UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 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: 001-38997

RAPT Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**47-3313701**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
561 Eccles Avenue, South San Francisco, California	**94080**
(Address of principal executive offices)	**(Zip Code)**

(650) 489-9000
(Registrant's telephone number, including area code)

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

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

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

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

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

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

If 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 May 3, 2024, there were 34,903,476 shares of the registrant's common stock outstanding.

RAPT THERAPEUTICS, INC.
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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

RAPT THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)
(Unaudited)

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 45,317	$ 47,478
Marketable securities	96,262	111,384
Prepaid expenses and other current assets	6,781	2,920
Total current assets	148,360	161,782
Property and equipment, net	2,239	2,448
Operating lease right-of-use assets	4,772	5,228
Other assets	447	3,871
Total assets	$ 155,818	$ 173,329
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 6,771	$ 5,176
Accrued expenses	11,807	14,103
Operating lease liabilities, current	2,508	2,448
Other current liabilities	82	109
Total current liabilities	21,168	21,836
Operating lease liabilities, non-current	3,815	4,458
Total liabilities	24,983	26,294
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Common stock	3	3
Additional paid-in capital	646,045	631,611
Accumulated other comprehensive gain (loss)	(10)	103
Accumulated deficit	(515,203)	(484,682)
Total stockholders' equity	130,835	147,035
Total liabilities and stockholders' equity	$ 155,818	$ 173,329

See accompanying notes to condensed consolidated financial statements.

RAPT THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2024	2023
Operating expenses:		
Research and development	24,781	25,574
General and administrative	7,737	5,988
Total operating expenses	32,518	31,562
Loss from operations	(32,518)	(31,562)
Other income, net	1,997	2,291
Net loss	$ (30,521)	$ (29,271)
Other comprehensive income (loss):		
Unrealized gain (loss) on marketable securities	(113)	365
Total comprehensive loss	$ (30,634)	$ (28,906)
Net loss per share, basic and diluted	$ (0.79)	$ (0.76)
Weighted average number of shares used in computing net loss per share, basic and diluted	38,625,365	38,280,539

See accompanying notes to condensed consolidated financial statements.

RAPT THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2023	34,398,312	$ 3	$ 631,611	$ 103	$ (484,682)	$ 147,035
Issuances of common stock under employee stock plans	36,074	—	67	—	—	67
Issuances of common stock in "at-the-market" offerings, net of issuance costs	365,316	—	8,969	—	—	8,969
Stock-based compensation	—	—	5,398	—	—	5,398
Unrealized loss on marketable securities	—	—	—	(113)	—	(113)
Net loss	—	—	—	—	(30,521)	(30,521)
Balance at March 31, 2024	34,799,702	$ 3	$ 646,045	$ (10)	$ (515,203)	$ 130,835

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2022	34,254,314	$ 3	$ 613,073	$ (26)	$ (367,884)	$ 245,166
Issuances of common stock under employee stock plans	35,417	—	116	—	—	116
Stock-based compensation	—	—	4,094	—	—	4,094
Unrealized gain on marketable securities	—	—	—	365	—	365
Net loss	—	—	—	—	(29,271)	(29,271)
Balance at March 31, 2023	34,289,731	$ 3	$ 617,283	$ 339	$ (397,155)	$ 220,470

See accompanying notes to condensed consolidated financial statements.

RAPT THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2024	2023
Operating activities		
Net loss	$ (30,521)	$ (29,271)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accretion of discounts on marketable securities	(983)	(1,441)
Depreciation and amortization	314	299
Stock-based compensation expense	5,398	4,094
Non-cash operating lease expense	584	584
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(437)	490
Accounts payable, accrued expenses and other current liabilities	(728)	7,277
Operating lease liabilities	(711)	(634)
Net cash used in operating activities	(27,084)	(18,602)
Investing activities		
Purchase of marketable securities	(16,814)	(37,878)
Proceeds from maturities of marketable securities	32,806	63,945
Purchase of property and equipment	(105)	(759)
Net cash provided by investing activities	15,887	25,308
Financing activities		
Proceeds from issuances of common stock in “at-the-market” offerings, net of issuance costs	8,969	—
Proceeds from issuance of common stock under employee stock plans	67	116
Net cash provided by financing activities	9,036	116
Net (decrease) increase in cash and cash equivalents	(2,161)	6,822
Cash and cash equivalents at beginning of period	47,478	38,946
Cash and cash equivalents at end of period	$ 45,317	$ 45,768

See accompanying notes to condensed consolidated financial statements.

RAPT THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Organization

Description of the Business

RAPT Therapeutics, Inc. ("RAPT" or the "Company") is a clinical stage, immunology-based therapeutics company focused on discovering, developing and commercializing oral small molecule therapies for patients with significant unmet needs in inflammatory diseases and oncology. Utilizing its proprietary drug discovery and development engine, the Company develops highly selective small molecules that are designed to modulate the critical immune responses underlying these diseases. The Company is located in South San Francisco, California.

Liquidity and Management Plans

The accompanying condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern. Since inception, the Company has incurred net losses and negative cash flows from operations. During the quarter ended March 31, 2024, the Company incurred a net loss of $30.5 million and used $27.2 million of cash in operations and capital expenditures. At March 31, 2024, the Company had cash and cash equivalents and marketable securities of $141.6 million and working capital of $127.2 million.

The Company plans to continue to incur substantial costs in order to conduct research and development activities, and additional capital will be needed to undertake these activities. The Company intends to raise such capital through the issuance of additional equity, borrowings or strategic alliances with other companies. However, if such arrangements are not available at adequate levels or on acceptable terms, the Company would be required to significantly reduce operating expenses and delay or reduce the scope of or eliminate some of its development programs. The Company believes that its current cash and cash equivalents and marketable securities will provide sufficient funds to enable it to meet its obligations for at least 12 months from the filing date of this Quarterly Report on Form 10-Q.

The Company's evaluation was based on the facts known as of the date of filing of this Quarterly Report on Form 10-Q, including the impacts of the clinical holds that the U.S. Food and Drug Administration ("FDA") has placed on the Phase 2b trial of zelnecirnon in atopic dermatitis ("AD") and the Phase 2a trial of zelnecirnon in asthma and the Company's decision to close and unblind both trials to support its discussions with the FDA.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") for interim financial information and pursuant to Article 10 of Regulation S-X of the Securities Act of 1933, as amended (the "Securities Act"). Accordingly, they do not include all of the information and notes required by U.S. GAAP for complete financial statements. These unaudited condensed consolidated financial statements include only normal and recurring adjustments that the Company believes are necessary to fairly state the Company's financial position and the results of its operations and cash flows. Interim-period results are not necessarily indicative of results of operations or cash flows for a full year or any subsequent interim period. The condensed consolidated balance sheet at December 31, 2023 has been derived from the audited financial statements at that date but does not include all disclosures required by U.S. GAAP for complete financial statements. Because all of the disclosures required by U.S. GAAP for complete financial statements are not included herein, these unaudited condensed consolidated financial statements and the notes accompanying them should be read in conjunction with the Company's audited consolidated financial statements included in its Annual Report on Form 10-K for the year ended December 31, 2023 filed on March 7, 2024 with the Securities and Exchange Commission ("SEC").

The accompanying condensed consolidated financial statements have been prepared in accordance with U.S. GAAP and include the consolidated accounts of the Company and its wholly owned subsidiary, RAPT Therapeutics Australia Pty Ltd., which was established in 2018 and deregistered during the quarter ended June 30, 2023. All intercompany balances and transactions have been eliminated in consolidation.

Stock-Based Compensation

The Company determines employee, nonemployee and director stock-based compensation expense for all stock-based awards based on their grant date fair value using the Black-Scholes option-pricing model. For stock-based awards with service conditions only, stock-based compensation expense is recognized over the requisite service period using the straight-line method. Forfeitures are recognized as they occur.

The fair value of restricted stock awards granted is determined based on the stock price on the date of grant. The estimated fair value is amortized as compensation expense over the service period of the award.

Net Loss Per Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding during the period, without consideration of potential dilutive securities. Diluted net loss per common share is computed by dividing the net loss by the sum of the weighted average number of common shares outstanding during the period plus the number of potential dilutive securities outstanding during the period calculated in accordance with the treasury stock method. Diluted net loss per share is the same as basic net loss per share since the effect of potentially dilutive securities is anti-dilutive.

Marketable Securities

Marketable securities primarily consist of commercial paper, corporate debt securities and U.S. government agency securities. The Company has classified its marketable securities as available-for-sale and may sell these securities prior to their stated maturities. The Company views these marketable securities as available to support current operations and classifies marketable securities with maturities beyond 12 months as current assets. The Company's marketable securities are carried at estimated fair value, which is derived from independent pricing sources based on quoted prices in active markets for similar securities. Unrealized gains and losses are reported as a component of accumulated other comprehensive income (loss). The cost of marketable securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in other income, net on the condensed consolidated statements of operations.

All of the Company's available-for-sale investments are subject to a periodic impairment review. For each available-for-sale investment whose fair value is below its amortized cost, the Company determines if the impairment is a result of a credit-related loss or other factors using both quantitative and qualitative factors, including the length of time and extent to which the market value has been less than amortized cost, the financial condition and near-term prospects of the issuer and the Company's intent and ability to retain its investment in the issuer for a period of time sufficient to allow for any anticipated recovery in market value. If the impairment is a result of a credit-related loss, the Company recognizes an allowance for credit losses. If the impairment is not a result of a credit loss, the Company recognizes the loss in other comprehensive loss.

Leases

At inception of a contract, the Company determines whether an arrangement is or contains a lease. For all leases, the Company determines the classification as either operating leases or financing leases. Operating leases are included in operating lease right-of-use ("ROU") assets and operating lease liabilities in the Company's condensed consolidated balance sheets.

Lease recognition occurs at the commencement date and lease liability amounts are based on the present value of lease payments over the lease term. The lease term may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. The Company uses an implicit rate when readily available, or its incremental borrowing rate based on the information available at lease commencement date, in determining the present value of lease payments. ROU assets represent our right to use underlying assets for the lease term and operating lease liabilities represent our obligation to make lease payments under the lease. ROU assets also include any lease payments made prior to the commencement date and exclude lease incentives received. Operating lease expense is recognized on a straight-line basis over the lease term. Lease agreements with both lease and nonlease components are generally accounted for together as a single lease component.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies and adopted by the Company as of the specified effective date. Under the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act"), the Company meets the definition of an emerging growth company and has elected the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act.

In November 2023, the FASB issued Accounting Standards Update ("ASU") (No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures ("ASU No. 2023-07"), which provides updates to qualitative and quantitative reportable segment disclosure requirements, including enhanced disclosures about significant segment expenses and increased interim disclosure requirements, among others. ASU No. 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods in fiscal years beginning after December 15, 2024. Early adoption is permitted, and the amendments should be applied retrospectively. The Company believes the adoption of this standard will not have a material impact on its consolidated financial statement disclosures.

In December 2023, the FASB issued ASU No. 2023-09, Improvements to Income Tax Disclosures ("ASU No. 2023-09"), which requires disclosure of disaggregated income taxes paid, prescribes standard categories for the components of the effective tax rate reconciliation and modifies other income tax-related disclosures. ASU No. 2023-09 is effective for fiscal years beginning after December 15, 2024 and allows for adoption on a prospective basis, with a retrospective option. Early adoption is permitted. The Company is currently evaluating the impact of this standard on the income tax disclosures within the consolidated financial statements.

3. Fair Value Measurements

Fair value accounting is applied for all financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). Financial instruments include cash and cash equivalents, marketable securities, accounts payable and accrued expenses that approximate fair value due to their relatively short maturities.

Assets and liabilities recorded at fair value on a recurring basis in the balance sheet are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1—Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2—Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

Level 3—Unobservable inputs that are significant to the measurement of the fair value of the assets or liabilities that are supported by little or no market data.

The Company estimates the fair values of investments in corporate debt securities, commercial paper and U.S. government agency securities using valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities, prepayment/default projections based on historical data and other observable inputs.

Cash equivalents and marketable securities, all of which are classified as available-for-sale securities and measured at fair value on a recurring basis, consisted of the following (in thousands):

		As of March 31, 2024			
	Fair Value Hierarchy Level	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Financial assets:					
Money market funds	Level 1	$ 10,337	$ —	$ —	$ 10,337
Corporate debt	Level 2	18,795	15	(9)	18,801
Asset-backed securities	Level 2	4,772	1	(2)	4,771
Commercial paper	Level 2	55,661	2	(5)	55,658
U.S. government agency securities	Level 2	52,024	17	(29)	52,012
Subtotal		141,589	35	(45)	141,579
Less: Cash equivalents		(45,317)	—	—	(45,317)
Marketable securities		$ 96,272	$ 35	$ (45)	$ 96,262

	Fair Value Hierarchy Level	As of December 31, 2023			
		Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Financial assets:					
Money market funds	Level 1	$ 10,869	$ —	$ —	$ 10,869
Corporate debt	Level 2	19,531	37	(9)	19,559
Asset-backed securities	Level 2	5,242	7	(4)	5,245
Commercial paper	Level 2	59,828	7	(8)	59,827
U.S. government agency securities	Level 2	63,206	91	(18)	63,279
Subtotal		158,676	142	(39)	158,779
Less: Cash equivalents		(47,395)	—	—	(47,395)
Marketable securities		$ 111,281	$ 142	$ (39)	$ 111,384

As of March 31, 2024, the unrealized losses on the Company's securities that were in an unrealized loss position were caused by interest rate changes and were not attributable to credit losses. As of March 31, 2024, the Company held debt securities with an aggregate unrealized loss position of $45,000 that had an aggregate fair value of $44.3 million. The Company does not intend to sell the securities that are in an unrealized loss position and the Company believes it is more likely than not that the investments will be held until recovery of the amortized cost bases. The Company did not record an allowance for credit losses or other impairment charges related to its marketable securities as of March 31, 2024.

