concerns in the medical community may hinder market acceptance.

Efforts to educate the medical community and third-party payors on the benefits of verekitug or any other potential future product candidates may require significant resources, including management time and financial resources, and may not be successful. If verekitug or any other potential future product candidates are approved but do not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of verekitug or any other potential future product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product;
- the potential advantages of the product compared to competitive therapies;
- the prevalence and severity of any side effects;
- whether the product is designated under physician treatment guidelines as a first-, second- or third-line therapy;
- our ability, or the ability of any future collaborators, to offer the product for sale at competitive prices;
- the product's convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- limitations or warnings, including distribution or use restrictions contained in the product's approved labeling;
- the strength of sales, marketing and distribution support;
- changes in the standard of care for the targeted indications for the product; and
- availability and adequacy of coverage and reimbursement from government payors, managed care plans and other third-party payors.

Any failure by verekitug or any other potential future product candidate that obtains regulatory approval to achieve market acceptance or commercial success would adversely affect our business prospects.

Competitive products may reduce or eliminate the commercial opportunity for verekitug or any other potential future product candidates, if approved. If our competitors develop technologies or product candidates more rapidly than we do, or their technologies or product candidates are more effective or safer than ours, our ability to develop and successfully commercialize verekitug or any other potential future product candidates may be adversely affected.

The clinical and commercial landscapes for the treatment of inflammatory diseases are highly competitive and subject to rapid and significant technological change. We face competition with respect to our indications for verekitug and will face competition with respect to any other drug candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies, such as Sanofi, Regeneron, AstraZeneca and Amgen, that currently market and sell drugs or are pursuing the development of drug candidates for the treatment of the indications that we are pursuing. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

We believe that a significant number of product candidates are currently under development for the same indications we are currently pursuing, and some or all may become commercially available in the future for the treatment of conditions for which we are trying or may try to develop product candidates. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. See the section titled “Business—Competition” included in our IPO final prospectus dated October 11, 2024, for examples of the competition that verekitug faces.

In most cases, we do not currently plan to run head-to-head clinical trials evaluating verekitug or any other potential future product candidates against the current standards of care, which may make it more challenging for verekitug or any other potential future product candidates to compete against the current standards of care due to the lack of head-to-head clinical trial data.

Our competitors may have significantly greater financial resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. Accordingly, our competitors may be more successful than we may be in obtaining regulatory approval for therapies and achieving widespread market acceptance. Our competitors’ products may be more effective, or more effectively marketed and sold, than verekitug or any other potential future product candidates we may commercialize and may render our therapies obsolete or non-competitive before we can recover development and commercialization expenses. If verekitug or any other potential future product candidates are approved, it could compete with a range of therapeutic treatments that are in development. In addition, our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective or less costly than verekitug or any other potential future product candidates, which could render verekitug or any other potential future product candidates obsolete and noncompetitive.

If we obtain approval for verekitug or any other potential future product candidates, we may face competition based on many different factors, including the efficacy, safety and tolerability of our products, the ease with which our products can be administered, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Existing and future competing products could present superior treatment alternatives, including being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing verekitug or any other potential future product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

In addition, our competitors may obtain patent protection, regulatory exclusivities or FDA approval and commercialize products more rapidly than we do, which may impact future approvals or sales of verekitug or any other potential future product candidates that receive regulatory approval. If the FDA approves the commercial sale of verekitug or any other potential future product candidates, we will also be competing with respect to marketing capabilities and manufacturing efficiency. We expect competition among products will be based on product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capabilities, product price, reimbursement coverage by government and private third-party payors, regulatory exclusivities and patent position. Our profitability and financial position will suffer if verekitug or any other potential future product candidates receives regulatory approval but cannot compete effectively in the marketplace.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other 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, as well as in acquiring technologies complementary to, or necessary for, our programs.

If we are unable to develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing verekitug or any other potential future product candidates.

We currently have no marketing, sales or distribution capabilities. We intend to establish a sales and marketing organization, either on our own or in collaboration with third parties, with technical expertise and supporting distribution capabilities to commercialize verekitug or any other potential future product candidates that may receive regulatory approval in key territories. These efforts will require substantial additional resources, some or all of which may be incurred in advance of any approval of the product candidate. Any failure or delay in the development of our or third parties' internal sales, marketing and distribution capabilities would adversely impact the commercialization of verekitug or any other potential future product candidates.

Factors that may inhibit our efforts to commercialize verekitug or any other potential future product candidates on our own include:

- our inability to recruit and retain an adequate number of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade an adequate number of physicians to prescribe any future products;
- 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; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

With respect to verekitug or any other potential future product candidates, we may choose to collaborate with third parties that have direct sales forces and established distribution systems to serve as an alternative to our own sales force and distribution systems. Our future product revenue may be lower than if we directly marketed or sold verekitug or any other potential future product candidates, if approved. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third parties, which may not be successful and are generally not within our control. If we are not successful in commercializing any approved products, our future product revenue will suffer and we may incur significant additional losses.

If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing verekitug or any other potential future product candidates.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our clinical development programs and the diseases our therapeutics are being developed to treat, and we intend to utilize appropriate social media in connection with our commercialization efforts following approval of our product candidates, if any. Social media practices in the biopharmaceutical industry continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation related to off-label marketing or other prohibited activities. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. When such disclosures occur, there is a risk that trial enrollment may be adversely impacted, that we fail to monitor and comply with applicable adverse event reporting obligations or that we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business.

Risks related to employee matters and managing growth

We expect to expand our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of regulatory affairs and sales, marketing and distribution, as well as to continue to support our public company operations. To manage these growth activities, we must continue to implement and improve our managerial, operational, quality and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Our management may need to devote a

significant amount of its attention to managing these growth activities. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion or relocation of our operations, retain key employees, or identify, recruit and train additional qualified personnel. Our inability to manage the expansion or relocation of our operations effectively may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy, including the successful commercialization of verekitug or any other potential future product candidates.

Our ability to develop verekitug or any other potential future product candidates and our future growth depends on attracting, hiring and retaining our key personnel and recruiting additional qualified personnel.

Our success depends upon the continued contributions of our key management and scientific personnel, many of whom have been instrumental for us and have substantial experience with developing therapies, identifying potential product candidates and building the technologies related to the clinical development of verekitug or any other potential future product candidates. As we continue developing verekitug or any other potential future product candidates, we will require personnel with medical, scientific, or technical qualifications specific to each program. The loss of key personnel would delay our research and development activities. Despite our efforts to retain valuable employees, members of our team may terminate their employment with us on short notice. The competition for qualified personnel in the biotechnology and biopharmaceutical industries is intense, and our future success depends upon our ability to attract, retain, and motivate highly skilled scientific, technical and managerial employees. We face competition for personnel from other companies, universities, public and private research institutions, and other organizations. If our recruitment and retention efforts are unsuccessful in the future, it may be difficult for us to implement our business strategy, which would have a material adverse effect on our business.

In addition, our clinical operations and research and development programs depend on our ability to attract and retain highly skilled scientists, data scientists, and engineers, particularly in Massachusetts. There is powerful competition for skilled personnel in these geographical markets, and we have from time to time experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications on acceptable terms, or at all. Many of the companies with which we compete for experienced personnel have greater resources than we do, and any of our employees may terminate their employment with us at any time. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, it may harm our ability to recruit and retain highly skilled employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects would be harmed.

Risks related to our dependence on third parties

We currently rely, and plan to rely in the future, on third parties to conduct and support our clinical trials. If they do not perform satisfactorily, we may not be able to obtain regulatory approval or commercialize verekitug or any other potential future product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed.

We have relied upon and plan to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials and expect to rely on these third parties to conduct clinical trials for verekitug or any other potential future product candidates that we develop. Our ability to complete clinical trials in a timely fashion depends on a number of key factors. These factors include protocol design, regulatory and IRB approval, or positive opinions from ethics committees, patient enrollment rates and compliance with GCPs. We have opened clinical trial sites and are enrolling patients in a number of countries where our experience is limited. In most cases, we use the services of third parties, including CROs, to carry out our clinical trial-related activities and rely on such parties to accurately report their results. Our reliance on third parties for clinical development activities may impact or limit our control over the timing, conduct, expense and quality of our clinical trials. Moreover, the FDA requires us to comply with GCPs 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. The FDA enforces these GCPs through periodic inspections of clinical trial sponsors, principal investigators, clinical trial sites and IRBs. For certain commercial prescription drug products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States. Comparable requirements and enforcement actions apply in foreign countries.

We remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, informed consent forms submitted to competent regulatory authorities, legal and regulatory requirements and scientific standards. Our failure or the failure of third parties to comply with the applicable protocol, informed consent forms, legal and regulatory requirements and scientific standards can result in rejection of our clinical trial data or other sanctions. If we or our third-party clinical trial providers or third-party CROs do not successfully carry out these clinical activities, our clinical trials or the potential regulatory approval of a product candidate may be delayed or be unsuccessful. Additionally, if we or our third-party contractors fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving verekitug or any other potential future product candidates, which would delay the regulatory approval process. We cannot be certain that, upon inspection, the FDA or comparable foreign regulatory authorities will determine that any of our clinical trials comply with GCPs. We are also required to register certain clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. Comparable transparency and publication requirements apply in foreign countries.

Furthermore, the third parties conducting clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we cannot control whether or not they devote sufficient time, skill and resources to our ongoing development programs. Moreover, many CROs, including some of those that we have engaged to conduct our clinical trials, are experiencing enrollment challenges as a result of, among other things, high employee turnover driven by the post-COVID macroeconomic environment and the inexperience of new employees. Furthermore, at clinical trial sites, the availability of staff and trial participants has been limited due to a decrease in the number of clinical investigative sites across the globe. These contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If these third parties, including clinical investigators, 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, we may not be able to obtain, or may be delayed in obtaining, regulatory approvals for verekitug or any other potential future product candidates. If that occurs, we will not be able to, or may be delayed in our efforts to, successfully commercialize verekitug or any other potential future product candidates. In such an event, our financial results and the commercial prospects for verekitug or any other potential future product candidates that we seek to develop could be harmed, our costs could increase and our ability to generate revenues could be delayed, impaired or foreclosed.

We also rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or regulatory approval of verekitug or any other potential future product candidates or commercialization of any resulting products, producing additional losses and depriving us of potential product revenue.

Any of the third-party organizations we utilize may terminate their engagements with us under certain circumstances. The replacement of an existing CRO or other third party may result in the delay of the affected trials or otherwise adversely affect our efforts to obtain regulatory approvals and commercialize verekitug or any other potential future product candidates. For example, although we believe there are a number of other CROs we could engage, we may not be able to enter into alternative arrangements or do so on commercially reasonable terms. In addition, while we believe there may be suitable replacements for one or more of these service providers, there is a natural transition period when a new service provider begins work. As a result, delays may occur, which could negatively impact our ability to meet our expected clinical development timelines and harm our business, financial condition, results of operations and growth prospects.

Our information technology systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches, which could adversely affect our business.

Our information technology systems and data and those of our current or future contract research organizations or other contractors and consultants are vulnerable to compromise or damage from computer hacking, computer viruses, and malware (e.g., ransomware malicious software), fraudulent activity, employee misconduct, human error, telecommunication and electrical failures, natural disasters, or other cybersecurity attacks or accidents. Future acquisitions could expose us to additional cybersecurity risks and vulnerabilities from any newly acquired information technology infrastructure. Cybersecurity attacks are increasing in frequency and sophistication and are made by groups and individuals with a wide range of motives (including industrial espionage) and expertise, including by organized criminal groups, “hacktivists,” nation states, and others. As a result of a continued hybrid working environment, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. Further, as a company with an increasingly global presence, our systems are subject to frequent attacks, which are becoming more commonplace in the industry, including attempted hacking, phishing attempts, such as cyber-related threats involving

spoofed or manipulated electronic communications, which increasingly represent considerable risk. Due to the nature of some of the attacks described herein, there is a risk that an attack may remain undetected for a period of time. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. While we continue to make investments to improve the protection of data and information technology, including in the hiring of information technology ("IT") personnel, periodic cyber security awareness trainings, improvements to IT infrastructure and controls, and conduct regular testing of our systems, there can be no assurance that our efforts will prevent service interruptions or security breaches.

We and certain of our service providers are from time to time subject to cyberattack attempts or incidents and security incidents. Any cybersecurity incident could adversely affect our business, by leading to, for example, the loss of trade secrets or other intellectual property, demands for ransom or other forms of blackmail, or the unauthorized disclosure of personal or other sensitive information of our employees, clinical trial patients, customers, and others. Although to our knowledge we have not experienced any significant cybersecurity incident to date, if such an event were to occur, it could seriously harm our development programs and our business operations. We could be subject to breach notification requirements, regulatory actions taken by governmental authorities, litigation under laws that protect the privacy of personal information, or other forms of legal proceedings, which could result in significant liabilities or penalties, result in substantial costs and distract management. Further, a cybersecurity incident may disrupt our business or damage our reputation, which could have a material adverse effect on our business, financial condition, results of operations, growth prospects, share price and shareholder value. We could also incur substantial remediation costs, including the costs of investigating the incident, repairing or replacing damaged systems, restoring normal business operations, implementing increased cybersecurity protections, and paying increased insurance premiums.

For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in or denials of our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. If a security breach or other incident were to result in the unauthorized access to or unauthorized use, disclosure, release or other processing of clinical trial data or personal data, it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media, and other parties pursuant to privacy and security laws. Likewise, we rely on our third-party research collaborators for research and development of verekitug and other third parties to conduct clinical trials, and similar events relating to their information technology systems could also seriously harm our business. Any security compromise affecting us, our collaborators or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures, and lead to regulatory scrutiny. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary or personal information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of verekitug or any other potential future product candidates could be delayed, result in substantial costs and distract management.

We may seek to establish collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

The advancement, development programs and potential commercialization of verekitug or any other potential future product candidates will require substantial additional cash to fund expenses. For some of our programs, we may decide to collaborate with other pharmaceutical and biotechnology companies with respect to development and potential commercialization. Likely collaborators may include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. In addition, if we are able to obtain regulatory approval for verekitug or any other potential future product candidates from foreign regulatory authorities, we may enter into collaborations with international biotechnology or pharmaceutical companies for the commercialization of such product candidate.

We face significant competition in seeking appropriate collaborators. 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 potential differentiation of verekitug or any other potential future product candidates from competing product candidates, design or results of clinical trials, the likelihood of approval by the FDA, the European Commission, or other comparable foreign regulatory authorities and the regulatory pathway for any such approval, the potential market for the product candidate, the costs and complexities of manufacturing and delivering the product to patients and the potential of competing products. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for verekitug or any other potential future product candidates. 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 verekitug or any other potential future product candidates or bring them to market and generate product revenue.

Collaborations are complex and time-consuming to negotiate and document. Further, 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. Any collaboration agreements that we enter into in the future may contain restrictions on our ability to enter into potential collaborations or to otherwise develop specified product candidates. 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 verekitug or any other potential future product candidates for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its 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.

Our existing research and development arrangement as well as any future collaborations with third parties for the development and commercialization of verekitug or any other potential future product candidates may not be successful, which could adversely affect our ability to advance verekitug or any other potential future product candidates.

We have entered into a research and development arrangement and may in the future enter into collaborations for the development and commercialization of verekitug or any other potential future product candidates. Any collaborations may limit our control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of verekitug or any other potential future product candidates. Our ability to generate revenues from these arrangements will depend on any future collaborators' abilities to successfully perform the functions assigned to them in these arrangements. For example, we granted Maruho Co., Ltd. ("Maruho") an exclusive, irrevocable, perpetual, royalty-free, sublicensable license for the development and commercialization of verekitug in Japan (the "Maruho License Agreement"). Under the Maruho License Agreement, we are responsible for and control the global research and development of verekitug in Japan. In addition, any future collaborators may have the right to abandon research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms.

Collaborations involving verekitug or any other potential future product candidates pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of verekitug or any other potential future product candidates or may elect not to continue or renew development or commercialization programs, based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, which divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon verekitug or any other potential future product candidates, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with verekitug or any other potential future product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, including trade secrets and intellectual property rights, contract interpretation, or the preferred course of development might cause delays or termination of the research, development or commercialization of verekitug or any other potential future product candidates, might lead to additional responsibilities for us with respect to such product candidate, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidate.

Collaboration agreements may not lead to development or commercialization of verekitug or any other potential future product candidates in the most efficient manner or at all. If any future collaborator of ours is involved in a business combination, it could

decide to delay, diminish or terminate the development or commercialization of verekitug or any other potential future product candidates licensed to it by us.

Our use of third parties to manufacture verekitug or any other potential future product candidates may increase the risk that we will not have sufficient quantities of verekitug or any other potential future product candidates, raw materials, active pharmaceutical ingredients ("APIs") or drug products when needed or at an acceptable cost.

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of verekitug or any other potential future product candidates, and we lack the resources and the capabilities to do so. Our current strategy is to outsource all manufacturing of verekitug or any other potential future product candidates to third parties.

We currently rely on and engage third-party manufacturers to provide all of the APIs and the final drug product formulation of verekitug that is being used in our clinical trials and preclinical studies. Although we believe that there are several potential alternative manufacturers who could manufacture verekitug, we primarily rely on one manufacturer, WuXi Biologics (Hong Kong) Limited ("WuXi"), for the production of product necessary to complete our ongoing clinical trials. If a replacement manufacturer becomes necessary in the future, we may incur added costs and delays in identifying and qualifying another manufacturer. There have been Congressional legislative proposals, such as the bill titled the BIOSECURE Act, which would, among other things, prohibit U.S. federal funding in connection with biotechnology equipment or services produced or provided by certain named Chinese "biotechnology companies of concern" (which includes WuXi) and loans and grants to, and federal contracts with any entity that uses biotechnology equipment or services from one of these entities in performance of the government contract, grant, or loan. The legislation also gives the federal government the authority to name additional "biotechnology companies of concern" that are engaged in research activities with the Chinese government and that pose a risk of U.S. national security. We continue to monitor the status of the BIOSECURE Act, the implementation of which could materially impact our agreement with WuXi.

In addition, we typically order raw materials, APIs and drug product and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements with any commercial manufacturer. We may not be able to timely secure needed supply arrangements on satisfactory terms, or at all. Our failure to secure these arrangements as needed could have a material adverse effect on our ability to complete the development of verekitug or any other potential future product candidates or, to commercialize them, if approved. We may be unable to conclude agreements for commercial supply with third-party manufacturers or may be unable to do so on acceptable terms. There may be difficulties in scaling up to commercial quantities and formulation of verekitug or any other potential future product candidates, and the costs of manufacturing could be prohibitive.