The following table presents the remaining contractual maturities of the Company's marketable securities as of March 31, 2024 (in thousands):

	March 31, 2024
Maturing in one year or less	$ 88,717
Maturing after one year through five years	7,545
Total	$ 96,262

4. Property and Equipment

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

	March 31, 2024	December 31, 2023
Laboratory equipment	$ 7,484	$ 7,399
Leasehold improvements	3,295	3,295
Computer equipment	745	727
Furniture and fixtures	394	394
Total property and equipment	11,918	11,815
Less accumulated depreciation and amortization	(9,679)	(9,367)
Property and equipment, net	$ 2,239	$ 2,448

Depreciation and amortization expense was $0.3 million for each of the three months ended March 31, 2024 and 2023.

5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2024	December 31, 2023
Accrued research and development expenses	$ 7,141	$ 7,281
Accrued compensation	3,932	6,303
Accrued professional and consulting services	531	341
Other	203	178
Total accrued expenses	$ 11,807	$ 14,103

6. Common Stock

As of March 31, 2024, the Company had reserved the following shares of common stock for future issuance:

Options issued and outstanding under the 2019 Equity Incentive Plan and 2015 Stock Plan	5,484,490
Shares available for future grants under the 2019 Equity Incentive Plan	3,009,835
Pre-funded warrants issued and outstanding	4,000,000
Shares reserved under the 2019 Employee Stock Purchase Plan	650,858
Total	13,145,183

On August 11, 2023, the Company filed a shelf registration statement on Form S-3 with the SEC, which was declared effective on August 17, 2023, related to the sale and issuance of up to $450 million of the Company's securities, including up to $150 million of shares of common stock that may be offered and sold from time to time in one or more "at-the-market" offerings pursuant to a Controlled Equity Offering^{SM} Sales Agreement (the "ATM Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor") and Leerink Partners LLC. The ATM Sales Agreement replaced the Controlled Equity Offering^{SM} Sales Agreement dated November 4, 2020 by and among the Company, Cantor and Stifel, Nicolaus & Company, Incorporated (the "Prior ATM Sales Agreement"). During the three months ended March 31, 2024, the Company sold 365,316 shares of common stock in "at-the-market" offerings pursuant to the ATM Sales Agreement for net proceeds of $9.0 million, after deducting commissions and other offering related costs. No shares were sold under the Prior ATM Sales Agreement during the three months ended March 31, 2023. As of March 31, 2024, $140.6 million remained available under the ATM Sales Agreement.

7. Stock-Based Compensation

Stock option activity under the 2019 Equity Incentive Plan (the "2019 Plan") is set forth below for the three months ended March 31, 2024:

	Number of Shares Outstanding	Weighted Average Exercise Price Per Share	Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Balances at December 31, 2023	4,099,947	$ 21.00	7.6	$ 23,206
Stock options granted	1,426,119	24.41		
Stock options exercised	(14,374)	4.67		
Stock options forfeited	(27,202)	23.25		
Balances at March 31, 2024	5,484,490	$ 21.92	8.0	$ 1,289

As of March 31, 2024, 3,009,835 shares remained available for issuance under the 2019 Plan.

Restricted stock unit ("RSU") activity under the 2019 Plan is set forth below for the three months ended March 31, 2024:

	Number of Shares Outstanding	Weighted Average Grant Date Fair Value Per Share
Balances at December 31, 2023	13,500	$ 44.66
RSUs granted	—	—
RSUs vested and settled	(13,500)	44.66
RSUs forfeited	—	—
Balances at March 31, 2024	—	$ —

Stock-based compensation expense

Total stock-based compensation expense recognized for options and RSUs granted to both employees and non-employees and for the 2019 Employee Stock Purchase Plan (the "2019 ESPP") was as follows (in thousands):

	For the Three Months Ended March 31,	
	2024	2023
Research and development	$ 2,637	$ 1,960
General and administrative	2,761	2,134
Total stock-based compensation expense	$ 5,398	$ 4,094

As of March 31, 2024, unrecognized stock-based compensation expense related to outstanding unvested stock options and RSUs that are expected to vest was $51.6 million. This unrecognized stock-based compensation expense is expected to be recognized over 3.1 years.

The Company recorded stock-based compensation expense related to the 2019 ESPP of $0.3 million for each of the three months ended March 31, 2024 and 2023.

8. Net Loss Per Share

Net loss per share

The following table sets forth the computation of the basic and diluted net loss per share for the three months ended March 31, 2024 and 2023 (in thousands, except share and per share data):

	Three Months Ended March 31,	
	2024	2023
Numerator:		
Net loss	$ (30,521)	$ (29,271)
Denominator:		
Weighted-average shares used to compute net loss per share, basic and diluted	38,625,365	38,280,539
Net loss per share, basic and diluted	$ (0.79)	$ (0.76)

For the three months ended March 31, 2024 and 2023, 4,000,000 pre-funded warrants to purchase the Company's shares of common stock, issued in the May 2022 private placement financing, were included on a weighted average basis in the basic and diluted net loss per share calculation. As of March 31, 2024, all the pre-funded warrants issued in the private placement financing were outstanding.

Potential dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	As of March 31,	
	2024	2023
Stock options issued and outstanding under the 2019 Plan and 2015 Stock Plan	5,484,490	3,786,831
Estimated shares issuable under the 2019 ESPP	61,848	46,101
RSUs subject to future vesting	—	13,500
Total	5,546,338	3,846,432

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

The following discussion and analysis of our financial condition and results of operations should be read together with the unaudited condensed consolidated financial statements and related notes included in Item 1 of Part I of this Quarterly Report on Form 10-Q and with the audited consolidated financial statements and the related notes included in our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the Securities and Exchange Commission (the "SEC") on March 7, 2024. This discussion includes forward-looking statements based upon current beliefs, plans and expectations that involve risk, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results may differ materially from management's expectations as a result of various factors, including, but not limited to, those discussed in the section titled "Risk Factors" in this report. In some cases, you can identify forward-looking statements by terms such as "anticipates," "believes," "could," "estimates," "expects," "may," "plans," "potential" "predicts," "projects," "should," "will," "would" and similar expressions intended to identify forward-looking statements. Forward-looking statements represent our estimates and assumptions only as of the date of this Quarterly Report on Form 10-Q. Except as required by law, we assume no obligation to update or revise any forward-looking statements to reflect new information or future events, even if new information comes available in the future. You should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements.

Overview

We are a clinical stage immunology-based therapeutics company focused on discovering, developing and commercializing oral small molecule therapies for patients with significant unmet needs in inflammatory diseases and oncology. Utilizing our proprietary drug discovery and development engine, we are developing highly selective small molecules designed to modulate the critical immune responses underlying these diseases. Our two lead drug candidates, zelnecirnon (RPT193) and tivumecirnon (FLX475), each target C-C motif chemokine receptor 4 ("CCR4"), a drug target that potentially has broad applicability in inflammatory diseases and oncology.

In February 2024, the U.S. Food and Drug Administration ("FDA") placed clinical holds on both our Phase 2b trial of zelnecirnon in atopic dermatitis ("AD") and our Phase 2a trial of zelnecirnon in asthma. The clinical hold determination was based on a serious adverse event of liver failure requiring transplant in one patient in the AD trial. Dosing of zelnecirnon and enrollment of new trial participants were halted immediately in both clinical trials. In May 2024, we announced our decision to close and unblind both the Phase 2b trial in AD and the Phase 2a trial in asthma to inform our path forward and support our discussions with the FDA. Prior to the imposition of the clinical hold, a total of 229 patients had been enrolled in the Phase 2b AD trial, of which approximately 110 had completed the 16-week dosing period.

In April 2024, we announced safety and efficacy data from our ongoing Phase 2 trial of tivumecirnon in combination with the anti-PD-1 checkpoint inhibitor ("CPI") pembrolizumab in the cohort of patients with advanced head and neck squamous cell carcinoma ("HNSCC") whose disease progressed despite previous treatment with CPI therapy ("CPI-experienced"). The 32-patient CPI-experienced HNSCC cohort had heavily pretreated disease, with 69% of patients having received three or more (up to six) prior lines of treatment. In the entire cohort, confirmed responses were observed in 5/32 patients (15.6%) regardless of PD-L1 or HPV status. In the 23 patients known to have PD-L1+ disease (CPS $\geq$1), an ORR of 17.4% (4/23) was observed, and in the 18 patients known to have HPV+ disease, an ORR of 22.2% (4/18) was observed.

Financial Overview

Since commencing operations in 2015, we have devoted substantially all of our efforts and financial resources to building our research and development capabilities and establishing our corporate infrastructure. As a result, we have incurred net losses since inception. As of March 31, 2024, we had an accumulated deficit of $515.2 million. We have incurred net losses of $30.5 million and $29.3 million for the three months ended March 31, 2024 and 2023, respectively. We do not expect to generate product revenue unless and until we obtain approval for the commercialization of a drug candidate and we cannot assure you that we will ever generate significant product revenue or profits.

Since inception, we have financed our operations primarily through the sale of equity securities. As of March 31, 2024, we had cash and cash equivalents and marketable securities of $141.6 million and working capital of $127.2 million. On August 11, 2023, we filed a shelf registration statement on Form S-3 with the SEC, which was declared effective on August 17, 2023, related to the sale and issuance of up to $450 million of the Company's securities, including up to $150 million of shares of common stock that may be offered and sold from time to time in one or more "at-the-market" offerings pursuant to a Controlled Equity Offering[SM] Sales Agreement (the "ATM Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor") and Leerink Partners LLC. The ATM Sales Agreement replaced the Controlled Equity Offering[SM] Sales Agreement, dated November 4, 2020, by and among the Company, Cantor and Stifel, Nicolaus & Company, Incorporated. During the three months ended March 31, 2024, the Company sold 365,316 shares of common stock in "at-the-market" offerings pursuant to the ATM Sales Agreement, for net proceeds of $9.0 million, after deducting commissions and other offering related costs. As of March 31, 2024, there were up to $140.6 million of shares of common stock available for future issuance under the ATM Sales Agreement. We believe our current cash and cash equivalents and marketable securities will be sufficient to fund our planned operations for a period of at least 12 months following the filing date of this Quarterly Report on Form 10-Q.

We expect to incur substantial expenditures in the foreseeable future as we expand our pipeline and advance our drug candidates through clinical development, undergo the regulatory approval process and, if our drug candidates are approved, launch commercial activities. Specifically, in the near term, we expect to incur substantial expenses relating to our ongoing and planned clinical trials, including efforts to resolve the clinical holds on the Phase 2b trial of zelnecirnon in AD and the Phase 2a trial in asthma, the development and validation of our manufacturing processes and other development activities.

We will need substantial additional funding to support our continuing operations and pursue our development strategy. Until we can generate significant revenue from sales of our drug candidates, if ever, we expect to finance our operations through equity or debt financings or other capital sources, including potential collaborations with other companies, or other strategic transactions. Adequate funding may not be available to us on acceptable 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 and commercialization of our drug candidates or delay our efforts to expand our product pipeline. We may also be required to sell or license to other parties rights to develop or commercialize our drug candidates.

Components of Operating Results

Research and Development Expenses

We expense both internal and external research and development costs as such expenses are incurred. We track the external research and development costs incurred for each of our drug candidates. However, we do not track our internal research and development costs by drug candidate as the related efforts and their costs are typically spread across multiple drug candidates.

We account for non-refundable advance payments for goods or services that will be used in future research and development activities as expenses when the goods have been received or when the service has been performed rather than when the payment is made.

Clinical trial costs are a component of research and development expenses. We expense costs for our clinical trial activities performed by third parties, including clinical research organizations ("CROs") and other service providers, as they are incurred, based upon estimates of the work completed over the life of the individual study in accordance with the associated agreements. We use information received from our personnel and outside service providers to estimate the clinical trial costs incurred.

External research and development expenses consist primarily of costs incurred for the development of our drug candidates and include:

- costs incurred under agreements with CROs, investigative sites and consultants to conduct our clinical trials and preclinical and non-clinical studies;
- costs to acquire, develop and manufacture supplies for clinical trials and other studies, including fees paid to contract manufacturing organizations ("CMOs"); and
- costs related to compliance with drug development regulatory requirements.

Internal research and development costs include:

- salaries and related costs, including stock-based compensation and travel expenses, for personnel in our research and development functions; and
- depreciation and other allocated facility-related and overhead expenses.

Although we expect our research and development expenses to decrease in the near term due to the clinical holds that have been placed on the zelnecirnon clinical trials described above, we expect to devote substantial resources towards research and development during the next few years as we seek to complete existing and initiate additional clinical trials, pursue regulatory approval of zelnecirnon and tivumecirnon and advance other programs into clinical development. Predicting the timing or the final cost to complete our clinical program or validation of our manufacturing and supply processes is difficult and delays may occur because of many factors.

General and Administrative Expenses

General and administrative expenses consist principally of personnel-related costs, including payroll and stock-based compensation for personnel in executive, finance, human resources, business and corporate development and other administrative functions; professional fees for legal, consulting and accounting services; rent and other facilities costs; depreciation and other general operating expenses not otherwise classified as research and development expenses.

We expect to continue to incur expenses to support our continued operations as a public company, including expenses related to compliance with the rules and regulations of the SEC and Nasdaq Global Market, insurance expenses, investor relations expenses, audit fees, professional services and general overhead and administrative costs.

Other Income, Net

Our cash and cash equivalents and marketable securities are invested in money market funds, corporate debt securities, commercial paper and U.S. government agency securities. Other income, net, consists primarily of interest earned on our cash and cash equivalents and marketable securities and remeasurement gains and losses on foreign currency transactions.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

There have been no significant changes in our critical accounting policies and estimates during the three months ended March 31, 2024, as compared to the critical accounting policies and estimates disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 7, 2024. Our significant accounting policies are also described in "Summary of Significant Accounting Policies" in Note 2 of the accompanying condensed consolidated financial statements.

Results of Operations

Comparison of the Three Months Ended March 31, 2024 and 2023

The following table summarizes our results of operations for the periods indicated (in thousands):

	Three Months Ended March 31,			
	2024	2023	$ Change	% Change
Operating expenses:				
Research and development	24,781	25,574	(793)	(3)%
General and administrative	7,737	5,988	1,749	29%
Total operating expenses	32,518	31,562	956	3%
Loss from operations	(32,518)	(31,562)	(956)	3%
Other income, net	1,997	2,291	(294)	(13)%
Net loss	$ (30,521)	$ (29,271)	$ (1,250)	4%

Research and Development Expenses

Research and development expenses decreased $0.8 million, or 3%, to $24.8 million for the three months ended March 31, 2024, from $25.6 million for the three months ended March 31, 2023. The decrease in research and development expenses was primarily due to decreases of $1.3 million in development costs related to zelnecirnon, $1.3 million in development costs related to tivumecirnon, $0.7 million in development costs related to early-stage programs and $0.5 million in lab supplies costs, partially offset by increases of $1.8 million in personnel costs, $0.3 million in consulting costs, $0.2 million in facilities costs and $0.7 million in stock-based compensation expense.