If our manufacturers have difficulty or suffer delays in successfully manufacturing material that meets our specifications, it may limit supply of verekitug or any other potential future product candidates and could delay our clinical trials. For example, during routine evaluation of drug samples as part of stability testing of material produced by a previous manufacturing process, particles were observed. This resulted in a brief pause in dosing in our Phase 1b MAD clinical trial of verekitug for the treatment of asthma while a standard investigation was conducted, after which dosing resumed. There can be no assurance that similar or longer delays will not be necessary in the future.

Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third-party manufacturer to comply with applicable regulatory requirements and reliance on third parties for manufacturing process development, regulatory compliance and quality assurance;
- manufacturing delays if our third-party manufacturers give greater priority to the supply of other products over verekitug or any other potential future product candidates or otherwise do not satisfactorily perform according to the terms of the agreement between us;
- limitations on supply availability resulting from capacity and scheduling constraints of third parties;
- the possible breach of manufacturing agreements by third parties because of factors beyond our control;
- the possible termination or non-renewal of the manufacturing agreements by the third party, at a time that is costly or inconvenient to us; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

If we are unable to maintain our key manufacturing relationships, we may fail to find replacement manufacturers or develop our own manufacturing capabilities, which could delay or impair our ability to obtain regulatory approval for verekitug or any other potential future product candidates. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms

and conditions favorable to us and there could be a substantial delay before new facilities could be qualified and registered with the FDA and comparable foreign regulatory authorities.

Additionally, if any third-party manufacturer with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different manufacturer. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture verekitug or any other potential future product candidates may be unique or proprietary to the original manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change third-party manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce verekitug or any other potential future product candidates according to the specifications previously submitted to the FDA, the EMA and the European Commission, or another comparable foreign regulatory authority. We may be unsuccessful in demonstrating the comparability of clinical supplies, which could require the conduct of additional clinical trials. The delays associated with the verification of a new third-party manufacturer could negatively affect our ability to develop or commercialize verekitug or any other potential future product candidates in a timely manner or within budget. Furthermore, a third-party manufacturer may possess technology related to the manufacture of verekitug or any other potential future product candidates that such third party owns independently. This would increase our reliance on such third-party manufacturer or require us to obtain a license from such third-party manufacturer in order to have another third party manufacture verekitug or any other potential future product candidates.

If verekitug is approved by any regulatory authority, we intend to utilize arrangements with third-party contract manufacturers for the commercial production of that product. This process is difficult and time consuming and we may face competition for access to manufacturing facilities as there are a limited number of contract manufacturers operating under cGMPs that are capable of manufacturing verekitug. Consequently, we may not be able to reach agreement with third-party manufacturers on satisfactory terms, which could delay our commercialization.

Some of our manufacturers are located outside of the United States. There is currently significant uncertainty about the future relationship between the United States and various other countries, including China, with respect to trade policies, treaties, government regulations and tariffs. It is possible further tariffs may be imposed that could affect imports of APIs used in verekitug or any other potential future product candidates, or our business may be adversely impacted by retaliatory trade measures taken by China or other countries, including restricted access to such raw materials used in verekitug or any other potential future product candidates. Given the unpredictable regulatory environment in China and the United States and uncertainty regarding how the U.S. or foreign governments will act with respect to tariffs, international trade agreements and policies, further governmental action related to tariffs, additional taxes, contracting matters, regulatory changes or other retaliatory trade measures in the future could occur with a corresponding detrimental impact on our business, financial condition, results of operations and growth prospects.

Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including shutdown of the third-party vendor or rejection of drug product lots or processes, clinical holds, fines, injunctions, civil penalties, delays, suspension, variation or withdrawal of approvals, license revocation, seizures or voluntary recalls of product candidates or drugs if approved, operating restrictions and criminal prosecutions, any of which could significantly affect supplies of verekitug or any other potential future product candidates. The facilities used by our contract manufacturers to manufacture verekitug or any other potential future product candidates must be evaluated by the FDA and comparable foreign regulatory authorities. We have limited control over the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMPs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, the European Union, or other comparable foreign regulatory authorities, we may not be able to secure and/or maintain regulatory approval for verekitug or any other potential future product candidates manufactured at these facilities. In addition, we limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds deficiencies or does not approve these facilities for the manufacture of verekitug or any other potential future product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market verekitug or any other potential future product candidates, if approved. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Any failure to comply with cGMP requirements or other FDA, European Union, and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop, and if approved, market verekitug or any other potential future product candidates.

The FDA and comparable foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm and monitor compliance with cGMPs.

If any third-party manufacturer of verekitug or any other potential future product candidates is unable to increase the scale of its production or the product yield of its manufacturing, then our manufacturing costs may increase and commercialization may be delayed.

In order to produce sufficient quantities to meet the demand for clinical trials and, if approved, subsequent commercialization of verekitug or any other potential future product candidates, our third-party manufacturers will be required to increase their production and optimize their manufacturing processes while maintaining the quality of verekitug or any other potential future product candidates. The transition to larger scale production could prove difficult. In addition, if our third-party manufacturers are not able to optimize their manufacturing processes to increase the product yield for verekitug or any other potential future product candidates, or if they are unable to produce increased amounts of verekitug or any other potential future product candidates while maintaining the same quality then we may not be able to meet the demands of clinical trials or market demands, which could decrease our ability to generate profits and have a material adverse impact on our business and results of operations.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As verekitug or any other potential future product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as the vendors used to manufacture drug product or manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause verekitug or any other potential future product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, notification or approval by the FDA, or comparable foreign regulatory authorities. This could delay or prevent completion of clinical trials, require conducting bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay or prevent approval of verekitug or any other potential future product candidates and jeopardize our ability to commence sales and generate revenue.

Risks related to government regulation

Obtaining and maintaining regulatory approval of verekitug or any other potential future product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval in other jurisdictions.

Obtaining and maintaining regulatory approval of verekitug or any other potential future 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. For example, even if the FDA grants marketing approval of a product candidate, the European Commission, or other comparable foreign regulatory authorities must also approve the manufacturing and marketing of the product candidate in those territories. 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 trials 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 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 products 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 verekitug or any other potential future product candidates will be harmed.

Even if we receive regulatory approval of verekitug or any other potential future product candidates, we will 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 verekitug or any other potential future product candidates.

If verekitug or any other potential future product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and

submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post-approval.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, European Union, and comparable foreign regulatory requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations and applicable product tracking and tracing requirements. As such, we and our contract manufacturers will be subject to continual review and inspections to assess continuous compliance with cGMP and adherence to commitments made in any BLA, other marketing application and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for verekitug or any other potential future product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. Certain endpoint data we hope to include in any approved product labeling also may not make it into such labeling, including exploratory or secondary endpoint data such as patient-reported outcome measures. The FDA may also require Risk Evaluation and Mitigation Strategies ("REMS") as a condition of approval of verekitug or any other potential future product candidates, which could entail requirements for long-term patient follow-up, 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. Comparable requirements may apply in foreign countries. In addition, if the FDA, the European Commission, or a comparable foreign regulatory authority approves verekitug or any other potential future product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

The FDA or comparable foreign regulatory authorities may impose consent decrees or withdraw or vary approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with verekitug or any other potential future product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical trials to assess new safety risks or imposition of distribution restrictions or other restrictions under a REMS program or a comparable foreign program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA or comparable foreign regulatory authorities to approve pending applications or supplements to approved applications filed by us or suspension, variation or withdrawal of approvals;
- product seizure or detention or refusal to permit the import or export of verekitug or any other potential future product candidates;
- total or partial suspension of production, distribution, manufacturing or clinical trials;
- operating restrictions;
- suspension of licenses; and
- injunctions, fines or the imposition of civil or criminal penalties.

Additionally, the FDA and comparable foreign regulatory authorities strictly regulate marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label.

The policies of the FDA, the EMA, and the European Commission, and comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of verekitug or any other potential future product candidates. In addition, the U.S. Supreme Court's July 2024 decision to overturn established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which the FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays, and/or changes. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. For more information, see the section titled "Business—Government regulation" included in our IPO final prospectus dated October 11, 2024.

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

Verekitug or any other potential future product candidates for which we intend to seek approval as biological products may face competition sooner than anticipated.

The Biologics Price Competition and Innovation Act of 200 (the "BPCIA") created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product.

We believe any of our potential future product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider verekitug or any other potential future product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors that are still developing.

In the European Union, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.

While we may in the future seek designations for verekitug or any other potential future product candidates with the FDA and comparable foreign regulatory authorities that are intended to confer benefits such as a faster development process, an accelerated regulatory pathway or regulatory exclusivity, there can be no assurance that we will successfully obtain such designations. In addition, even if verekitug or any other potential future product candidates are granted such designations, we may not be able to realize the intended benefits of such designations.

The FDA and comparable foreign regulatory authorities offer certain designations for product candidates that are designed to encourage the research and development of product candidates that are intended to address conditions with significant unmet medical need. These designations may confer benefits such as additional interaction with regulatory authorities, a potentially accelerated regulatory pathway and priority review. However, there can be no assurance that we will successfully obtain such designations for verekitug or any other potential future product candidates. In addition, while such designations could expedite the development or approval process, they generally do not change the standards for approval. Even if we obtain such designations for verekitug or any other potential future product candidates, there can be no assurance that we will realize their intended benefits.

For example, we may seek a Fast Track Designation for verekitug or any other potential future product candidates we develop. If a product is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may rescind the Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development activities.

We also may seek Breakthrough Therapy Designation for verekitug or any other potential future product candidates we develop. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval and priority review.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe a product candidate we develop meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if any product candidate we develop qualifies as a breakthrough therapy, the FDA may later decide that the drug no longer meets the conditions for qualification and rescind the designation.