The following is a comparison of research and development expenses for the three months ended March 31, 2024 and 2023 (in thousands):

	Three Months Ended March 31,	
	2024	2023
External development expenses:		
Zelnecirnon (formerly RPT193)	$ 7,841	$ 9,091
Tivumecirnon (formerly FLX475)	2,157	3,510
Other programs	203	938
Internal research and development expenses	14,580	12,035
Total research and development expenses	$ 24,781	$ 25,574

As previously noted, we do not track our internal research and development expenses by drug candidate, as the related efforts and their costs are typically spread across multiple drug candidates.

General and Administrative Expenses

General and administrative expenses increased $1.7 million, or 29%, to $7.7 million for the three months ended March 31, 2024, from $6.0 million for the three months ended March 31, 2023. The increase in general and administrative expenses was primarily due to increases of $0.6 million in personnel costs, $0.6 million in stock-based compensation expense, $0.4 million in consulting costs and $0.1 million in facilities costs.

Other Income, Net

Other income, net decreased $0.3 million, or 13%, to $2.0 million for the three months ended March 31, 2024, from $2.3 million for the three months ended March 31, 2023. The decrease was driven primarily by a decrease in interest income due to lower invested cash balances for the three months ended March 31, 2024.

Liquidity and Capital Resources; Plan of Operations

Since inception, we have financed our operations primarily through the sale of equity securities. During the three months ended March 31, 2024, we sold 365,316 shares of common stock in “at-the-market” offerings pursuant to the ATM Sales Agreement, for net

proceeds of $9.0 million, after deducting commissions and other offering related costs. As of March 31, 2024, up to $140.6 million of shares of common stock were available for future issuance under the ATM Sales Agreement. As of March 31, 2024, we had cash and cash equivalents and marketable securities of $141.6 million and working capital of $127.2 million. Our cash equivalents and marketable securities consist of commercial paper, corporate debt securities and U.S. government agency securities. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view towards liquidity and capital preservation. Since inception, we have incurred net losses and negative cash flows from operations.

As of March 31, 2024, we had an accumulated deficit of $515.2 million. We expect to incur substantial costs in order to conduct research and development activities necessary to develop and commercialize our existing and future drug candidates. Additional capital will be needed to undertake these activities and we intend to raise such capital through the issuance of additional equity or debt, strategic alliances with other companies or other sources of financing. However, if such capital is not available at adequate levels or on acceptable terms, we could be required to significantly reduce operating expenses and delay or reduce the scope of, or eliminate, some of our research or development programs. We believe our current cash and cash equivalents and marketable securities will be sufficient to fund our anticipated level of operations through at least the next 12 months following the filing date of this report.

We will continue to require additional capital to develop our drug candidates and fund operations for the foreseeable future. We may seek to raise capital through private or public equity or debt financings, collaborative or other arrangements with other companies or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. We anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including:

- the scope, rate of progress and costs of our drug discovery, preclinical development activities, laboratory testing and clinical trials for our drug candidates;
- the number and scope of clinical programs we decide to pursue;
- the scope and costs of manufacturing development and commercial manufacturing activities;
- the extent to which we acquire or in-license other drug candidates and technologies;
- the cost, timing and outcome of regulatory review of our drug candidates;
- the cost and timing of establishing sales and marketing capabilities, if any of our drug candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our drug candidates;
- the costs associated with being a public company; and
- the cost associated with commercializing our drug candidates, if they receive marketing approval.

Additionally, the global financial markets have experienced significant disruptions due to various macroeconomic factors, including, among other things, the impact of ongoing overseas conflicts, resulting in a general global economic slowdown. Furthermore, inflation rates, particularly in the United States and the United Kingdom, have increased to levels not seen in decades. In addition, the U.S. Federal Reserve has raised, and may further raise, interest rates in response to concerns about inflation. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may further increase economic uncertainty and heighten these risks. Moreover, the failures of Silicon Valley Bank, Signature Bank and First Republic Bank have resulted in broader financial institution liquidity risk and concerns. If other banks and financial institutions fail or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our cash, cash equivalents and investments may be threatened and our ability to raise additional capital could be substantially impaired. If the disruptions and slowdown deepen or persist, we may not be able to access additional capital on favorable terms, or at all, which could in the future negatively affect our ability to pursue our business strategy. See “Risk Factors” for additional risks associated with our substantial capital requirements.

If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any equity or debt financing may contain terms that are not favorable to us or our stockholders. If we are unable to raise additional funds when needed, we may be required to delay, reduce or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to other parties rights to develop or commercialize our drug candidates that we would prefer to retain.

Summary Condensed Consolidated Statement of Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented below (in thousands):

	Three Months Ended March 31,	
	2024	**2023**
Net cash (used in) provided by:		
Operating activities	$ (27,084)	$ (18,602)
Investing activities	15,887	25,308
Financing activities	9,036	116
Net (decrease) increase in cash and cash equivalents	$ (2,161)	$ 6,822

Cash Used in Operating Activities

Net cash used in operating activities was $27.1 million for the three months ended March 31, 2024, reflecting a net loss of $30.5 million and changes in operating assets and liabilities of $1.9 million, partially offset by non-cash charges primarily for depreciation, amortization, non-cash operating lease expense and stock-based compensation expense totaling $5.3 million. The $8.5 million increase in cash used in operating activities for the quarter ended March 31, 2024, as compared to the quarter ended March 31, 2023, was primarily due to a $9.0 million net change in net operating assets and liabilities and a $1.3 million increase in our net loss, partially offset by a $0.5 million decrease in accretion of discount on marketable securities and a $1.3 million increase in stock-based compensation expense.

Net cash used in operating activities was $18.6 million for the three months ended March 31, 2023, reflecting a net loss of $29.3 million, partially offset by non-cash charges primarily for depreciation, amortization, non-cash operating lease expense and stock-based compensation expense totaling $3.5 million and net cash provided by changes in operating assets and liabilities of $7.2 million.

Cash Provided by Investing Activities

Cash provided by investing activities was $15.9 million for the three months ended March 31, 2024, primarily from the proceeds from maturities of marketable securities of $32.8 million, partially offset by the purchases of marketable securities of $16.8 million and purchase of property and equipment for $0.1 million. Cash provided by investing activities was $25.3 million for the three months ended March 31, 2023, primarily from the proceeds from maturities of marketable securities of $63.9 million, partially offset by the purchases of marketable securities of $37.8 million and purchase of property and equipment for $0.8 million.

Cash Provided by Financing Activities

Net cash provided by financing activities was $9.0 million for the three months ended March 31, 2024, consisting of net proceeds from the sale of shares under the ATM Sales Agreement. Net cash provided by financing activities was $0.1 million for the three months ended March 31, 2023 from exercises of stock options under our employee stock plans.

Material Cash Requirements

Our cash requirements in the ordinary course of business have not materially changed from those disclosed under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Material Cash Requirements” in our Annual Report on Form 10-K for the year ended December 31, 2023, filed on March 7, 2024 with the SEC.

Emerging Growth Company Status 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. We are choosing to elect the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates. We may take advantage of these provisions until December 31, 2024.

In addition, we are also a smaller reporting company as defined in the Securities Exchange Act of 1934, as amended (the "Exchange Act"). We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, we are not required to provide this information.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of March 31, 2024. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2024, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

Management determined that, as of March 31, 2024, there were no changes in our internal control over financial reporting that occurred during the fiscal quarter then ended 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 legal proceedings arising in the ordinary course of our business. Our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which would have a material adverse effect on our results of operations, financial condition or cash flows.

Item 1A. Risk Factors

Our business and investing in our common stock involve a high degree of risk. You should consider and read carefully all of the risks and uncertainties described below, as well as other information included in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and related notes, our "Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as our other public filings. The risks described below are not the only ones facing us. The occurrence of any of 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, prospects and stock price. In such a case, the market price of our common stock could decline and you may lose all or part of your original investment. This Quarterly Report on Form 10-Q also contains forward-looking statements and estimates that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of specific factors, including the risks and uncertainties described below.

Summary of Risk Factors

The risks described below are not the only ones facing us. The occurrence of any of 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, prospects and stock price. Some of these risks are:

- Our Phase 2 clinical trials of zelnecirnon are on clinical hold and, if the FDA does not lift the holds, we may be unable to continue clinical development of zelnecirnon.
- Our current or future product candidates may fail or suffer delays in clinical development that materially and adversely affect their commercial viability.
- We are a clinical stage therapeutics company with a history of losses. We expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.
- We may not be successful in our efforts to use and expand our proprietary drug discovery and development engine to build a pipeline of drug candidates, and as an organization we have no history of successfully developing drugs.
- Even if regulatory approval is obtained for zelnecirnon, tivumecirnon or any other potential drug candidate, the drug candidate we commercialize may not achieve market acceptance and we may not generate any revenue from the sale or licensing of our drug candidates.
- Undesirable side effects caused by zelnecirnon, tivumecirnon or any other potential drug candidate could cause regulatory authorities to interrupt, delay or halt clinical trials and could result in the delay or denial of regulatory approval by the FDA or other regulatory authorities, which could compromise our ability to market and derive revenue from our drug candidates. For example, the clinical holds placed on our Phase 2b trial of zelnecirnon in AD and our Phase 2a trial of zelnecirnon in asthma were based on a serious adverse event of liver failure requiring transplant in one patient in the AD trial. In May 2024, we announced our decision to close and unblind both studies to support our discussions with the FDA. However, we may be unable to establish causation of the serious adverse event or satisfactorily address the issues required to resolve the clinical holds in a timely manner or at all and we expect to incur additional expenses in connection with our efforts to resolve the clinical holds.
- We will need substantial additional funds to advance development of drug candidates and our drug discovery and development engine, and we cannot guarantee that we will have sufficient funds available in the future to develop and commercialize our current or potential future drug candidates. For example, our efforts to address the clinical holds and advance zelnecirnon may result in significant additional expenses.
- Because we may rely on third parties for manufacturing and supply of our drug candidates, some of which are sole source vendors, our supply may become limited or interrupted or may not be of satisfactory quantity or quality.

- If third parties on which we rely to conduct certain preclinical studies and clinical trials do not perform as contractually required, fail to satisfy regulatory or legal requirements or miss expected deadlines, our development program could be delayed with material and adverse impacts on our business and financial condition.
- We face intense competition from companies that have developed or may develop biologics and small molecule drugs for the treatment of inflammatory diseases and cancer. If these companies develop technologies or drug candidates more rapidly than we do, or if their technologies or drug candidates are more effective, our ability to develop and successfully commercialize drug candidates may be adversely affected.
- If any of our drug candidates is approved for marketing and commercialization in the future and we are unable to develop sales, marketing and distribution capabilities on our own or enter into agreements with third parties to perform these functions on acceptable terms, we will be unable to successfully commercialize any such future products.
- Our business could be materially and adversely affected in the future by effects of disease outbreaks, epidemics and pandemics.
- If we are unable to obtain, maintain, enforce or defend intellectual property rights related to our technology and current or future drug candidates, or if our intellectual property rights are inadequate, we may not be able to compete effectively.
- Our stock price may be volatile. Raising additional capital and other future issuances of our common stock or rights to purchase common stock could result in additional dilution and could cause our stock price to fall.
- Our principal stockholders and management own a significant percentage of our stock and are able to exert significant control over matters subject to stockholder approval.
- Failure or perceived failure to comply with existing or future laws, regulations, contracts, self-regulatory schemes, standards and other obligations related to data privacy and security (including security incidents) could harm our business. Compliance or the actual or perceived failure to comply with such obligations could increase the costs of our products, limit their use or adoption and otherwise negatively affect our operating results and business.

Risks Related to Our Business

Our Phase 2 clinical trials of zelnecirnon are on clinical hold and, if the FDA does not lift the holds, we may be unable to continue clinical development of zelnecirnon. Our current or future product candidates may fail or suffer delays in clinical development that materially and adversely affect their commercial viability.

In February 2024, the FDA placed clinical holds on both our Phase 2b trial of zelnecirnon in AD and our Phase 2a trial of zelnecirnon in asthma. The clinical hold determination was based on a serious adverse event of liver failure requiring transplant in one patient in the AD trial. Dosing of zelnecirnon and enrollment of new trial participants were halted immediately in both clinical trials. In May 2024, we announced our decision to close and unblind both the Phase 2b trial in AD and the Phase 2a trial of zelnecirnon in asthma to inform our path forward and support our discussions with the FDA. We may be unable to establish causation of the serious adverse event or satisfactorily address the issues required to resolve the clinical holds in a timely manner or at all, and we expect to incur additional expenses in connection with our efforts to resolve the clinical holds, which may be significant. If the FDA does not lift the clinical holds, we may be unable to continue clinical development of zelnecirnon, which would have a material adverse effect on our business, financial position and prospects.

We have no products on the market or that have gained regulatory approval. Other than zelnecirnon and tivumecirnon, none of our drug candidates has ever been tested in humans. None of our drug candidates has advanced into late-stage development or a pivotal clinical trial and it may be years before any such trial is initiated, if at all. Our ability to achieve and sustain profitability depends on us developing, obtaining regulatory approval for and successfully commercializing one or more drug candidates, either alone or with partners.

Before obtaining regulatory approval for any of our drug candidates, we must conduct extensive preclinical studies and clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. As noted above, the FDA has placed both our clinical trials of zelnecirnon on clinical hold following a serious adverse event of liver failure requiring transplant, and we may be unable to demonstrate the safety of zelnecirnon to the FDA's satisfaction. With respect to tivumecirnon, although we have successfully completed preclinical studies and a Phase 1 clinical trial with healthy volunteers, and are conducting a Phase 1/2 clinical trial investigating tivumecirnon as a single agent and in combination with pembrolizumab in a range of tumors, more clinical trials are needed. There is no guarantee that the FDA will lift the clinical holds on the Phase 2 clinical trials of zelnecirnon or permit us to conduct additional clinical trials for zelnecirnon, tivumecirnon or any other potential drug candidates. Further, we cannot be certain of the timely completion or outcome of any of our clinical trials and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs, or if the outcome of any preclinical studies or clinical trials will ultimately support the further development of zelnecirnon, tivumecirnon or any other potential drug candidates.