Even in the absence of obtaining fast track and/or breakthrough therapy designations, a sponsor can seek priority review at the time of submitting a marketing application. The FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting adverse reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months. Priority review designation may be rescinded if a product no longer meets the qualifying criteria.

We may be unsuccessful in obtaining or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U.S. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user fee waivers.

Similarly, in the EU, a medicinal product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish that: (i) the product is intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions; (ii) either (a) such conditions affect not more than 5 in 10,000 persons in the EU when the application is made, or (b) the product without the benefits derived from orphan status, would not generate sufficient return in the EU to justify the necessary investment in developing the medicinal product; and (iii) there exists no satisfactory authorized method of diagnosis, prevention, or treatment of the condition that has been authorized in the EU, or even if such method exists, the product will be of significant benefit to those affected by that condition. In the EU, orphan medicinal product designation entitles a party to incentives such as reduction of fees or fee waivers protocol assistance, and access to the centralized marketing authorization procedure.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same product and indication for that time period, except in limited circumstances. In the EU, marketing exclusivity prevents the EMA from accepting another marketing authorization application or accepting an application to extend for a similar product and the European Commission cannot grant a marketing authorization for the same indication. The applicable period is seven years in the U.S. and ten years in the EU. The EU exclusivity period is extended by two years for orphan medicinal products that have also complied with an agreed Pediatric Investigation Plan. However, the EU exclusivity period can be reduced to six years, if at the end of the fifth, it is established that a product no longer meets the criteria on the basis of which it received orphan medicinal product designation, including where it can be demonstrated on the basis of available evidence that the product is sufficiently profitable so that market exclusivity is no longer justified or where the prevalence of the condition has increased above the threshold.

Even if we obtain orphan drug exclusivity for a drug, that exclusivity may not effectively protect the designated drug from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA or the European Commission can subsequently approve the same drug for the same condition if the FDA or the European Commission concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

Where appropriate, we may secure approval from the FDA, the European Commission or other comparable foreign regulatory authorities through the use of expedited approval pathways, such as accelerated approval or comparable foreign abbreviated pathways. If we are unable to obtain such approvals, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA or approval following comparable foreign abbreviated pathways by foreign regulatory authorities, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA or such comparable foreign regulatory authorities may seek to withdraw the accelerated approval.

Where possible, we plan to pursue accelerated development strategies in areas of high unmet need. We may seek an accelerated approval pathway for our one or more of our potential future product candidates from the FDA, EMA or other comparable foreign regulatory authorities. Under the accelerated approval provisions in the Federal Food, Drug, and Cosmetic Act, and the FDA's implementing regulations, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022 ("FDORA"), the FDA is permitted to require, as appropriate, that a post-approval confirmatory study or studies be underway prior to approval or within a specified time period after the date of approval for a product granted accelerated approval. FDORA also gives the FDA increased authority to withdraw approval of a drug or biologic granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send status updates on such studies to the FDA every 180 days to be publicly posted by the agency, or if such post-approval studies fail to verify the drug's predicted clinical benefit. The FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress.

Prior to seeking accelerated approval, or approval following comparable foreign abbreviated pathways, we would seek feedback from the FDA or other comparable foreign regulatory authorities and would otherwise evaluate our ability to seek and receive such accelerated approval or approval following comparable foreign abbreviated pathways. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit a BLA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent feedback from the FDA, or other comparable foreign regulatory authorities, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval, or comparable foreign abbreviated pathways, there can be no assurance that such application will be accepted or that any approval will be granted on a timely basis, or at all. The FDA, the EMA, or the European Commission, or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type, including, for example, if other products are approved via the accelerated pathway, or comparable foreign abbreviated pathway, and subsequently converted by FDA or comparable foreign regulatory authorities to full approval. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

Our relationships with healthcare professionals and physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

It is possible that governmental and enforcement authorities will conclude that our 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. Healthcare professionals, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct research and would sell, market and distribute our products. As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare,

Medicaid or other third-party payors, supranational, national, federal and state healthcare laws and regulations that may affect our ability to operate may apply. For more information on healthcare laws and regulations that may impact our company, see the section titled "Business—Government regulation—Other healthcare laws" included in our IPO final prospectus dated October 11, 2024.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare professionals, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare and privacy laws, as well as responding to possible investigations by government authorities, can be time and resource-consuming and can divert a company's attention from the business.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency or other competent authority guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment, reputational harm and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, defending against any such actions can be costly and time consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other professionals or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

Coverage and reimbursement may be limited or unavailable in certain market segments for verekitug or any other potential future product candidates, if approved, which could make it difficult for us to sell them profitably.

The success of verekitug or any other potential future product candidates, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors. 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. 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 other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including 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.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors, and the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services ("CMS"). CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Even if we obtain coverage for a given product, 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. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates, once approved. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for verekitug or any other potential future product candidates. Even if we do receive a favorable coverage determination for our products by third-party payors, coverage policies and third-party payor reimbursement rates may change at any time.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than

in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for verekitug or any other potential future product candidates that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives.

Moreover, increasing efforts by governmental and other third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for verekitug or any other potential future product candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted 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. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological 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.

We expect that 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 receive for any approved product. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. 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 or clearances of verekitug or any other potential future product candidates, if any, may be.

In addition, in some foreign countries, the proposed pricing for a product must be approved before it may be lawfully marketed. The requirements governing product pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for verekitug or any other potential future product candidates. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

For more information on the laws and regulations that may impact coverage and reimbursement of verekitug or any other potential future product candidates, see the section titled “Business—Government regulation—Coverage and reimbursement” included in our IPO final prospectus dated October 11, 2024.

Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example, (1) changes to our manufacturing arrangements, (2) additions or modifications to product labeling, (3) the recall or discontinuation of our products or (4) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. See the sections titled “Business—Government regulation—Coverage and reimbursement” and “—Healthcare reform” included in our IPO final prospectus dated October 11, 2024.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of products have been a focus in this effort. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical products, limiting coverage and the amount of reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our revenue generated from the sale of any approved products.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in several Congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. Congress has indicated that it will continue to seek new legislative measures to control drug costs.

In December 2021, Regulation No 2021/2282 on Health Technology Assessment ("HTA") amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and will apply in January 2025, is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation foresees a three-year transitional period and will permit EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement.

These laws, and future supranational, national state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for verekitug or any other potential future product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Our employees, independent contractors, consultants, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our current and any future employees, independent contractors, consultants, contract manufacturing organizations, CROs and vendors. Misconduct by these parties could include intentional, reckless, and/or negligent conduct that fails to comply with FDA or other regulations, provide true, complete and accurate information to the FDA, the national competent authorities of individual EU Member States, and other comparable foreign regulatory authorities, comply with manufacturing standards we may establish, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately, or disclose unauthorized activities to us. If we obtain FDA approval of verekitug or any other potential future product candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly, and our costs associated with compliance with these laws are likely to increase. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or 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 material and adverse effect on our business, financial condition, results of operations and growth prospects.

Off-label use or misuse of verekitug or any other potential future product candidates may harm our reputation in the marketplace or result in injuries that lead to costly product liability suits.

If verekitug or any other potential future product candidates are approved by the FDA, we may only promote or market them in a manner consistent with their FDA-approved labeling. We will train our marketing and sales force against promoting verekitug or any other potential future product candidates for uses outside of the approved indications for use, known as "off-label uses." We cannot, however, prevent a physician from verekitug or any other potential future product candidates off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. Furthermore, the use of verekitug or any other potential future product candidates for indications other than those approved by the FDA may not effectively treat such conditions. Any such off-label use of verekitug or any other potential future product candidates could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use verekitug or any other potential future product candidates for these uses for which they are not approved, which could lead to product liability suits that might require significant financial and management resources and that could harm our reputation. Similar requirements and considerations apply abroad.

Inadequate funding for the FDA, other government agencies or comparable foreign regulatory authorities 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 business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA or comparable foreign regulatory authorities 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 the 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 other government agencies or comparable foreign regulatory authorities on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA, other government agencies or comparable foreign regulatory authorities 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. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, including as a result of reaching the debt ceiling, 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 could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

EU drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the EU Member States.

We intend to seek approval to market verekitug or any other potential future product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for verekitug or any other potential future product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of products is subject to governmental control and other market regulations which could put pressure on the pricing and usage of verekitug or any other potential future product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of verekitug or any other potential future product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for them and may be affected by existing and future healthcare reform measures.

Much like the federal Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians and other healthcare professionals to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. Interactions between pharmaceutical companies and healthcare professionals, including the provision of benefits or advantages, are governed by strict laws, such as national anti-bribery laws of individual EU Member States and the Bribery Act 2010 in the UK, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians and other healthcare professionals in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often may require prior notification or approval by the healthcare professional's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

In addition, in some foreign countries, including some countries in the European Union, the proposed pricing for a product must be approved before it may be lawfully marketed. The requirements governing product pricing and reimbursement vary widely from country to country. The European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU Member State may approve a specific price for the medicinal product, it may refuse to reimburse a product at the price set by the manufacturer or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Many EU Member States also periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in the individual EU Member States will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down. Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile

additional data comparing the cost-effectiveness of our products to other available therapies. This HTA of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. Reference pricing used by various EU Member States and parallel distribution, or arbitrage between low-priced and high-priced EU Member States, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales and the potential profitability of verekitug or any other potential future product candidates in those countries would be negatively affected.

We are subject to export and import controls, economic sanctions, and anti-corruption laws and regulations of the United States and other jurisdictions. We can face criminal liability and other serious consequences for violations of these laws and regulations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control. Export controls and trade sanctions laws and regulations may restrict or prohibit altogether the provision, sale, or supply of our products to certain governments, persons, entities, countries, and territories, including those that are the target of comprehensive sanctions or an embargo. We are also subject to anti-corruption and anti-bribery laws, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, and other state and national anti-bribery laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violation of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

If we or any third-party manufacturer we engage now or in the future fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs or liabilities that could have a material adverse effect on our business.

We and third-party manufacturers we engage now are, and any third-party manufacturer we may engage in the future will be, 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 and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use 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.

Although we maintain general liability insurance as well as 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, hazardous or radioactive materials.

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

Further, with respect to the operations of our current and any future third-party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated

with our products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of verekitug or any other potential future product candidates. In addition, our supply chain may be adversely impacted if any of our third-party contract manufacturers become subject to injunctions or other sanctions as a result of their non-compliance with environmental, health and safety laws and regulations.

Risks related to our intellectual property

Our success is largely based upon our intellectual property and proprietary technologies, and we may be unable to protect and/or enforce our intellectual property.

Our success depends, in large part, on our ability to obtain and maintain patent protection and trade secret protection for verekitug or any other potential future product candidates and their formulations and uses, as well as successfully enforcing our patents against third-party infringers and/or defending these patents against third-party challenges. If we (or our licensees should such licensees be granted the right to prosecute or enforce certain patents within our portfolio) fail to appropriately prosecute or are unable to obtain and maintain patent protection for verekitug or any other potential future product candidates (or aspects thereof), our ability to develop, license and/or commercialize these product candidates may be adversely affected and we may not be able to prevent competitors from making, using, selling or importing competing products. This failure or inability to properly or adequately protect the intellectual property rights relating to these product candidates could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or our partners will be successful in protecting verekitug or any other potential future product candidates by obtaining, enforcing and defending patents. These risks and uncertainties include the following:

- patent applications may not result in any patent being issued;
- patents that may be issued may not include claims that cover a broad enough scope to prevent design around solutions by competitors;
- patents that may be issued may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or otherwise may not provide adequate barriers to entry or any competitive advantage;
- because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before a potential product can be commercialized, any related patent may expire, or remain in existence for only a short period following commercialization, reducing, or eliminating any advantage of the patent;
- our competitors, many of which have substantially greater resources than us or our partners do, and many of which have made significant investments in competing technologies, may seek, or may already have sought or obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential products;
- there may be significant pressure on the U.S. government and other international governmental bodies to limit the scope of patent protection 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 United States courts, allowing foreign competitors a better opportunity to create, develop, and market competing products; and
- we may be involved in lawsuits to protect or enforce our patents or the patents we have rights to enforce, which could be expensive, time consuming and/or unsuccessful.

In addition to patents, we also rely on trade secrets and proprietary know-how. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and assignment agreements with employees, consultants, and advisors, there exists the potential that third parties may still somehow obtain this information or arrive at the same or similar information independently, which would reduce or eliminate our competitive advantage. Moreover, we may become subject to claims that we directly or indirectly (through our consultants, advisors, or independent contractors that we may engage to assist us in developing verekitug or any other potential future product candidates) have wrongfully or inadvertently disclosed, acquired or used trade secrets or other proprietary information of third parties.

We may be forced to litigate to enforce or defend our intellectual property rights.

We may be forced to litigate to enforce or defend our intellectual property rights against infringement by competitors, and to protect our trade secrets against unauthorized use. In so doing, we may place our intellectual property at risk of being invalidated, rendered unenforceable, or limited or narrowed in scope such that we may no longer be used to adequately prevent the manufacture, sale or import of competitive product. Further, an adverse result in any litigation or other proceedings before government agencies such as the

United States Patent and Trademark Office (the "USPTO"), may place pending applications at risk of non-issuance or limitations in scope. Further, derivation proceedings, entitlement proceedings, ex parte reexamination, inter partes review, post grant review, and opposition proceedings provoked by third parties or brought by the USPTO or any foreign patent authority may be used to challenge the inventorship, ownership, claim scope, or validity of our patents. Additionally, because of the substantial amount of discovery typically required in connection with intellectual property litigation, there is a risk that some of our confidential and proprietary information or trade secrets could be compromised by disclosure during this type of litigation. 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 value of the company. 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 conduct such litigation or proceedings adequately. 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.

If we enter into future arrangements involving government funding, and we make inventions as a result of such funding, our intellectual property rights to such discoveries may be subject to the applicable provisions of the Bayh Dole Act of 1980. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh Dole Act may similarly apply. Any exercise by the government of certain of our rights could harm our competitive position, business, financial condition, results of operations and growth prospects.

If we or our partners are sued for infringing or misappropriating the intellectual property rights of third parties, it could be costly and time consuming, and an unfavorable outcome in any such litigation could have a material adverse effect on our business.

Our success also depends upon our ability and the ability of us any of our future partners to develop, manufacture, market and sell verekitug or any other potential future product candidates without infringing on the proprietary rights of third parties. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products, some of which may be directed at claims that overlap with the subject matter of our intellectual property. Because patent applications can take many years to issue, there may be currently pending applications, now unknown to us, which may later result in issued patents that verekitug or any other potential future product candidates or proprietary technologies may be alleged to infringe upon. Similarly, there may be issued patents relevant to verekitug or any other potential future product candidates of which we are not aware.

In addition, third parties may sue us alleging that we infringe, or have infringed, on their patents. Even if we are successful in defending any claims of infringement, the defense of such claims may be costly and present a time consuming distraction. In the event of a successful claim of infringement against us, we may be required to:

- pay substantial damages and/or ongoing royalty payments;
- stop using some or all of our technologies and methods;
- stop certain research and development efforts;
- develop non infringing products or methods (i.e., develop or design around); and/or
- obtain one or more licenses from third parties for an upfront lump sum, an ongoing royalty, or a combination thereof.

If required, there can be no assurance that we will be able to obtain such licenses on acceptable terms, or at all. If we are sued for infringement, we could encounter substantial delays in the development, manufacture, and commercialization of verekitug or any other potential future product candidates. Any litigation, whether to enforce our patent rights or to defend against allegations that we allegedly infringe on third-party rights, could be costly, time consuming, and may distract management from other important tasks.

As is commonplace in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. To the extent our employees are involved in research endeavors that are similar to those which they were involved in at their former place of employment, we may be subject to claims that such employees and/or we have inadvertently or otherwise used or disclosed the alleged trade secrets or other proprietary information of such former employers. Litigation may be necessary to defend against such claims, which could result in substantial costs, be a distraction to management and ultimately have a material adverse effect on us, even if we are successful in defending such claims.

The biotechnology and pharmaceutical industries have experienced substantial litigation and other proceedings concerning intellectual property rights, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which could be uncertain and may prevent, delay, or otherwise interfere with our product discovery and development efforts. Our commercial success depends upon our ability or may depend on the ability of future collaborators to develop, manufacture, market, and sell our products. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights as well as administrative proceedings for challenging patents, including derivation, inter partes review, post grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be subject to, and may in the future become party to, or threatened with, adversarial proceedings or litigation concerning intellectual property rights with respect to verekitug or any other potential future product candidates we may develop, including interference proceedings, post grant review, inter partes review, and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions such as oppositions before the European Patent Office. Numerous United States and foreign issued patents and pending patent applications that are owned by third parties exist in the fields in which we are developing verekitug or any other potential future product candidates and infringement claims may be asserted against us or our partners based on existing patents or patents that may be granted in the future, regardless of their merit.

It is not always clear to industry participants, including us, which patents cover various types of therapies, products or their methods of use or manufacture. Moreover, as with many technology-based products, there may be third-party patent applications that, if issued, may include the claims that could be or are construed to cover components of verekitug or any other potential future product candidates. There may also be third-party patents of which we are currently unaware with claims to our technologies, compositions, methods of manufacture or methods of use.

Our ability to commercialize verekitug or any other potential future product candidates in the United States and abroad may be adversely affected if we cannot successfully defend against infringement claims or obtain a license on commercially reasonable terms to relevant third-party patents that cover verekitug or any other potential future product candidates. Even if we have a strong defense and/or believe that third-party intellectual property claims are without merit, there can be no assurance that a court would find in our favor on questions of infringement, validity, enforceability, and/or priority. A court of competent jurisdiction could hold that these third-party patents are valid and enforceable and have been infringed upon, which could materially and adversely affect our ability to commercialize verekitug or any other potential future product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claims, there is no assurance that a court of competent jurisdiction would invalidate the asserted claims of any such U.S. patent. If we are found to be infringing on a third party's intellectual property rights, and we are unsuccessful in demonstrating that any such patents are invalid or unenforceable, we could be required to pay damages and/or an ongoing royalty or obtain a license from such third party to continue developing, manufacturing, and marketing verekitug or any other potential future product candidates and our technologies. 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 such a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to it, and it could require us to pay substantial licensing fees and/or make ongoing royalty payments. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize verekitug or any other potential future product candidates or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business. While less likely given the high bar required for injunction, we also could be temporarily or permanently forced, including by court order, to cease developing, manufacturing, and commercializing the infringing technology or product candidates. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed on a patent or other intellectual property right. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations and growth prospects.

The defense of third-party claims of alleged infringement or misappropriation of a third party's intellectual property rights often involves substantial litigation expense and could also be a substantial diversion of management and employee time and resources from our business. Some third parties may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, financial condition, results of operations and growth prospects. There could also 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, this could have a substantial adverse effect on the price of our common stock.