Our clinical development efforts are subject to the risks of failure inherent in the development of drug candidates based on novel approaches, targets and mechanisms of action. Although zelnecirnon has shown activity in several preclinical models and in the placebo-controlled Phase 1b portion of the Phase 1a/1b trial in a small number of patients with AD, there is no guarantee that the data from our Phase 2b trial in patients with AD or our Phase 2a trial in patients with asthma, or from any future clinical trials if we are permitted by the FDA to continue the clinical development of zelnecirnon, will show benefit to patients. Additionally, while tivumecirnon is currently in a Phase 1/2 clinical trial and has shown activity in a small number of patients with non-small cell lung cancer, there is no guarantee that tivumecirnon will ultimately prove to benefit patients. In the ongoing Phase 1/2 clinical trial of tivumecirnon, drug responses have been observed in a small number of patients. It is possible that no further responses will be observed in other patients or that the observed responses in patients who received tivumecirnon and pembrolizumab were caused solely by the pembrolizumab administered to the patient and not by tivumecirnon, or that the responses were spontaneous and unrelated to either tivumecirnon or pembrolizumab. We have discontinued, and may elect in the future to discontinue, development of tivumecirnon in certain indications if, among other reasons, data does not warrant moving forward. For example, in 2022, we made the decision not to move forward with development of tivumecirnon in nasopharyngeal cancer and checkpoint-naïve head and neck squamous cell carcinoma. Additionally, we may be unable to enroll the trial or complete the dosing interval due to the impact of unexpected world events. There can be no assurance that the intended effects of our drug candidates will be observed or avoided, as the case may be, in clinical trials or that the drug candidate will offer any significant clinical benefit to humans. Results in preclinical studies do not necessarily predict the results of clinical studies. Additionally, even though our drug candidates are designed to address the same indications as existing drugs and therapies, we have not conducted head-to-head clinical trials comparing our drug candidates with such existing drugs and therapies. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by clinical and preclinical stage therapeutics companies such as ours.

Tivumecirnon is currently undergoing clinical development and testing as a single agent and in combination with pembrolizumab (supplied by Merck under our existing collaboration agreement). Were Merck to terminate our collaboration agreement, we would be required to purchase pembrolizumab to continue our current and planned clinical trials or to introduce another anti-PD-1 therapy for co-administration with tivumecirnon in place of pembrolizumab, which may require us to restart preclinical studies or clinical trials. This could result in a change to our business plan and materially harm our business, financial condition, or results of operations and prospects. In addition, if tivumecirnon is approved as a treatment in combination with pembrolizumab, then the future availability of pembrolizumab for administration with tivumecirnon would affect our ability to commercialize tivumecirnon. For example, if the supply of pembrolizumab were constrained for any reason it could have the effect of limiting the commercial uptake of tivumecirnon, if approved for commercial sale.

We may not have the financial resources to continue development of, or to enter into new collaborations or partnerships for our existing or any potential future drug candidates. Our position may be exacerbated if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, a drug candidate, such as :

- the clinical holds that have been placed on our Phase 2b trial of zelnecirnon in AD and our Phase 2a trial of zelnecirnon in asthma;
- negative or inconclusive results from our clinical trials or the clinical trials of others for drug candidates similar to ours, leading to a decision or requirement to conduct additional preclinical studies or clinical trials or abandon a program;
- product-related side effects experienced by participants in our clinical trials or by individuals using drugs or therapeutics similar to ours;

- delays in submitting Investigational New Drug Applications ("INDs") or comparable foreign applications, or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA, or other regulatory authorities, regarding the scope or design of our clinical trials;
- suspension or termination of our clinical trials for various reasons, including a clinical hold based on a finding that our drug candidates have undesirable side effects or other unexpected characteristics, or that the participants are being exposed to unacceptable health risks, such as the clinical hold described above;
- delays in enrolling research subjects in clinical trials;
- high drop-out rates of research subjects;
- inadequate supply or quality of drug candidate components or materials or other supplies necessary for the conduct of our clinical trials;
- greater-than-anticipated clinical trial costs;
- poor effectiveness of our drug candidates during clinical trials;
- unfavorable FDA or other regulatory agency inspections and review of a clinical trial or manufacturing site;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policies and guidelines; or
- the FDA's or other regulatory agencies' data interpretation.

Further, we and our potential future partners may never receive approval to market and commercialize any drug candidate. Even if we or a potential future partner obtain regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We or a potential future partner may be subject to post-marketing testing requirements to maintain regulatory approval.

We are a clinical stage therapeutics company with a history of losses. We expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability, which could result in a decline in the market value of our common stock.

Since our inception, we have devoted substantially all of our resources to research and development, including our drug discovery and development engine, preclinical studies and clinical trials; raising capital; building our management team; and developing and maintaining our intellectual property portfolio. Our net loss was $30.5 million and $29.3 million for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024, we had an accumulated deficit of $515.2 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. Furthermore, we do not expect to generate any revenue from product sales for the foreseeable future, and we expect to continue to incur significant operating losses for the foreseeable future due to the cost of research and development, preclinical studies, clinical trials and the regulatory approval process for our current and potential future drug candidates.

We expect to continue incurring net losses as we make efforts to advance the clinical development of our lead drug candidates, zelnecirnon and tivumecirnon. However, the amount of our future losses is uncertain. Our ability to generate revenue from product sales and achieve or sustain profitability, if ever, will depend on, among other things, successfully developing drug candidates, obtaining regulatory approvals to market and commercialize drug candidates, manufacturing any approved products on commercially reasonable terms, entering into any future collaborations or other partnerships, establishing a sales and marketing organization or suitable third-party alternatives for any approved product and raising sufficient capital to finance our operations. If we, or any of our future partners, are unable to develop and commercialize one or more of our drug candidates, or if sales revenue from any drug candidate that receives regulatory approval is insufficient, we will not achieve or sustain profitability, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

Zelnecirnon, tivumecirnon or other future drug candidates may not demonstrate the safety and efficacy necessary to support further clinical development or commercial viability. Further, success in research and preclinical studies or early clinical trial results may not be indicative of results obtained in later trials. Likewise, preliminary, initial or interim data from clinical trials may be materially different from final data.

We have completed a Phase 1a/1b trial of zelnecirnon in healthy volunteers and in patients with AD. We were previously conducting a Phase 2b trial of zelnecirnon in patients with AD and a Phase 2a trial in asthma. However, in February 2024, the FDA placed clinical holds on those studies based on a serious adverse event of liver failure requiring transplant in one patient in the AD trial. Dosing of zelnecirnon and enrollment of new trial participants were halted immediately in both clinical trials. In May 2024, we announced our decision to close and unblind both trials to inform our path forward and support our discussions with the FDA. We may be unable to establish causation of the serious adverse event or satisfactorily address the issues required to resolve the clinical holds in a timely manner or at all and we expect to incur additional expenses in connection with our efforts to resolve the clinical holds. If the FDA does not lift the clinical holds, we may be unable to continue clinical development of zelnecirnon.

In addition, we have completed a Phase 1 clinical trial with healthy volunteers for tivumecirnon. We are conducting a Phase 1/2 clinical trial investigating tivumecirnon as a single agent and in combination with pembrolizumab. We may ultimately discover that neither zelnecirnon nor tivumecirnon meet criteria to be determined to be therapeutically effective or safe. As a result, we may never succeed in developing a marketable product based on zelnecirnon or tivumecirnon. If zelnecirnon, tivumecirnon or any of our potential future drug candidates prove to be ineffective, unsafe or commercially unviable, our entire pipeline could have little, if any, value, which could require us to change our focus and approach to small molecule discovery and development, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

Additionally, results from research and preclinical studies or early clinical trials are not necessarily predictive of future clinical trial results, and preliminary, initial and interim results of a clinical trial are not necessarily indicative of final results. From time to time, we have and may in the future publish or report preliminary, initial or interim data. Preliminary, initial or interim data from our clinical trials and those of our collaborators may not be indicative of the final results of the trial and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and/or more patient data become available. In this regard, such data may show initial evidence of clinical benefit but, as patients continue to be followed and more patient data becomes available, there is a risk that any therapeutic effects will not be durable in patients and/or will decrease over time, or cease entirely. Preliminary, initial or interim data also remain subject to audit and verification procedures that may result in the final data being materially different from such preliminary, initial or interim data. As a result, preliminary, initial or interim data should be considered carefully and with caution until the final data are available.

In addition, there is a high failure rate for product candidates proceeding through clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. Any such setbacks could adversely affect our business, financial condition, results of operations and prospects.

We may not be successful in our efforts to use and expand our proprietary drug discovery and development engine to build a pipeline of drug candidates, and as an organization we have no history of successfully developing drugs.

A key element of our strategy is to use and expand our proprietary drug discovery and development engine to build a pipeline of potential drug candidates and advance these drug candidates through preclinical studies and clinical development for the treatment of various diseases. As an organization, we have never developed a drug candidate through to commercialization nor have we ever conducted a pivotal clinical trial. Although our research and development efforts to date have resulted in our identification and development of zelnecirnon, tivumecirnon and other potential future drug candidates, neither our proprietary drug discovery and development engine nor our organization has a track record of success. Our current drug candidates may not be safe or effective therapeutics and we may not be able to develop any successful drug candidates. Our proprietary drug discovery and development engine is evolving and may not reach a state at which building a pipeline of drug candidates is possible. Even if we are successful in building our pipeline of drug candidates, the potential drug candidates that we identify may not be suitable for clinical development or generate acceptable clinical data, including unacceptable toxicity or other characteristics that indicate that the drug candidates are unlikely to be products that will receive marketing approval from the FDA or other regulatory authorities or achieve market acceptance. Even if the drug candidates we identify are suitable for clinical development, our lack of experience as an organization at developing drugs may cause us to fail in successfully developing the drug candidate through to commercialization. If we do not successfully develop and commercialize drug candidates, we will not be able to generate product revenue in the future.

Failure to successfully validate, develop and obtain regulatory approval for companion diagnostics for our drug candidates could harm our drug development strategy and operational results.

As one of the elements of our clinical development approach, we may seek to screen and identify subsets of patients who are more likely to benefit from our drug candidates. To achieve this, we may seek to develop and commercialize companion diagnostics by us or by third-party collaborators. Companion diagnostics are sometimes developed in conjunction with clinical programs for an associated product. The approval of a companion diagnostic as part of the product label would limit the use of the drug candidate to those patients who are more likely to benefit from our drug candidate.

Companion diagnostics are subject to regulation by the FDA and other regulatory authorities as medical devices and require separate clearance or approval prior to their commercialization. To date, the FDA has required premarket approval of all companion diagnostics for oncology therapies. We may encounter difficulties in developing and obtaining approval for these companion diagnostics. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval of a companion diagnostic could delay or prevent approval of our related drug candidates. The time and cost associated with developing a companion diagnostic may not prove to have been necessary in order to successfully market the product.

The market may not be receptive to our current or potential future drug candidates, and we may not generate any revenue from the sale or licensing of our drug candidates.

Even if regulatory approval is obtained for a drug candidate, including zelnecirnon or tivumecirnon, we may not generate or sustain revenue from sales of such products. Market acceptance of our current and potential future drug candidates will depend on, among other factors:

- the timing of our receipt of any marketing and commercialization approvals;
- the terms of any approvals and the countries in which approvals are obtained;
- the safety and efficacy of our drug candidates;
- the prevalence and severity of any adverse side effects associated with our drug candidates;
- limitations or warnings contained in any labeling approved by the FDA or other regulatory authority;
- relative convenience and ease of administration of our drug candidates;
- the extent to which physicians recommend our products to their patients;
- the availability of coverage and adequate government and third-party payor reimbursement;
- the pricing of our products, particularly as compared to alternative treatments; and
- the availability of alternative effective treatments for the disease indications our drug candidates are intended to treat and the relative risks, benefits and costs of those treatments.

If any drug candidate we commercialize fails to achieve market acceptance, it could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We may not be successful in our efforts to expand indications for approved drug candidates.

Part of our drug development strategy is to clinically test and seek regulatory approval for our drug candidates in indications in which we believe there is the most evidence that we will be able to quickly generate proof of concept data. We then intend to expand clinical testing and seek regulatory approvals in other indications within oncology and inflammatory diseases. Conducting clinical trials for additional indications for our drug candidates requires substantial technical, financial and human resources and is prone to the risks of failure inherent in drug development. We cannot provide you any assurance that we will be successful in our effort to obtain regulatory approval for our drug candidates for additional indications even if we obtain approval for an initial indication.

If we or others later identify undesirable side effects caused by zelnecirnon or tivumecirnon, our ability to market and derive revenue from the drug candidate could be compromised.

Undesirable side effects caused by zelnecirnon, tivumecirnon or any other potential future drug candidate could cause regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. For example, in February 2024, the FDA placed clinical holds on both our Phase 2b trial of zelnecirnon in AD and our Phase 2a trial of zelnecirnon in asthma based on a serious adverse event of liver failure requiring transplant in one patient in the AD trial. Dosing of zelnecirnon and enrollment of new trial participants were halted immediately in both clinical trials. In May 2024, we announced our decision to close and unblind both the Phase 2b trial in AD and the Phase 2a trial in asthma to inform our path forward and support our discussions with the FDA. We may be unable to establish causation of the serious adverse event or satisfactorily address the issues required to resolve the clinical holds in a timely manner or at all and we expect to incur additional expenses in connection with our efforts to resolve the clinical holds, which may be significant. If the FDA does not lift the clinical holds, we may be unable to continue clinical development of zelnecirnon, which would have a material adverse effect on our business, financial position and prospects.