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

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications are due to be paid to the USPTO and foreign patent agencies outside of the United States over the lifetime of our patents and applications. If, in the future, we in-license patent rights, in the case of any in-licensed patent rights, we generally rely on our licensors to pay these fees due to U.S. and non U.S. patent agencies. For patent rights we own, we may rely on our outside patent counsel and/or annuity services in the United States and foreign countries to monitor these deadlines and to pay these fees when so instructed by us.

The USPTO and foreign patent agencies require compliance with procedural, documentary, fee payment, and other similar provisions, such as the requirement to disclose known prior art, during the patent application process. In the case of any in-licensed patent rights, we will generally depend on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property, and for our owned patent applications, we engage counsel and other professionals to help us comply with these requirements. While certain inadvertent lapses can be cured by payment of a late fee, by petition, or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in a partial or complete loss of patent rights in the relevant jurisdiction. In the unlikely event that a non-compliance event were to occur, our competitors might be able to enter the market with similar or identical products or technology given our partial or complete loss of patent rights, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Patent terms may be inadequate to protect our competitive position on verekitug or any other potential future product candidates for an adequate amount of time.

Patents have a limited lifespan. The terms of individual patents depend upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from the earliest non provisional filing date in the applicable country. However, the actual protection afforded by a patent varies from country to country, and also depends upon many factors, including the type of patent, the scope of coverage, the availability of regulatory related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent, and whether a portion of the patent term has been terminally disclaimed based on other patents. Various extensions including patent term extension and patent term adjustment may be available, but the lives of such extensions, and the protections they afford, are limited. Even if patents covering verekitug or any other potential future product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting verekitug or any other potential future product candidates might expire before or shortly after we or our partners commercialize those candidates. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours for an adequate time period.

If we do not obtain sufficient patent term protections for verekitug or any other potential future product candidates, our business may be materially harmed.

Patents have a limited term. In the United States, the statutory expiration of a patent is generally 20 years after it is filed. Additional patent terms may be available through a patent term adjustment process, resulting from USPTO delays during prosecution. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering verekitug or any other potential future product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from generics or biosimilars.

Depending upon the timing, duration, and specifics of FDA regulatory approval of verekitug or any other potential future product candidates, one or more patents issued from U.S. patent applications that we file or those of our future licensors may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Amendments”). The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during the FDA regulatory review process based on the first regulatory approval for a particular drug or biologic. A maximum of one patent may be extended per FDA-approved drug as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval, and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of verekitug or any other potential future product candidates.

Despite the possibility of an extension, we may not be granted an extension for which it applies in the United States or any other jurisdiction because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to

apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time or the scope of patent protection afforded could be less than we request.

If we are unable to obtain patent term extension or restoration, or the foreign equivalent, or the term of any such extension is less than we request, our competitors or other third parties may obtain approval of competing drugs following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors or other third parties may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their drug earlier than might otherwise be the case. Any of the foregoing could materially harm our business, financial condition, results of operations and growth prospects.

Changes in patent law in the United States and in non U.S. jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our technologies and verekitug or any other potential future product candidates.

As is the case with other biotech and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and are therefore costly, time consuming and inherently uncertain. Recent rulings from the U.S. Supreme Court and the Court of Appeals for the Federal Circuit have narrowed the scope of patent protection available in specified circumstances and weakened the rights of patent owners in specified 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.

In addition, U.S. Supreme Court rulings over the past decade 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 validity and enforceability of issued patents. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce and/or defend our existing patents and patents that we might obtain in the future.

The USPTO has issued subject matter eligibility guidance instructing USPTO examiners on the ramifications of the Supreme Court rulings in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* and *Association for Molecular Pathology v. Myriad Genetics, Inc.*, and applied the *Myriad* ruling to natural products and principles including all naturally occurring molecules. In addition, the USPTO continues to provide updates to its guidance continues to be a developing area. The USPTO guidance may make it impossible for us to obtain similar patent claims in future patent applications. Currently, our patent portfolio contains claims of various types and scope, including methods of medical treatment. The presence of varying types of claims in our patent portfolio significantly reduces, but may not eliminate, our exposure to potential validity challenges.

On May 10, 2024, the USPTO issued a proposed rule to change terminal disclaimer practice to add a new requirement for terminal disclaimers filed to obviate (overcome) nonstatutory double patenting. Under the proposed rule, to overcome double patenting a patentee would need to agree that a patent with a terminal disclaimer will be enforceable only if the patent is not tied and has never been tied through one or more terminal disclaimers to a patent in which any claim has been finally held unpatentable or invalid over prior art. If this proposed rule becomes a final rule, it could significantly limit our patent rights and the ability to enforce them.

For our U.S. patent applications, which contain claims entitled to priority after March 16, 2013, there is a greater level of uncertainty due to the Leahy-Smith Act. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO has promulgated regulations and developed procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, did not come into effect until March 16, 2013. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

An important change introduced by the Leahy-Smith Act is that, as of March 16, 2013, the United States transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either: (i) file

any patent application related to verekitug or any other potential future product candidates or (ii) invent any of the inventions claimed in our patents or patent applications.

Among some of the other changes introduced by the Leahy-Smith Act are changes that limit where a patentee may file a patent infringement suit and new procedures providing opportunities for third parties to challenge any issued patent in the USPTO. Included in these new procedures is a process known as Inter Partes Review ("IPR"), which has been generally used by many third parties since the enactment of the Leahy-Smith Act to invalidate patents. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal court 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. Additionally, the rights of review and appeal for IPR decisions is an area of law that is still developing.

Geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of patent applications and the maintenance, enforcement or defense of issued patents. For example, the United States and foreign government actions related to Russia's invasion of 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 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 that have citizenship or nationality in, are registered in, or have predominately primary place of business or profit-making activities in the United States and other countries that Russia has deemed unfriendly without consent or compensation. Consequently, we would not be able to prevent third parties from practicing its inventions in Russia or from selling or importing products made using its inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and growth prospects may be adversely affected.

In addition, a European Unified Patent Court ("UPC") came into force on June 1, 2023. The UPC will be a common patent court to hear patent infringement and revocation proceedings effective for member states of the European Union. This could enable third parties to seek revocation of a European patent in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which the European patent is validated. Although we do not currently own any European patents, if we obtain such patents and applications in the future, any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Moreover, the controlling laws and regulations of the UPC will develop over time and may adversely affect our ability to enforce or defend the validity of any European patents obtained. We may decide to opt out from the UPC for any future European patent applications that we may file and any patents we may obtain. If certain formalities and requirements are not met, however, such European patents and patent applications could be challenged for non-compliance and brought under the jurisdiction of the UPC. We cannot be certain that future European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be harmed.

In addition to seeking patents for our technologies and verekitug or any other potential future product candidates, we also rely on trade secret protection, as well as confidentiality agreements, non-disclosure agreements and assignment agreements with our employees, consultants and third parties, to protect our know-how and other confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable.

It is our policy to require our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements generally provide that all confidential information concerning our business or financial affairs developed by or made known to an individual or entity during the course of that party's relationship with us are to be kept confidential and not disclosed to third parties, except in certain specified circumstances. In the case of employees, the agreements also provide that all inventions conceived by the individual, and that are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In the case of consultants and other third-party service providers, the agreements provide us with certain rights to all inventions arising from the services provided to us by those individuals or entities. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technologies and processes. Additionally, the assignment of intellectual property rights may not be self-executing, or 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. We may not be able to obtain adequate remedies for any breaches of such

agreements. Ultimately, enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time consuming, and the outcome is unpredictable.

In addition to contractual measures, we protect the confidential nature of our proprietary information through other appropriate precautions, such as physical and technological security measures. However, trade secrets and know-how can be difficult to protect despite these precautions. These measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and any recourse we might take against this type of misconduct may not provide an adequate remedy to protect our interests fully. In addition, our trade secrets may be independently developed by others in a manner that could prevent us from receiving legal recourse. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any of that information was independently developed by a competitor, our competitive position could be harmed.

If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. In addition, courts inside and outside the United States are sometimes less willing or unwilling to protect trade secrets. Even if we are successful, these types of lawsuits may consume, in addition to substantial costs, significant amounts of our time and other resources. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Third parties may assert that our employees, consultants, or advisors have wrongfully used or disclosed confidential information or misappropriated trade secrets.

As is common in the biotechnology and pharmaceutical industries, we employ individuals that are currently or were previously employed at universities, research institutions or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we employ measures to ensure that our employees, consultants, and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. We may then be directly or indirectly involved in litigation proceedings to defend against these claims. If we fail in defending against any such claims, in addition to potentially paying monetary damages, we may lose valuable intellectual property rights and/or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and distract 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, that perception could have a substantial adverse effect on the price of our common stock.

Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish verekitug or any other potential future product candidates that are approved for marketing from the products of our competitors. However, our trademarks or trade names may be challenged, infringed, circumvented, or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we benefit from to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be allegations of trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversions of resources and could adversely affect our business, financial condition, results of operations and growth prospects.

In addition, any proprietary name we propose to use with verekitug or any other potential future 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. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties, and be acceptable to the FDA.

Intellectual property rights do not necessarily address all potential threats.