While we have not discovered any adverse side effects of tivumecirnon in healthy subjects that have limited our ability to test tivumecirnon in humans, it is possible that there will be undesirable side effects associated with its use. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of these side effects. In such an event, our trials could be suspended or terminated, and the FDA or other regulatory authorities could order us to cease further development, or deny approval, of a drug candidate for any or all targeted indications. Such side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may materially and adversely affect our business and financial condition and impair our ability to generate revenue.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of a drug candidate may only be uncovered when a significantly larger number of patients are exposed to the drug candidate or when patients are exposed for a longer period of time.

If any of our current or potential future drug candidates receive regulatory approval and we or others identify undesirable side effects caused by one of these products, any of the following adverse events could occur, which could result in the loss of significant revenue to us and materially and adversely affect our results of operations and business:

- regulatory authorities may withdraw their approval of the product or seize the product;
- we may be required to recall the product or change the way the product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we may be required to create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

We will need substantial additional funds to advance development of drug candidates and our drug discovery and development engine, and we cannot guarantee that we will have sufficient funds available in the future to develop and commercialize our current or potential future drug candidates.

Since our inception, we have used substantial amounts of cash to fund our operations and expect our expenses to increase substantially in the foreseeable future. Developing our drug candidates and conducting clinical trials for the treatment of inflammatory diseases, cancer and any other indications that we may pursue in the future will require substantial amounts of capital. Accordingly, we expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, initiate clinical trials of and seek marketing approval for, our drug candidates. In addition, if we obtain marketing approval for any of our drug candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Furthermore, we expect to continue to incur costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

As of March 31, 2024 we had $141.6 million in cash and cash equivalents and marketable securities. Based on current business plans, we believe that our current cash and cash equivalents and marketable securities will provide sufficient funds to enable us to meet our obligations for at least the next 12 months from the date of this Quarterly Report on Form 10-Q. Our future capital requirements and the period for which we expect our existing resources to support our operations may vary significantly from what we expect. Our monthly spending levels vary based on new and ongoing research and development and other corporate activities. Because of the numerous risks and uncertainties associated with the development and commercialization of our current and potential future drug candidates and the extent to which we may enter into collaborations with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated preclinical studies, clinical trials and any approved marketing and commercialization activities. The timing and amount of our operating expenditures will depend largely on:

- the timing and progress of preclinical and clinical development activities;
- the timing and progress of the advancement of our drug discovery and development engine, including our ability to satisfactorily address the issues resulting in the clinical holds in a timely manner or at all;
- the price and pricing structure that we are able to obtain from our third-party contract manufacturers to manufacture our preclinical study and clinical trial materials and supplies;
- the number and scope of preclinical and clinical programs we decide to pursue;
- our ability to maintain our current licenses, collaboration and research and development programs, including the continued agreement of Merck to supply pembrolizumab to us for use in our clinical trials;
- our ability to establish new collaborations;
- the progress of the development efforts of parties with whom we may in the future enter into collaboration and research and development agreements;
- the costs involved in obtaining, maintaining, enforcing and defending patents and other intellectual property rights;
- the cost and timing of regulatory approvals; and
- our efforts to enhance operational systems, secure sufficient laboratory space and hire additional personnel, including personnel to support development of our drug candidates and satisfy our obligations as a public company.

To date, we have primarily financed our operations through the sale of equity securities. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. We cannot assure you that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us. While the long-term economic impact of ongoing overseas conflicts and potential future disruptions in access to bank deposits or lending commitments due to bank failures are difficult to assess or predict, each of these events has caused significant disruptions to the global financial markets and contributed to a general global economic slowdown. Furthermore, inflation rates, particularly in the United States and the U.K., have increased to levels not seen in decades. Increased inflation may result in increased operating costs (including labor costs) and may affect our operating budgets. In addition, the U.S. Federal Reserve has raised, and may further raise, interest rates in response to concerns about inflation. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may further increase economic uncertainty and heighten these risks. Moreover, the failures of Silicon Valley Bank, Signature Bank and First Republic Bank have resulted in broader financial institution liquidity risk and concerns. If the equity and credit markets deteriorate, including as a result of macroeconomic or other global conditions such as inflation, rising interest rates, prospects of a recession, government shutdowns, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. In any event, if the disruptions and slowdown deepen or persist, we may not be able to access additional capital on favorable terms, or at all, which could in the future negatively affect our financial condition and our ability to pursue our business strategy.

If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our preclinical studies, clinical trials, research and development programs or commercialization efforts. To the extent that we raise additional capital through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our current and potential future drug candidates, future revenue streams or research programs or to grant licenses on terms that may not be favorable to us. If we do raise additional capital through public or private equity or convertible debt offerings, the ownership interest of our existing stockholders will be diluted and the terms of these securities may include liquidation preferences or other rights that adversely affect our and our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

We do not expect to realize revenue from product sales in the foreseeable future, if at all, and unless and until our current and potential future drug candidates are clinically tested, approved for commercialization and successfully marketed.

We may expend our limited resources to pursue a particular drug candidate and fail to capitalize on drug candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we intend to prioritize our efforts on specific research and development programs, including clinical development of zelnecirnon, tivumecirnon or other future drug candidates. As a result, we may forgo or delay pursuit of other opportunities, including with potential future drug candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and drug candidates for specific indications may not yield any commercially viable drug candidates. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through partnership, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate.

We may not be able to enter into collaborations or strategic transactions on acceptable terms, if at all, which could adversely affect our ability to develop and commercialize current and potential future drug candidates, impact our cash position and increase our expenses.

From time to time, we may consider strategic transactions, such as collaborations, acquisitions of companies, asset purchases, joint ventures and out- or in-licensing of drug candidates or technologies. For example, we entered a Collaboration and License Agreement with Hanmi in December 2019, pursuant to which we granted Hanmi the exclusive rights to develop, manufacture and commercialize tivumecirnon in the Hanmi Territory. The competition for partners is intense, and the negotiation process may be time-consuming and complex. If we are not able to enter into collaborations or other strategic transactions, or continue our existing collaboration, we may not have access to necessary capital or expertise to further develop our potential future drug candidates or our drug discovery and development engine. Any such collaboration or other strategic transaction may require us to incur non-recurring or other charges, increase our near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. We may acquire additional technologies and assets, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business, but we may not be able to realize the benefit of acquiring such assets. Conversely, any new collaboration that we do enter into may be on terms that are not optimal for us. These transactions would entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, drug candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs;
- higher-than-expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges or increased amortization expenses;
- difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business;
- impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership; and
- the inability to retain key employees of any acquired business.

Accordingly, although there can be no assurance that we will undertake or successfully complete any collaborations or other strategic transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and our business could be materially harmed by such transactions. Conversely, any failure to enter any collaboration or other strategic transaction that would be beneficial to us could delay the development and potential commercialization of our drug candidates and have a negative impact on the competitiveness of any drug candidate that reaches market.

In addition, to the extent that any of our current or future partners were to terminate a collaboration agreement, we may be forced to seek additional partnerships, which may be less favorable to us, or independently develop our current and future drug candidates, including funding preclinical studies or clinical trials, assuming marketing and distribution costs and obtaining, maintaining, enforcing and defending intellectual property rights or, in certain instances, abandoning drug candidates altogether, any of which could result in a change to our business plan and materially harm our business, financial condition, results of operations and prospects.

If third parties on which we rely to conduct certain preclinical studies and clinical trials do not perform as contractually required, fail to satisfy regulatory or legal requirements or miss expected deadlines, our development program could be delayed with material and adverse impacts on our business and financial condition.

We rely on third-party clinical investigators, CROs, clinical data management organizations ("CDMOs") and consultants to design, conduct, supervise and monitor certain preclinical studies and any clinical trials. Because we intend to rely on these third parties and will not have the ability to conduct certain preclinical studies or clinical trials independently, we will have less control over the timing, quality and other aspects of such preclinical studies and clinical trials than we would have had if we conducted them on our own. These investigators, CROs, CDMOs and consultants will not be our employees and we will have limited control over the amount of time and resources that they dedicate to our programs. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. The third parties with which we may contract might not be diligent, careful or timely in conducting our preclinical studies or clinical trials, resulting in the preclinical studies or clinical trials being delayed or unsuccessful.

If we cannot contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not carry out their contractual duties, satisfy legal and regulatory requirements for the conduct of preclinical studies or clinical trials or meet expected deadlines, our clinical development programs could be delayed and otherwise adversely affected. In all events, we will be responsible for ensuring that each of our preclinical studies and clinical trials are conducted in accordance with the general investigational plan and protocols for the trial. The FDA may require preclinical studies to be conducted in accordance with good laboratory practices and clinical trials to be conducted in accordance with good clinical practices, including for designing, conducting, recording and reporting the results of preclinical studies and clinical trials, to ensure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control will not relieve us of these responsibilities and requirements. Any adverse development or delay in our clinical trials could have a material and adverse impact on our commercial prospects and may impair our ability to generate revenue.

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

We may not be able to initiate or continue clinical trials for our current or potential future drug candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other regulatory authorities on anticipated timelines. For example, in March 2020 we temporarily paused enrollment for a few months in the Phase 1b portion of our Phase 1a/1b trial to evaluate zelnecirnon in patients with AD due to circumstances and uncertainties created by the COVID-19 pandemic. Additionally, in February 2024, following the clinical holds placed by the FDA on our Phase 2b trial of zelnecirnon in AD and our Phase 2a trial of zelnecirnon in asthma, we stopped dosing zelnecirnon in both trials and halted enrollment of new trial participants. In May 2024, we announced our decision to close and unblind both trials. We cannot predict how difficult it will be to enroll patients for our current or future clinical trials or whether we will be able to meet our anticipated timelines. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- the severity of the disease under investigation;
- the patient eligibility criteria defined in the clinical trial protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity and availability of clinical trial sites for prospective patients;
- the patient referral practices of physicians;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the drug candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents;
- ramifications of the clinical hold, including the reluctance of patients to participate in a trial involving zelnecirnon; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our future clinical trials will compete with other clinical trials for drug candidates that are in the same therapeutic areas as our drug 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 expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Additionally, because some of our clinical trials will be conducted in patients with advanced solid tumors, the patients are typically in the late stages of the disease and may experience disease progression or adverse events independent from our drug candidates, making them unevaluable for purposes of the trial and requiring additional enrollment. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our drug candidates.

We may not be able to conduct, or contract others to conduct, animal testing in the future, which could harm our research and development activities.

Certain laws and regulations relating to drug development require us to test our drug candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted or delayed.

Because we may rely on third parties, some of which are or may be sole source vendors, for manufacturing and supply of our drug candidates for preclinical and clinical development materials and commercial supplies, our supply may become limited or interrupted or may not be of satisfactory quantity or quality.

We currently rely on third-party contract manufacturers for our current and future clinical trial product materials and supplies. We do not produce any meaningful quantity of our drug candidates for clinical development, and we do not currently own manufacturing facilities for producing such supplies. Furthermore, some of our manufacturers represent our sole source of supplies of current and future clinical development materials, including our source for the manufacture of zelnecirnon and tivumecirnon. We cannot assure you that our preclinical or current or future clinical development product supplies and commercial supplies will not be limited or interrupted, especially with respect to our sole source third-party manufacturing and supply partners, or will be of satisfactory quality or continue to be available at acceptable prices. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. For our current and future sole source third-party manufacturing and supply partners, we may be unable to negotiate binding agreements with them or find replacement manufacturers to support our preclinical and current and future clinical activities at commercially reasonable terms in the event that their services to us are interrupted for any reason. We do not always have arrangements in place for a redundant or second-source supply for our sole source vendors in the event they cease to provide their products or services to us or do not timely provide sufficient quantities to us. Establishing additional or replacement sole source vendors, if required, may not be accomplished quickly. Any delays resulting from manufacturing or supply interruptions associated with our reliance on third-party manufacturing and supply partners, including those that are sole source, could impede, delay, limit or prevent our drug development efforts, which could harm our business, result of operations, financial condition and prospects.

The manufacturing process for a drug candidate is subject to FDA and other regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as current Good Manufacturing Practices ("cGMP"). If any of our manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third party, which we may not be able to do on reasonable terms, or at all. In some cases, the technical skills or technology required to manufacture our current and future drug candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third party and a feasible alternative may not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third-party manufacture our drug candidates. If we are required to change 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 and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop drug candidates in a timely manner or within budget.

We also expect to rely on third-party manufacturers if we receive regulatory approval for any drug candidate. We have existing, and may enter into future, manufacturing arrangements with third parties. We will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. If we are unable to obtain or maintain third-party manufacturing for any drug candidate, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our drug candidates successfully. Our or a third party's failure to execute on our manufacturing requirements and comply with cGMP could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of drug candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for drug candidates;
- loss of the cooperation of a potential future partner;

- subjecting third-party manufacturing facilities or our potential future manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of drug candidates; and
- in the event of approval to market and commercialize a drug candidate, an inability to meet commercial demands for our products.

Our third-party manufacturers may be unable to successfully scale manufacturing of zelnecirnon, tivumecirnon or potential future drug candidates in sufficient quality and quantity, which would delay or prevent us from developing drug candidates and commercializing approved products, if any.

In order to conduct further clinical trials for zelnecirnon and tivumecirnon, as well as any potential future drug candidates, we will need to manufacture large quantities of these drug candidates. We may continue to use third parties for our manufacturing needs. Our manufacturing partners may be unable to successfully increase the manufacturing capacity for any current or potential future drug candidate in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If our manufacturing partners are unable to successfully scale the manufacture of any current or potential future drug candidate in sufficient quality and quantity, the development, testing and clinical trials of that drug candidate may be delayed or infeasible, and regulatory approval or commercial launch of any potential resulting product may be delayed or not obtained, which could significantly harm our business.

If the market opportunities for our current and potential future drug candidates, including zelnecirnon and tivumecirnon, are smaller than we believe they are, our ability to generate product revenue may be adversely affected and our business may suffer.

Our understanding of the number of people who suffer from certain types of inflammatory disease and cancers that zelnecirnon and tivumecirnon, respectively, may have the potential to treat is based on estimates. These estimates may prove to be incorrect, and new studies may demonstrate or suggest a lower estimated incidence or prevalence of these diseases. The number of patients in the United States or elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with our current or potential future drug candidates or patients may become increasingly difficult to identify and access, all of which would adversely affect our business prospects and financial condition. In particular, the treatable population for our candidates may be further reduced if our estimates of addressable populations are erroneous or sub-populations of patients do not derive benefit from zelnecirnon or tivumecirnon.