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

- verekitug or any other potential future product candidates, if approved, may eventually become commercially available in generic or biosimilar product forms;
- others may be able to make similar antibodies to verekitug or any other potential future product candidates that are not covered by the claims of the patents that we license or may own in the future;
- we, or current or future licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future, potentially resulting in the invalidation of such patents or refusal of such applications;
- we, or current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- we, or current or future licensors or collaborators, may fail to meet our obligations to the U.S. government regarding any in licensed patents and patent applications funded by U.S. government grants, leading to the loss or unenforceability of patent rights;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing on our owned or licensed intellectual property rights;
- it is possible that our pending patent applications or those that we may own or license in the future will not lead to issued patents;
- it is possible that there are prior public disclosures that could invalidate our patents;
- it is possible that there are unpublished patent applications that may later issue with claims covering verekitug or any other potential future product candidates or technology similar to ours;
- it is possible that our patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable or result in a change in ownership;
- issued patents to which we hold rights may be held invalid, unenforceable, or narrowed in scope, including as a result of legal challenges by our competitors;
- the claims of our issued patents or patent applications, if and when issued, may not cover verekitug or any other potential future product candidates or narrowly cover them in such a way that competitors may be able to design around to avoid infringement allegations;
- the laws of foreign countries may not protect our proprietary rights or the proprietary rights of current or future licensors or collaborators to the same extent as the laws of the United States;
- the inventors of our patents or patent applications may become involved with competitors, develop products or processes that design around our patents, or become hostile to it or the patents or patent applications on which they are named as inventors;
- 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 have engaged in scientific collaborations in the past and we intend to continue to do so in the future, and our collaborators may develop adjacent or competing products that are outside the scope of our patents;
- we may not develop additional proprietary technologies that are patentable;
- verekitug or any other potential future product candidates we develop may be covered by third-party patents or other exclusive rights;
- the patents of others may prohibit or otherwise harm our business; or
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently commercialize the technology and/or file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Risks related to ownership of our common stock

An active trading market for our common stock may not be sustained.

An active or liquid market in our common stock may not be sustained. The lack of an active market may impair the value of our stockholders' shares, and our stockholders' ability to sell their shares at the desired time and price. An inactive market may also impair our ability to raise capital by selling our common stock and our ability to acquire other companies, products, or technologies by using our common stock as consideration.

The price of our common stock may be volatile, which could result in substantial losses for our stockholders.

The trading price of our common stock may be volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this section and elsewhere in this Quarterly Report, these factors include:

- the commencement, enrollment, completion or results of our current or future preclinical and clinical trials for verekitug or any other potential future product candidates;
- any delay in identifying and advancing a clinical candidate for our other programs;
- any delay in our regulatory filings for verekitug or any other potential future product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results or delays, suspensions or terminations in future preclinical studies or clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of verekitug or any other potential future product candidates or the failure of a regulatory authority to accept data from preclinical studies or clinical trials conducted in other countries;
- changes in laws or regulations applicable to verekitug or any other potential future product candidates, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations, if needed;
- our failure to commercialize verekitug or any other potential future product candidates, if approved;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to verekitug or any other potential future product candidates;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or verekitug or any other potential future product candidates in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- changes in the structure of the healthcare payment systems;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;

- changes in accounting practices, such as the adoption of a new accounting standard;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the market for biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs, reputational harm and a diversion of management's attention and resources.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations.

Our quarterly and annual operating results may fluctuate significantly, due to a variety of factors, many of which are outside of our control and may be difficult to predict, including:

- the timing and cost of, and level of investment in, research, development and, if approved, commercialization activities relating to verekitug or any other potential future product candidates, which may change from time to time;
- the timing and status of enrollment for clinical trials;
- the cost of manufacturing verekitug or any other potential future product candidates, as well as building out our supply chain, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;
- timing and amount of any milestone, royalty or other payments due under any collaboration or license agreement;
- future accounting pronouncements or changes in our accounting policies;
- the timing and success or failure of preclinical studies and clinical trials for verekitug or any other potential future product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- the timing of receipt of approvals for verekitug or any other potential future product candidates from regulatory authorities in the United States and internationally;
- exchange rate fluctuations;
- coverage and reimbursement policies with respect to verekitug or any other potential future product candidates, if approved, and potential future drugs that compete with our products; and
- the level of demand for verekitug or any other potential future product candidates, if approved, which may vary significantly over time.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our future revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if any forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

If securities or industry analysts do not continue to publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. Similarly, if one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Our executive officers, directors, principal stockholders and their respective affiliates own a significant percentage of our common stock and have the ability to exert significant control over matters subject to stockholder approval.

Our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates collectively own a significant percentage of our outstanding common stock. As a result, these stockholders, if acting together, have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, amendment of our organizational documents, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction. In addition, certain of our principal stockholders, including Maruho Deutschland GmbH, entities affiliated with OrbiMed, AI Upstream LLC, Decheng Capital Global Life Sciences Fund IV, L.P., entities affiliated with Enavate Sciences, and entities affiliated with Venrock Healthcare Capital Partners, have designated certain members of our board of directors. The interests of these stockholders may not be the same as or may even conflict with the interests of our other stockholders. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

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

Our common stock price could decline as a result of sales of a large number of shares of common stock or the perception that these sales could occur, which might also make it more difficult for us to sell equity securities in the future at a time and price that we deem appropriate.

Additionally, certain holders of our common stock have rights, subject to some conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or other stockholders, until such shares can otherwise be sold without restriction under Rule 144 under the Securities Act or until the rights terminate pursuant to the terms of the stockholder agreements between us and such holders. We have registered the offer and sale of all shares of common stock that we may issue under our equity compensation plans, and those shares are available for sale in the open market, unless such shares are subject to vesting restrictions with us or lock-up restrictions. Once we register the offer and sale of shares for the holders of registration rights, they can be freely sold in the public market upon issuance, subject to the lock-up agreements.

In addition, in the future, we may issue additional shares of common stock, or other equity or debt securities convertible into common stock, in connection with a financing, acquisition, employee arrangement, or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline.

Our issuance of additional capital stock in connection with financings, acquisitions, investments, our stock incentive plans or otherwise will dilute all other stockholders.

We expect to issue additional capital stock in the future that will result in dilution to all other stockholders. We expect to grant equity awards to employees, directors and consultants under our stock incentive plans. We may also raise capital through equity financings in the future. As part of our business strategy, we may acquire or make investments in complementary companies, products or technologies and issue equity securities to pay for any such acquisition or investment. Any such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests and the per share value of our common stock to decline.

We do not currently intend to pay dividends on our common stock and, consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation of the value of our common stock.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. We do not intend to declare or pay any

cash dividends on our capital stock in the foreseeable future. As a result, any investment return on our common stock will depend upon increases in the value for our common stock, which is not certain.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current directors and members of management.

Our third amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that only one of three classes of directors is elected each year;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of not less than two-thirds of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our third amended and restated certificate of incorporation or amended and restated bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (the "DGCL"), which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our second amended and restated bylaws designate certain courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by 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 second amended and restated bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of, or a claim based on, fiduciary duty owed by any of our current or former directors, officers, and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our third amended and restated certificate of incorporation or our second amended and restated bylaws (including the interpretation, validity or enforceability thereof), or (iv) any action asserting a claim that is governed by the internal affairs doctrine (the "Delaware Forum Provision"). The Delaware Forum Provision does not apply to any causes of action arising under the Securities Act or the Exchange Act. Our second amended and restated bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the sole and exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act or the Exchange Act (the "Federal Forum Provision"). In addition, our second amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision in our second amended and restated bylaws may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, the forum selection clauses in our second amended and

restated bylaws may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court and others state courts have upheld the validity of federal forum selection provisions purporting to require claims under the Securities Act or the Exchange Act be brought in federal court, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the United States may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

We may not be able to continue to satisfy the listing requirements of Nasdaq.

We must meet certain financial and liquidity criteria to maintain the listing of our common stock on Nasdaq. If we fail to meet any of Nasdaq's listing standards, our common stock may be delisted. In addition, our board of directors may determine that the cost of maintaining our listing on a national securities exchange outweighs the benefits of such listing. A delisting of our common stock from Nasdaq may materially impair our stockholders' ability to buy and sell our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. The delisting of our common stock could significantly impair our ability to raise capital and the value of our stockholders' investment.

Other general risks

Unfavorable global economic and geopolitical conditions could adversely affect our business, financial condition, stock price, and results of operations.

The global credit and financial markets have experienced extreme volatility and disruptions (including as a result of actual or perceived changes in interest rates, inflation and macroeconomic uncertainties), which has included severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, high inflation, uncertainty about economic stability, global supply chain disruptions, and increases in unemployment rates. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of the 2024 presidential election in the United States, military conflict, including the ongoing conflicts between Russia and Ukraine, and Israel and Hamas, terrorism, or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also continue to adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including a decrease in the demand for verekitug or any other potential future product candidates and in our ability to raise additional capital when needed on acceptable terms, if at all.

There are also current geopolitical tensions with China that may affect our operations. For example, there have been Congressional legislative proposals, such as the bill titled the BIOSECURE Act, which would, among other things, prohibit U.S. federal funding in connection with biotechnology equipment or services produced or provided by certain named Chinese "biotechnology companies of concern" (which includes WuXi) and loans and grants to, and federal contracts with any entity that uses biotechnology equipment or services from one of these entities. The legislation also gives the federal government the authority to name additional "biotechnology companies of concern" that are engaged in research activities with the Chinese government and that pose a risk of U.S. national security. The most recent version of the BIOSECURE Act which would delay the application of the BIOSECURE Act's provisions (1) until January 1, 2032, with respect to biotechnology equipment and services provided or produced by WuXi and other named biotechnology companies of concern under a contract or agreement entered before the effective date of the legislation and (2) for a period of five years after the identification of new biotechnology companies of concern, with respect to biotechnology equipment and services provided or produced by an entity that the government identifies in the future as a biotechnology company of concern. Any additional executive action, legislative action or potential sanctions with China could materially impact one of our current manufacturing partners, WuXi, and our agreement with them. We continue to assess the legislation as it develops to determine the effect, if any, on our contractual relationships. Furthermore, any disruptions to our supply chain as a result of unfavorable global economic conditions, including due to geopolitical conflicts or public health crises, could negatively impact the timely execution of our ongoing and future clinical trials.