Further, there are several factors that could contribute to making the actual number of patients who receive our current or potential future drug candidates less than the potentially addressable market, including the lack of widespread limited reimbursement for new therapies in many markets.

We face intense competition from entities that have developed or may develop drug candidates for the treatment of the diseases that we are currently targeting or may target in the future. If these companies develop technologies or drug candidates more rapidly than we do, or if their technologies or drug candidates are more effective, our ability to develop and successfully commercialize drug candidates may be adversely affected.

The development and commercialization of drugs and therapeutic biologics is highly competitive. We compete with a variety of large pharmaceutical companies, multinational biopharmaceutical companies, other biopharmaceutical companies and specialized biotechnology companies, as well as technology being developed at universities and other research institutions. Our competitors are often larger and better funded than we are. Our competitors have developed, are developing or will develop drug candidates and processes competitive with ours. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments that are currently in development or that enter the market. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we are developing or may try to develop drug candidates. There is intense and rapidly evolving competition in the biotechnology, biopharmaceutical, immuno-oncology and inflammation fields.

We are aware of numerous companies that are developing biologics and small molecule drugs for the treatment of inflammatory diseases and cancer. Many of these companies are well-capitalized and, in contrast to us, have significant clinical experience, and may include our future partners. In addition, these companies compete with us in recruiting scientific and managerial talent. Our success will partially depend on our ability to obtain, maintain, enforce and defend patents and other intellectual property rights with respect to small molecule drugs or biologics that are safer and more effective than competing products. Our commercial opportunity and success will be reduced or eliminated if competing products that are safer, more effective or less expensive than the drugs we develop are or become available.

We expect to compete with small molecule, biologics and other therapeutic platforms and development companies, including, but not limited to, companies such as Agenus/Gilead, Amgen and Tusk/Roche for oncology, and AnaptysBio and Dermira/Lilly for inflammatory diseases. In addition, we expect to compete with large, multinational pharmaceutical companies that discover, develop and commercialize small molecule drugs and other therapeutics for use in treating inflammatory diseases and cancer such as AbbVie, Amgen, AstraZeneca, Bristol-Myers Squibb, GlaxoSmithKline, Incyte, Kyowa Hakko Kirin, Merck, Novartis, Pfizer, Roche/Genentech and Sanofi/Regeneron. If zelnecirnon, tivumecirnon or any other future drug candidate is eventually approved, it will compete with a range of treatments that are either in development or currently marketed.

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. If we successfully obtain approval for any drug candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any product we develop obsolete or noncompetitive before we recover the expense of developing and commercializing such product. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

Any inability to attract and retain qualified key management, technical personnel and employees would impair our ability to implement our business plan.

Our success largely depends on the continued service of key management, advisors and other specialized personnel, including Brian Wong, M.D., Ph.D., our President and Chief Executive Officer, Rodney Young, our Chief Financial Officer, William Ho, M.D., Ph.D., our Chief Medical Officer, and Dirk Brockstedt, Ph.D., our Chief Scientific Officer, as well as our ability to attract and retain other highly qualified personnel. The loss of one or more members of our executive team, management team or other key employees or advisors could delay our research and development programs and have a material and adverse effect on our business, financial condition, results of operations and prospects.

The relationships that our key managers have cultivated within our industry make us particularly dependent upon their continued employment with us. We are dependent on the continued service of our technical personnel because of the highly technical nature of our drug candidates and technologies and the specialized nature of the regulatory approval process. Because our management team and key employees are not obligated to provide us with continued service, they could terminate their employment with us at any time without penalty.

Our future success will also depend in large part on our ability to attract and retain other highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical testing, manufacturing, governmental regulation and commercialization. We face significant competition for personnel from other companies, universities, public and private research institutions, government entities and other organizations.

As of March 31, 2024, we had 126 full-time employees. Our focus on the development of zelnecirnon, tivumecirnon and other potential future drug candidates will require adequate staffing. We may need to hire and retain new employees to execute our future clinical development and manufacturing plans. We cannot provide assurance that we will be able to hire or retain adequate staffing levels to develop our current and potential future drug candidates or to run our operations or to accomplish all of our objectives.

We may experience difficulties in managing our growth and expanding our operations.

We have limited experience in product development. As our current and potential future drug candidates enter and advance through preclinical studies and any clinical trials, we will need to expand our development, regulatory and manufacturing capabilities or contract with other organizations to provide these capabilities for us.

We may also experience difficulties in the discovery and development of potential future drug candidates using our drug discovery and development engine if we are unable to meet demand as we grow our operations. In the future, we also expect to have to manage additional relationships with collaborators, suppliers and other organizations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures and to secure adequate facilities for our operational needs. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls.

If any of our drug candidates is approved for marketing and commercialization in the future and we are unable to develop sales, marketing and distribution capabilities on our own or enter into agreements with third parties to perform these functions on acceptable terms, we will be unable to successfully commercialize any such future products.

We currently have no sales, marketing or distribution capabilities or experience. We will need to develop internal sales, marketing and distribution capabilities to commercialize each current and potential future drug candidate that gains FDA approval, which would be expensive and time-consuming, or enter into partnerships with third parties to perform these services. If we decide to market any approved products directly, we will need to commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and supporting distribution, administration and compliance capabilities. If we rely on third parties with such capabilities to market any approved products or decide to co-promote products with partners, we will need to establish and maintain marketing and distribution arrangements with third parties, and there can be no assurance that we will be able to enter into such arrangements on acceptable terms or at all. In entering into third-party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of the third parties and we cannot assure you that such third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance for any approved product. If we are not successful in commercializing any product approved in the future, either on our own or through third parties, our business and results of operations could be materially and adversely affected.

Our present and potential future international operations may expose us to business, political, operational and financial risks associated with doing business outside of the United States.

Our business is subject to risks associated with conducting business internationally. Some of our suppliers and clinical trial centers are located outside of the United States, and we are party to an agreement with Hanmi with respect to clinical development and other activities in the Hanmi Territory. Furthermore, if we or any future collaborator succeeds in developing any products, we anticipate marketing them in the European Union and other jurisdictions in addition to the United States. If approved, we or our collaborator may hire sales representatives and conduct physician and patient association outreach activities outside of the United States. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- rejection or qualification of foreign clinical trial data by the competent authorities of other countries;
- additional potentially relevant third-party patent and other intellectual property rights that may be necessary to develop and commercialize our products and drug candidates;
- complexities and difficulties in obtaining, maintaining, enforcing and defending our patent and other intellectual property rights;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters; political and economic instability, including wars, terrorism and political unrest, including as a result of ongoing overseas conflicts; outbreak of disease; boycotts, curtailment of trade and other business restrictions and implementation of tariffs;

- certain expenses, including among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its accounting provisions or its anti-bribery provisions or provisions of anti-corruption or anti-bribery laws in other countries.

Any of these factors could harm our ongoing international clinical operations and supply chain, as well as any future international expansion and operations and, consequently, our business, financial condition, prospects and results of operations.

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

Our future growth may depend, in part, on our ability to develop and commercialize drug candidates in foreign markets for which we may rely on partnering with third parties. We will not be permitted to market or promote any drug candidate before we receive regulatory approval from the applicable regulatory authority in a foreign market, and we may never receive such regulatory approval for any drug candidate. To obtain separate regulatory approval in foreign countries, we generally must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy, and governing, among other things, clinical trials and commercial sales, pricing and distribution of a drug candidate, and we cannot predict success in these jurisdictions. If we obtain approval of any of our current or potential future drug candidates and ultimately commercialize any such drug candidate in foreign markets, we would be subject to risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and the reduced protection of intellectual property rights in some foreign countries.

Price controls imposed in foreign markets may adversely affect our future profitability.

In some countries, particularly member states of the European Union, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure exerted by governments and other stakeholders on prices and reimbursement levels, including as part of cost-containment measures. Political, economic and regulatory developments, in the United States or internationally, may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we or future partners may be required to conduct clinical trials or other studies that compare the cost-effectiveness of a drug candidate to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of any current or potential future drug candidate that is approved for marketing in the future is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business and results of operations or prospects could be materially and adversely affected and our ability to commercialize such drug candidate could be materially impaired.

Our business could be materially and adversely affected in the future by the effects of disease outbreaks, epidemics and pandemics.

Disease outbreaks, epidemics and pandemics in regions where we have concentrations of clinical trial sites and other business operations, could adversely affect our business, including by causing significant disruptions in our operations and/or in the operations of manufacturers and CROs we rely on. Disease outbreaks, epidemics and pandemics may have negative impacts on our ability to initiate new clinical trial sites, enroll new patients and to maintain existing patients who are participating in clinical trials, which may result in increased clinical trial costs, longer timelines and delay in our ability to obtain regulatory approvals of our product candidates, if at all. For example, in March 2020, we temporarily paused enrollment for a few months in the Phase 1b portion of our Phase 1a/1b trial to evaluate zelnecirnon in patients with AD due to circumstances and uncertainties created by the COVID-19 pandemic, including vulnerability of our studied patient populations, site staff shortages, clinical trial site suspensions, reallocation of medical resources and the challenges of working remotely due to shelter-in-place and similar government orders and guidelines, among other factors.

General supply chain issues may be exacerbated during disease outbreaks, epidemics or pandemics and may also impact the ability of our clinical trial sites to obtain basic medical supplies used in our trials in a timely fashion, if at all.

Moreover, the extent to which disease outbreaks, epidemics and pandemics may impact our business, results of operations and financial position will depend on future developments, which are highly uncertain and cannot be predicted with confidence. New health epidemics or pandemics may emerge that result in similar or more severe disruptions to our business. To the extent any future disease outbreak, epidemic or pandemic adversely affects our business, financial condition, results of operations and growth prospects, it could also have the effect of heightening many of the other risks and uncertainties described in this "Risk Factors" section.

Our current operations are concentrated in one location, and we or the third parties upon whom we depend may be adversely affected by natural or other disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current operations are concentrated in the San Francisco Bay Area. Any unplanned event, such as earthquake, flood, fire, explosion, extreme weather, medical epidemic, pandemic, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities or the manufacturing facilities of our third-party contract manufacturers, or lose our repository of preclinical and clinical human samples and other valuable laboratory samples, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis. Such an event would have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our drug candidates or interruption of our business operations. Natural disasters such as earthquakes or wildfires, both of which are prevalent in Northern California, floods or tsunamis could further disrupt our operations, and have a material negative impact on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business and financial condition.

Risks Related to Our Intellectual Property

If we are unable to obtain, maintain, enforce or defend intellectual property rights related to our technology and current or future drug candidates, or if our intellectual property rights are inadequate, we may not be able to compete effectively.

Our success depends in large part on our ability to obtain and maintain protection in the United States and other countries for our intellectual property rights and proprietary technology. We rely on patents and other forms of intellectual property rights to protect our current or future drug discovery and development engine, drug candidates, methods used to manufacture our current or future drug candidates and methods for treating patients using our current or future drug candidates. We do not currently own any patents or patent applications relating to our proprietary drug discovery and development engine.

The patent prosecution process is expensive, complex and time-consuming. Patent license negotiations also can be complex and protracted, with uncertain results. We may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patents and patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. The patent applications that we own or may in-license may fail to result in issued patents, and, even if they do issue as patents, such patents may not cover our current or future technologies or drug candidates in the United States or in other countries or provide sufficient protection from competitors. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued and its scope can be reinterpreted after issuance.

Further, although we make reasonable efforts to ensure patentability of our inventions, we cannot guarantee that all of the potentially relevant prior art relating to our patent applications and any issued patents we obtain has been found. For example, publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing and, in some cases, not at all. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our drug discovery and development engine, our drug candidates or the use of our technologies. We thus cannot know with certainty whether we or any of our future licensors were the first to make the inventions claimed in our pending patent applications or any issued patents we obtain, or that we or our any of our future licensors were the first to file for patent protection of such inventions. For this reason, and because there is no guarantee that any prior art search is correct and comprehensive, we may be unaware of prior art that could be used to invalidate an issued patent or to prevent our pending patent applications from issuing as patents. Invalidation of any of our patent rights, including in-licensed patent rights, could materially harm our business, financial condition, results of operations and prospects.

Moreover, the patent positions of biopharmaceutical companies are generally uncertain because they may involve complex legal and factual considerations that have, in recent years, been the subject of legal development and change. As a result, the issuance, scope, validity, enforceability and commercial value of our pending patent rights is uncertain. The standards applied by the United States Patent and Trademark Office ("USPTO") and foreign patent offices in granting patents are not always certain and, moreover, are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in patents. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patent rights or narrow the scope of our patent protection.

Even if patents do successfully issue and even if such patents cover our current or any future technologies or drug candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful challenge to any patents we own or may in-license could deprive us of rights necessary for the successful commercialization of any current or future technologies or drug candidates that we may develop. Likewise, if patent applications we own or may in-license with respect to our development programs and current or future technologies or drug candidates fail to issue, if their breadth or strength is threatened or if they fail to provide meaningful exclusivity, other companies could be dissuaded from collaborating with us to develop current or future technologies or drug candidates. Lack of valid and enforceable patent protection could threaten our ability to commercialize current or future products and could prevent us from maintaining exclusivity with respect to the invention or feature claimed in the patent applications. Any failure to obtain, or any loss of, patent protection could have a material adverse impact on our business and ability to achieve profitability. We may be unable to prevent competitors from entering the market with a product that is similar to or the same as zelnecirnon, tivumecirnon or other future drug candidates that emerge from our discovery program.

The filing of a patent application or the issuance of a patent is not conclusive as to its ownership, inventorship, scope, patentability, validity or enforceability. Issued patents and patent applications may be challenged in the courts and in the patent office in the United States and abroad. For example, our patent applications or patent applications filed by any of our future licensors may be challenged through third-party submissions, opposition or derivation proceedings. By further example, issued patents may be challenged through reexamination, inter partes review or post-grant review proceedings before the USPTO or patent offices in other jurisdictions or in declaratory judgment actions or counterclaims. An adverse determination in any such submission, proceeding or litigation could prevent the issuance of, reduce the scope of, invalidate or render unenforceable our patent rights; limit our ability to stop others from using or commercializing similar or identical products; allow third parties to compete directly with us without payment to us; or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patent rights is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Moreover, some of our intellectual property, including patents and patent applications, are or may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such intellectual property, including patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. We may need the cooperation of any such co-owners of our patent rights to enforce such patent rights against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business prospects and financial conditions.