In addition, current inflationary trends in the global economy may impact salaries and wages, costs of goods and transportation expenses, among other things, and recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures may create market and economic instability. We cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business.

We maintain the majority of our cash and cash equivalents in accounts with major U.S. and multi-national financial institutions, and our deposits at certain of these institutions may exceed insured limits. Market conditions and changes in financial regulations and policies can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position. In addition, changes in regulations governing financial institutions are beyond our control and difficult to predict; consequently, the impact of such changes on our business and results of operations is difficult to predict and may have an adverse effect on us.

We, or the third parties upon whom we depend, may be adversely affected by natural disasters, public health crises or other business interruptions and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters or public health crises could severely disrupt our operations, and have a material adverse impact on our business, financial condition, results of operations and growth prospects. If a natural disaster, power outage, public health crisis or other event occurred that prevented us from conducting our clinical trials, releasing clinical trial results or delaying our ability to obtain regulatory approval for verekitug or any other potential future product candidates, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time.

We are eligible to be treated as an "emerging growth company" and a "smaller reporting company" and our election of reduced reporting requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act ("JOBS Act"). For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements;
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved;
- an exemption from compliance with the auditor attestation requirements of Section 404 in the assessment of our internal control over financial reporting; and
- an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on the financial statements.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of $1.235 billion; (ii) December 31, 2029; (iii) the date on which we have issued more than $1.0 billion in non-convertible debt during any three-year period before that time; or (iv) the date on which we are deemed to be a "large accelerated filer", which would occur if the aggregate market value of our equity securities held by non-affiliates exceeds $700.0 million as of the last business day of our most recently completed second fiscal quarter. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies.

In addition, the JOBS Act provides that an emerging growth company can also take advantage of an extended transition period for complying with new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards, and therefore we are not subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies.

Even after we no longer qualify as an emerging growth company, we could still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements and reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile.

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

As a public company, we incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act of 2002, as amended (the "Sarbanes-Oxley Act"), as well as rules subsequently adopted by the SEC and The Nasdaq Global Select Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements, including requiring establishment and maintenance of effective disclosure and financial reporting controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act") was enacted. 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. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period lasting up to five years after completion of a company's IPO. 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 rules and regulations applicable to public companies have substantially increased, and will continue to increase, our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have an adverse effect on our business. These increased costs will continue to decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

If we fail to establish and maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be reevaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. We have begun the process of documenting, reviewing and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act, which requires an annual management assessment of the effectiveness of our internal control over financial reporting. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an emerging growth company or a non-accelerated filer, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act. We could be an emerging growth company for up to five years following the completion of our IPO. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation.

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 must design our disclosure controls and procedures to reasonably assure 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. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. 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.

Our ability to use our net operating loss carryforwards and other tax attributes may be limited.

As of December 31, 2023, we had federal and state net operating loss ("NOLs") carryforwards of $25.0 million and $27.6 million, respectively. The federal NOLs are not subject to expiration and are limited in utilization to 80% of our taxable income and the state NOLs begin to expire in 2041. As of December 31, 2023, we had $0.8 million of federal and state research and development credits, which will begin to expire in 2043 and 2037, respectively.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by "5 percent shareholders" over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. A corporation that experiences an ownership change will generally be subject to an annual limitation on the use of its pre-ownership change NOLs equal to the value of the corporation immediately before the ownership change, multiplied by the long-term tax-exempt rate (subject to certain adjustments). We may have experienced ownership changes in the past and may experience ownership changes in the future. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs by federal or state taxing authorities or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to reduce future income tax liabilities. As a result, our ability to use our pre-change NOLs and tax credits to offset future taxable income, if any, could be subject to limitations. Similar provisions of state tax law may also apply. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and tax credits.

Changes in tax law could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the U.S. Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application), including with respect to net operating losses and research and development tax credits, could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

We may become involved in securities class action litigation that could divert management's attention and harm our business, and insurance coverage may not be sufficient to cover all costs and damages.

In the past, securities class action litigation has often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, or the announcement of negative events, such as negative results from clinical trials. These events may also result in or be concurrent with investigations by the SEC. We may be exposed to such litigation or investigation even if no wrongdoing occurred. Litigation and investigations are usually expensive and divert management's attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential strategic transaction or the ultimate value our stockholders receive in any such transaction.

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

(a) Recent sales of unregistered equity securities

During the period between July 1, 2024 and September 30, 2024, we issued options to purchase an aggregate of 35,666 shares of our common stock to certain employees under our 2021 Stock Option and Grant Plan at a weighted-average exercise price of $10.62 per share. We deemed these issuances to be exempt from registration under the Securities Act of 1933, as amended (the "Securities Act"), either in reliance on Rule 701 of the Securities Act as sales and offers under compensatory benefit plans and contracts relating to compensation in compliance with Rule 701, or in reliance on Section 4(a)(2), as transactions by an issuer not involving a public offering. On October 11, 2024, we filed a registration statement on Form S-8 under the Securities Act to register all of the shares of our common stock subject to outstanding options and all shares of our common stock otherwise issuable pursuant to our equity compensation plans.

(b) Use of proceeds from initial public offering

On October 10, 2024, our Registration Statement on Form S-1 (No. 333-282197) for our initial public offering ("IPO") was declared effective by the Securities and Exchange Commission ("SEC"), pursuant to which we issued and sold an aggregate of 17,250,000 shares of common stock (inclusive of 2,250,000 shares of common stock sold pursuant to the underwriters' full exercise of their option to purchase additional shares) at a public offering price of $17.00 per share, for aggregate net cash proceeds of approximately $268.7 million, after deducting $20.5 million in underwriting discounts and commissions, and approximately $4.0 million in other offering costs.

J.P. Morgan Securities LLC, TD Securities (USA) LLC, Piper Sandler & Co. and William Blair & Company, L.L.C. acted as joint book-running managers for the offering, which closed on October 15, 2024.

In connection with our IPO, no payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on October 11, 2024 (File No. 333-282197).

(c) Issuer repurchases of securities

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

(a) None.

(b) Not applicable.

(c) During the quarter ended September 30, 2024, none of our directors or officers adopted or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement, as each term is defined in Item 408 of Regulation S-K.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Third Amended and Restated Certificate of Incorporation of Upstream Bio, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on October 15, 2024).
3.2	Second Amended and Restated Bylaws of Upstream Bio, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on October 15, 2024).
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 filed on September 18, 2024).
10.1#	Upstream Bio, Inc. 2024 Stock Option and Incentive Plan and form of award agreements thereunder (incorporated by reference to Exhibit 10.2 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on October 7, 2024).
10.2#	Upstream Bio, Inc. 2024 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.3 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on October 7, 2024).
10.3#	Form of Indemnification Agreement, by and between the Company and each of its directors and executive officers (incorporated by reference to Exhibit 10.4 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on October 7, 2024).
10.4#	Senior Executive Cash Incentive Bonus Plan (incorporated by reference to Exhibit 10.5 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on October 7, 2024).
10.5#	Executive Severance Plan (incorporated by reference to Exhibit 10.6 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on October 7, 2024).
10.6#	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1 filed on September 18, 2024).
10.7+	Lease Agreement, by and between the Company and BXP Waltham Woods LLC, dated as of July 3, 2024 (incorporated by reference to Exhibit 10.18 to the Company's Registration Statement on Form S-1 filed on September 18, 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**	Certifications of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents.
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document and included in Exhibit 101).

* Filed herewith.

** The certifications furnished in Exhibit 32.1 hereto are deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the registrant specifically incorporates it by reference.

# Indicates a management contract or compensatory plan, contract or arrangement.

+ Certain exhibits and schedules to these agreements have been omitted pursuant to Item 601(a)(5) and (6) of Regulation S-K. The registrant will furnish copies of any of the exhibits and schedules to the Securities and Exchange Commission upon request.

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.

UPSTREAM BIO, INC.

Date: November 7, 2024

By: /s/ E. Rand Sutherland
E. Rand Sutherland
Chief Executive Officer
(Principal Executive Officer)

Date: November 7, 2024

By: /s/ Michael Paul Gray
Michael Paul Gray
Chief Financial and Operating Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION 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, E. Rand Sutherland, certify that:

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

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

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

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

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

   (b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   (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/ E. Rand Sutherland

E. Rand Sutherland, M.D., M.P.H.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION 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, Michael Paul Gray, certify that:

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

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

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

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

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

   (b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   (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/ Michael Paul Gray

Michael Paul Gray, M.B.A.
Chief Financial and Operating Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Upstream Bio, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officers of the Company hereby 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/ E. Rand Sutherland

E. Rand Sutherland, M.D., M.P.H.
Chief Executive Officer
(Principal Executive Officer)

Date: November 7, 2024

By: /s/ Michael Paul Gray

Michael Paul Gray, M.B.A.
Chief Financial and Operating Officer
(Principal Financial Officer and Principal Accounting Officer)