If we fail to comply with our obligations under any license, collaboration or other intellectual property-related agreements, we may be required to pay damages and could lose intellectual property rights that may be necessary for developing, commercializing and protecting our current or future technologies or drug candidates or we could lose certain rights to grant sublicenses.

Any license, collaboration or other intellectual property-related agreements impose, and any future license, collaboration or other intellectual property-related agreements we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If we breach any of these obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license. Despite our best efforts, any of our future licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technologies covered by these license agreements. Any license agreements we enter into may be complex and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may seek to obtain licenses from licensors in the future. However, we may be unable to obtain any such licenses at a reasonable cost or on reasonable terms, if at all. In addition, if any of our future licensors terminate any such license agreements, such license termination could result in our inability to develop, manufacture and sell products that are covered by the licensed technology or could enable a competitor to gain access to the licensed technology. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations and ability to achieve profitability.

Furthermore, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications that we license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our future licensors fail to prosecute, maintain, enforce and defend patents we may in-license, or they lose rights to licensed patents or patent applications, our license rights may be reduced or eliminated. In such circumstances, our right to develop and commercialize any of our products or drug candidates that is the subject of such licensed rights could be materially adversely affected. In certain circumstances, our licensed patent rights are subject to our reimbursing our licensors for their patent prosecution and maintenance costs.

Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing, misappropriating or otherwise violating the licensor's intellectual property rights and the amount of any damages or future royalty obligations that would result if any such claims were successful would depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

Patent terms may not be able to protect our competitive position for an adequate period of time with respect to our current or future technologies or drug candidates.

Patents have a limited lifespan. In the United States, the standard patent term is typically 20 years after filing. Various extensions may be available. Even so, the life of a patent and the protection it affords are limited. As a result, our patent portfolio provides us with limited rights that may not last for a sufficient period of time to exclude others from commercializing products similar or identical to ours. For example, given the large amount of time required for the research, development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

Extensions of patent term may be available, but there is no guarantee that we would succeed in obtaining any particular extension or that any such extension would lengthen the patent term for a sufficient period of time to exclude others from commercializing products similar or identical to ours. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication or any additional indications approved during the period of extension. A patent term extension cannot extend the remaining term of a patent beyond 14 years from the date of product approval; only one patent may be extended; and extension is available for only those claims covering the approved drug, a method for using it or a method for manufacturing it. The applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to any patents we obtain, or may grant more limited extensions than we request. An extension may not be granted or may be limited where there is, for example, a failure to exercise due diligence during the testing phase or regulatory review process, failure to apply within applicable deadlines, failure to apply before expiration of relevant patents or some other failure to satisfy applicable requirements. If this occurs, our competitors may be able to launch their products earlier by taking advantage of our investment in development and clinical trials along with our clinical and preclinical data. This could have a material adverse effect on our business and ability to achieve profitability.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our current or any future technologies or drug candidates.

As is the case with other therapeutics companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs of, and may diminish our ability to protect, our inventions, obtaining, maintaining, and enforcing our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patents. In September 2011, the Leahy-Smith America Invents Act (the "Leahy-Smith Act") was signed into law, which increased uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act included a number of significant changes to U.S. patent law. These provisions affected the way patent applications are prosecuted, redefined prior art and provided more efficient and cost-effective avenues for competitors to challenge the validity of patents. This included allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures that attacked the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. In March 2013, under the Leahy-Smith Act, the United States transitioned to a first-to-file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application would be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. This required us to be cognizant of the time from invention to filing of a patent application. The Leahy-Smith Act and its implementation resulted in 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 impact on our business prospects, financial condition and results of operations.

Courts in the U.S. continue to refine the heavily fact-and-circumstance-dependent jurisprudence defining the scope of patent protection available for therapeutics, narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. This creates uncertainty about our ability to obtain patents in the future and the value of such patents. We cannot provide assurance that future developments in Congress, the federal courts and the USPTO will not adversely impact our patent rights. The laws and regulations governing patents could change in unpredictable ways that could weaken our and our licensors' ability to obtain new patents or to enforce our existing patent rights or patent rights that we might obtain or in-license in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may have a material adverse effect on our and our licensors' ability to obtain new patents or to protect and enforce our owned or in-licensed patent rights or patent rights that we may obtain or in-license in the future.

In Europe, a new unitary patent system took effect in June 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications will have the option, upon grant of a patent, of becoming a Unitary Patent, which will be subject to the jurisdiction of the Unitary Patent Court (UPC). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

Other companies or organizations may challenge our patent rights or may assert patent rights that prevent us from developing and commercializing our current or future products.

Third parties may attempt to invalidate our intellectual property rights. Even if such rights are not directly challenged, disputes could lead to the weakening of our intellectual property rights. Our defense against any attempt by third parties to circumvent or invalidate our intellectual property rights could be costly to us, could require significant time and attention of our management and could have a material and adverse impact on our profitability, financial condition, prospects or ability to successfully compete.

Further, we cannot guarantee that we are aware of all patents and patent applications potentially relevant to our technology or products. There may be issued and pending patents that claim aspects of our current or potential future drug candidates and modifications that we may need for our current or potential future drug candidates. We may not be aware of potentially relevant third-party patents or applications for several reasons. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our drug candidates or technologies could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our drug candidates or the use of our technologies.

We may be subject to priority disputes, inventorship disputes and similar proceedings that could, if resolved unfavorably, narrow the scope of our intellectual property protection. We cannot provide any assurances that third-party patents do not exist that might be enforced against our drug candidates or technologies or future methods or products, resulting in either an injunction prohibiting our manufacture or sales or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties, which could be significant.

Thus, it is possible that one or more third parties will hold patent rights to which we will need a license, which may not be available on reasonable terms or at all. If such third parties refuse to grant us a license to such patent rights on reasonable terms or at all, we may be required to expend significant time and resources to redesign our technology, drug candidates or the methods for manufacturing our drug candidates, or to develop or license replacement technology, all of which may not be commercially or technically feasible. In such case, we may not be able to market such technology or drug candidates and may not be able to perform research and development or other activities covered by these patents. This could have a material adverse effect on our ability to commercialize our drug candidates and our business and financial condition.

We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

Filing, prosecuting and defending patents on current or future technologies or drug candidates in all countries throughout the world would be prohibitively expensive. Competitors or other third parties may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export infringing products to territories where we have patent protection or licenses, but where enforcement is not as strong as that in the United States. These products may compete with our products and our patent or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Additionally, the laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Many companies have encountered significant difficulties in protecting and defending intellectual property rights in such foreign jurisdictions. The legal systems of certain countries, including certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patent rights or the marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and could divert our efforts and attention from other aspects of our business. Such proceedings could also put our patent rights at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us or any of our future licensors. We may not prevail in any lawsuits or other adversarial proceedings that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce such intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or in-license.

Further, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of its patents. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position in the relevant jurisdiction may be impaired and our business prospects, financial condition and results of operations may be materially adversely affected.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse impact on the success of our business.

Our commercial success depends, in part, upon our ability or the ability of any of our future collaborators to develop, manufacture, market and sell our current or any future drug candidates and to use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary and intellectual property rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights.

We or any of our future licensors or strategic partners may be party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current or any potential future drug candidates and technologies, including derivation, reexamination, inter partes review, post-grant review or interference proceedings before the USPTO and similar proceedings in jurisdictions outside of the United States, such as opposition proceedings. If we or our licensors or strategic partners are unsuccessful in any interference proceedings or other priority or validity disputes (including through any patent oppositions) to which we or they are subject, we may lose valuable intellectual property rights through the loss of one or more patents or our patent claims may be narrowed, invalidated or held unenforceable. In some instances, we may be required to indemnify our licensors or strategic partners for the costs associated with any such adversarial proceedings or litigation. Third parties may also assert infringement, misappropriation or other claims against us, our licensors or our strategic partners based on existing patents or patents that may be granted in the future, as well as other intellectual property rights, regardless of their merit. There is a risk that third parties may choose to engage in litigation or other adversarial proceedings with us, our licensors or our strategic partners to enforce or otherwise assert their patent rights or other intellectual property rights. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents and other intellectual property rights are valid, enforceable and infringed, which could have a material adverse impact on our ability to utilize our drug discovery and development engine or to commercialize our current or any future drug candidates. 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 by presenting clear and convincing evidence of invalidity. There is no assurance that a court of competent jurisdiction, even if presented with evidence we believe to be clear and convincing, would invalidate the claims of any such U.S. patent.

Further, we cannot guarantee that we will be able to successfully settle or otherwise resolve such adversarial proceedings or litigation. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or to continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing our drug candidates. If we or any of our licensors or strategic partners are found to infringe, misappropriate or violate a third-party patent or other intellectual property rights, we could be required to pay damages, including treble damages and attorney's fees, if we are found to have willfully infringed. In addition, we or any of our licensors or strategic partners may choose to seek, or be required to seek, a license from a third party, which may not be available on commercially reasonable terms, if at all. Even if a license can be obtained on commercially reasonable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us, and we could be required to make substantial licensing and royalty payments. We also could be forced, including by court order, to cease utilizing, developing, manufacturing and commercializing our drug discovery and development engine or drug candidates deemed to be infringing. We may be forced to redesign current or future technologies or products. Any of the foregoing could have a material adverse effect on our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations.

In addition, we or our licensors or strategic partners may find it necessary to pursue claims or to initiate lawsuits to protect or enforce our patent or other intellectual property rights. If we or our licensors or strategic partners were to initiate legal proceedings against a third party to enforce a patent covering one of our drug candidates or our technology, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, claiming patent-ineligible subject matter, lack of novelty, indefiniteness, lack of written description, non-enablement, anticipation or obviousness. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome of such invalidity and unenforceability claims is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we or our licensors or strategic partners and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection for one or more of our drug candidates. The narrowing or loss of our owned and licensed patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products. All of these events could have a material adverse effect on our business, financial condition, results of operations and prospects. Patent and other intellectual property rights also will not protect our drug candidates and technologies if competitors or third parties design around such drug candidates and technologies without legally infringing, misappropriating or violating our patent or other intellectual property rights.

The cost to us in defending or initiating any litigation or other proceeding relating to our patent or other intellectual property rights, even if resolved in our favor, could be substantial, and any litigation or other proceeding would divert our management's attention and distract our personnel from their normal responsibilities. Such litigation or proceedings could materially 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 better able to sustain the costs of complex patent litigation because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and materially limit our ability to continue our operations. Furthermore, because of the substantial amount of discovery required in connection with certain such proceedings, there is a risk that some of our confidential information could be compromised by disclosure. 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, such announcements could have a material adverse effect on the price of our common stock.

Intellectual property rights of third parties could adversely affect our ability to commercialize our current or future technologies or drug candidates, and we might be required to litigate or obtain licenses from third parties to develop or market our current or future technologies or drug candidates, which may not be available on commercially reasonable terms or at all.

Because the inflammation disease and immuno-oncology landscapes are still evolving, it is difficult to conclusively assess our freedom to operate. Thus, we may unknowingly pursue development of a product or technology that infringes, misappropriates or otherwise violates third-party rights. There are numerous companies that have pending patent applications and issued patents broadly covering immune-therapies generally or covering small molecules directed against the same targets as, or targets similar to, those we are pursuing. Our competitive position may materially suffer if patents issued to third parties or other third-party intellectual property rights cover our current or future technologies, drug candidates or elements thereof or our manufacture or uses relevant to our development plans. In such cases, we may not be in a position to develop or commercialize current or future technologies, drug candidates or elements thereof unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned, or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms. There may be issued patents of which we are not aware, held by third parties, that, if found to be valid and enforceable, could be alleged to be infringed by our current or future technologies or drug candidates. There also may be pending patent applications of which we are not aware that may result in issued patents, which could be alleged to be infringed by our current or future technologies or drug candidates. Should such an infringement claim be successfully brought, we may be required to pay substantial damages or be forced to abandon our current or future technologies or drug candidates or to seek a license from any patent holders. No assurances can be given that a license will be available on commercially reasonable terms, if at all.

Third-party intellectual property right holders may also actively bring infringement, misappropriation or other claims alleging violations of intellectual property rights against us. We cannot guarantee that we will be able to successfully settle or otherwise resolve such claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or to continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing our drug candidates. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our current or future technologies or drug candidates that are held to be infringing, misappropriating or otherwise violating third-party intellectual property rights. We might, if possible, also be forced to redesign current or future technologies or drug candidates so that we no longer infringe, misappropriate or violate the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business, which could have a material adverse effect on our financial condition and results of operations.

We may not be successful in obtaining necessary or exclusive rights to any drug candidates or products we may develop through acquisitions and in-licensing.

We may be unable to acquire or otherwise in-license any compositions, methods of use, processes or other intellectual property rights from third parties that we identify as necessary for drug candidates that we may wish to develop. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or drug candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Patent rights we may in-license in the future may be subject to a reservation of rights by one or more third parties. For example, the research resulting in any in-licensed patent rights and technology may be funded in part by the U.S. government. As a result, the government may have certain rights, or march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention for non-commercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the U.S. government of such rights could harm our competitive position, business, financial condition, results of operations and prospects.

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

As referenced above, in addition to seeking patent protection for certain aspects of our current or future technologies and drug candidates, we also consider trade secrets, including confidential and unpatented know-how, important to the maintenance of our competitive position. However, trade secrets and know-how can be difficult to protect. We protect and plan to protect trade secrets and confidential and unpatented know-how, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants under which they are obligated to maintain confidentiality and to assign their inventions to us. Despite these efforts, we may not obtain these agreements in all circumstances and 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 information.

Moreover, individuals with whom we have such agreements may not comply with their terms. Any of these parties may breach such agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for any such breaches. We may be forced to bring claims against third parties, including current or former employees or consultants, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property, including our patent rights. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret or securing title to an employee- or consultant-developed invention if a dispute arises, is difficult, expensive and time-consuming, and the outcome is unpredictable. If we are unsuccessful in any inventorship disputes to which we are subject, we may lose valuable intellectual property rights, such as ownership of our patent rights. In addition, some courts in the United States and certain foreign jurisdictions disfavor or are unwilling to protect trade secrets. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent that competitor from using the technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be materially and adversely harmed.

We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets or other proprietary information of our employees' or consultants' former employers or their clients.

Many of our employees or consultants and our licensors' employees or consultants were previously employed at universities or biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that one or more of these employees or consultants or we have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information of any such individual's current or former employers. Litigation or arbitration may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or may be enjoined from using such intellectual property. Any such proceedings and possible aftermath would likely divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. A loss of key research personnel or their work product could limit our ability to commercialize, or prevent us from commercializing, our current or future technologies or drug candidates, which could materially harm our business. Even if we are successful in defending against any such claims, litigation or arbitration could result in substantial costs and could be a distraction to management.

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 or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our patent rights and any patent rights we may own or in-license in the future. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply with these requirements, and we may also be dependent on our licensors to take the necessary action to comply with these requirements with respect to our in-licensed intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products, which could have a material adverse effect on our business prospects and financial condition.

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

Our trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We own a U.S. registered trademark for RAPT and a U.S. registered trademark for a design used in our corporate logo. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we use for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be materially adversely affected.

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

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. The following examples are illustrative:

- others may be able to make small molecule drugs, inhibitors or formulations that are similar to our drug candidates, but that are not covered by the claims of any patents that we own, license or control;
- we or any strategic partners might not have been the first to make the inventions covered by the patent rights that we own, license or control;
- we or our licensors might not have been the first to file patent applications covering certain of our owned and in-licensed inventions;
- others may independently develop the same, similar or alternative technologies without infringing, misappropriating or violating our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we may own, in-license or control may not provide us with any competitive advantages, or may be narrowed or held invalid or unenforceable, including as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such trade secrets or know-how; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could have a material adverse impact on our business and financial condition.

Legal and Regulatory Risks

Clinical development includes a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Our drug candidates, zelnecirnon and tivumecirnon, are in clinical development, and their risk of failure is high. It is impossible to predict when or if our candidates or any potential future drug candidates will prove effective in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any drug candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of a drug candidate in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the development process. The results of preclinical studies and clinical trials of any of our current or potential future drug candidates may not be predictive of the results of later-stage clinical trials. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or safety profiles, notwithstanding promising results in earlier trials.

In February 2024, the FDA placed clinical holds on both our Phase 2b trial of zelnecirnon in AD and our Phase 2a trial of zelnecirnon in asthma. The clinical hold determination was based on a serious adverse event of liver failure requiring transplant in one patient in the AD trial. Dosing of zelnecirnon and enrollment of new trial participants were halted immediately in both clinical trials. In May 2024, we announced our decision to close and unblind both the Phase 2b trial in AD and the Phase 2a trial in asthma to inform our path forward and support our discussions with the FDA. We may be unable to establish causation of the serious adverse event or satisfactorily address the issues required to resolve the clinical holds in a timely manner or at all and we expect to incur additional expenses in connection with our efforts to resolve the clinical holds, which may be significant. If the FDA does not lift the clinical holds, we may be unable to continue clinical development of zelnecirnon, which would have a material adverse effect on our business, financial position and prospects.

We are conducting a Phase 1/2 clinical trial investigating tivumecirnon as a single agent and in combination with pembrolizumab in a range of tumors. We may experience delays in initiating or completing our clinical trials. We do not know whether planned clinical trials will be completed on schedule or at all, or whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Our development programs may be delayed for a variety of reasons, including delays related to:

- the FDA or other regulatory authorities requiring us to submit additional data or imposing other requirements before permitting us to initiate or continue a clinical trial;
- obtaining regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining institutional review board ("IRB") approval at each clinical trial site;
- recruiting suitable patients to participate in a clinical trial;
- having patients complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of our drug candidates for use in clinical trials.

Furthermore, we expect to rely on our CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and, while we expect to enter into agreements governing their committed activities, we have limited influence over their actual performance.

We could encounter delays if prescribing physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our current or potential future drug candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, our partners, the IRBs of the institutions in which such trials are being conducted, the Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug or therapeutic biologic, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. For example, in February 2024, the FDA placed clinical holds on both our Phase 2b trial of zelnecirnon in AD and our Phase 2a trial of zelnecirnon in asthma. The clinical hold determination was based on a serious adverse event of liver failure requiring transplant in one patient in the AD trial. Dosing of zelnecirnon and enrollment of new trial participants were halted immediately in both clinical trials. In May 2024, we announced our decision to close and unblind both the Phase 2b trial in AD and the Phase 2a trial in asthma to support our discussions with the FDA. We may be unable to establish causation of the serious adverse event or satisfactorily address the issues required to resolve the clinical holds in a timely manner or at all and we expect to incur additional expenses in connection with our efforts to resolve the clinical holds, which may be significant. If the FDA does not lift the clinical holds, we may be unable to continue clinical development of zelnecirnon, which would have a material adverse effect on our business, financial position and prospects.

We may be unable to obtain U.S. or foreign regulatory approval and, as a result, be unable to commercialize zelnecirnon, tivumecirnon or other future drug candidates.

Zelnecirnon, tivumecirnon and other future drug candidates are and will be subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs and therapeutic biologics. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process are required to be successfully completed in the U.S. and in many foreign jurisdictions before a new drug, therapeutic or biologic can be marketed. Satisfaction of these and other regulatory requirements is costly, time-consuming, uncertain and subject to unanticipated delays. It is possible that none of the drug candidates we may develop will obtain the regulatory approvals necessary for us or our potential future partners to begin selling them.

We have very limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. The time required to obtain FDA and other approvals is unpredictable but typically takes many years following the commencement of clinical trials, depending upon the type, complexity and novelty of the drug candidate. The standards that the FDA and its foreign counterparts use when regulating us and other companies developing drugs require judgment and can change, which makes it difficult to predict with certainty how they will be applied. Any analysis we perform of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be.

Any delay or failure in obtaining required approvals could have a material and adverse effect on our ability to generate revenue from the particular drug candidate for which we are seeking approval. Further, we and our potential future partners may never receive approval to market and commercialize any drug candidate. Even if we or a potential future partner obtains regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We or a potential future partner may be subject to post-marketing testing requirements to maintain regulatory approval. If any of our drug candidates prove to be ineffective, unsafe or commercially unviable, we may have to re-engineer zelnecirnon, tivumecirnon or other future drug candidates, and our entire pipeline could have little, if any, value, which could require us to change our focus and approach to small molecule discovery and development, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities outside the United States and vice versa.

Even if we receive regulatory approval for any of our current or potential future drug candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our current or potential future drug candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we or potential future partners obtain for zelnecirnon, tivumecirnon or other future drug candidates may also be subject to limitations on the approved indicated uses for which a 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 such drug candidate. In addition, if the FDA or other regulatory authority approves zelnecirnon, tivumecirnon or other future drug candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, import, export, advertising, promotion and recordkeeping for such product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration and continued compliance with cGMP and good clinical practices for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our strategic partners;
- suspension or revocation of product license approvals;
- product seizure or detention or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. 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. 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, which would adversely affect our business.

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

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA") was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, in June 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Moreover, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. In August 2022, President Biden signed the Inflation Reduction Act of 2022 (the "IRA") into law, which, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. The Budget Control Act of 2011, among other things, includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments, will remain in effect until 2032. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law which, among other things, further reduced Medicare payments to several types of providers.

Additionally, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. For example, there have been several Congressional inquiries, Presidential executive orders and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drug products. At the federal level, in July 2021, the Biden administration released an executive order that included multiple provisions aimed at prescription drugs. In response to President Biden's executive order, in September 2021, the U.S. Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform. The plan sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions take effect progressively starting in fiscal year 2023. In August 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be implemented, but it is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare & Medicaid Services ("CMS") Innovation Center that will be evaluated on their ability to lower the cost of drugs, promote accessibility and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, in December 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. Also in December 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights that, for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While the government has not previously exercised march-in rights, it is uncertain if that practice will change under the new framework. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to (i) 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 (ii) encourage importation from other countries and bulk purchasing. For example, in January 2024, the FDA approved Florida's Section 804 Importation Program ("SIP") proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs. These new laws and initiatives may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our future customers and accordingly, our financial operations.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our drug candidates or additional pricing pressures.

If we or potential future partners, manufacturers or service providers fail to comply with healthcare laws and regulations, we or they could be subject to enforcement actions, which could affect our ability to develop, market and sell our products and may harm our reputation.

Healthcare providers and third-party payors, among others, will play a primary role in the prescription and recommendation of any drug candidates for which we obtain marketing approval. Our current and future arrangements with third-party payors, providers and customers, among others, may expose us 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 research, market, sell and distribute our drug candidates for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, a person or entity from knowingly and willfully soliciting, offering, paying, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease order, arranging for or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, by a federal healthcare program, such as Medicare or Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, a violation of the Anti-Kickback Statute can form the basis for a violation of the federal False Claims Act (discussed below);

- federal civil and criminal false claims laws and civil monetary penalties laws, including the federal False Claims Act, which provides for civil whistleblower or qui tam actions, that impose penalties against individuals or entities for knowingly presenting or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a referral made in violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the Health Insurance Portability and Accountability Act ("HIPAA") which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. As amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), HIPAA also imposes obligations on certain covered entity healthcare providers, health plans and healthcare clearinghouses as well as their business associates and subcontractors that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;
- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements known as the federal Physician Payments Sunshine Act, created as part of ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the CMS information related to payments and other transfers of value made by that entity to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physicians assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous local, state and foreign laws and regulations, such as state anti-kickback and false claims laws that may apply to healthcare items or services reimbursed by third-party payors, including private insurers; local, state and foreign transparency laws that require manufacturers to report information related to payments and transfers of value to other healthcare providers and healthcare entities, marketing expenditures or drug pricing; state laws that require pharmaceutical companies to register certain employees engaged in marketing activities in the location and comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. If our operations are found to be in violation of any such requirements, we may be subject to significant penalties, including criminal and significant civil monetary penalties, damages, fines, individual imprisonment, disgorgement, contractual damages, reputational harm, exclusion from participation in government healthcare programs, integrity obligations, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private qui tam actions brought by individual whistleblowers in the name of the government, refusal to allow us to enter into supply contracts, including government contracts, additional reporting requirements and oversight if subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

If we fail to comply with U.S. and foreign regulatory requirements, regulatory authorities could limit or withdraw any marketing or commercialization approvals we may receive and subject us to other penalties that could materially harm our business.

Even if we receive marketing and commercialization approval of a drug candidate, we will be subject to continuing regulatory requirements, including in relation to adverse patient experiences with the product and clinical results that are reported after a product is made commercially available, both in the United States and any foreign jurisdiction in which we seek regulatory approval. The FDA has significant post-market authority, including the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate safety risks related to the use of a product or to require withdrawal of the product from the market. The FDA also has the authority to require a Risk Evaluation and Mitigation Strategy ("REMS"), after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug or therapeutic biologic. The manufacturer and manufacturing facilities we use to make a future product, if any, will also be subject to periodic review and inspection by the FDA and other regulatory agencies, including for continued compliance with cGMP requirements. The discovery of any new or previously unknown problems with our third-party manufacturers, manufacturing processes or facilities may result in restrictions on the product, manufacturer or facility, including withdrawal of the product from the market. We intend to rely on third-party manufacturers and we will not have control over compliance with applicable rules and regulations by such manufacturers. Any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. If we or our existing or future partners, manufacturers or service providers fail to comply with applicable continuing regulatory requirements in the U.S. or foreign jurisdictions in which we seek to market our products, we or they may be subject to, among other things, fines, warning letters, holds on clinical trials, delay of approval or refusal by the FDA to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions, injunction, civil penalties and criminal prosecution.

Even if we are able to commercialize any drug candidate, such drug candidate may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

Our ability to commercialize any products successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, such as government authorities, private health insurers and health maintenance organizations. Patients who are prescribed medications for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Coverage and adequate reimbursement from government healthcare programs, such as Medicare and Medicaid, and private health insurers are critical to new product acceptance. Patients are unlikely to use our future products, if any, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost. We plan to develop, either by ourselves or with collaborators, in vitro companion diagnostic tests for our drug candidates for certain indications. We, or our collaborators, will be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our drug candidates, once approved. The failure to obtain coverage reimbursement for the companion diagnostic tests may hinder our ability to commercialize our product candidates, once approved.

Cost-containment is a priority in the U.S. healthcare industry and elsewhere. As a result, government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. 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. Third-party payors also may request additional clinical evidence beyond the data required to obtain marketing approval, requiring a company to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of its product. Commercial third-party payors often rely upon Medicare coverage policy and payment limitations in setting their reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Therefore, coverage and reimbursement for pharmaceutical products in the U.S. can differ significantly from payor to payor. We cannot be sure that coverage and adequate reimbursement will be available for any product that we commercialize and, if reimbursement is available, that the level of reimbursement will be adequate. Further, coverage policies and third-party reimbursement rates may change at any time. Thus, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future. Coverage and reimbursement may impact the demand for, or the price of, any drug candidate for which we obtain marketing approval. If coverage and reimbursement are not available or are available only at limited levels, we may not be able to successfully commercialize any drug candidate for which we obtain marketing approval.

Additionally, the regulations that govern regulatory approvals, pricing and reimbursement for new drugs and therapeutic biologics vary widely from country to country. Some countries require approval of the sale price of a drug or therapeutic biologic before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if our drug candidates obtain regulatory approval.

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

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

Our Code of Business Conduct and Ethics mandates compliance with the FCPA and other anti-corruption laws applicable to our business throughout the world. However, we cannot assure you that our employees and third-party intermediaries will comply with this code or such anti-corruption laws. Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas, investigations or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor, which can result in added costs and administrative burdens.

Our business entails a significant risk of product liability, and our inability to obtain sufficient insurance coverage could have a material and adverse effect on our business, financial condition, results of operations and prospects.

As we conduct clinical trials of zelnecirnon and tivumecirnon, we will be exposed to significant product liability risks inherent in the development, testing, manufacturing and marketing of inflammatory disease and cancer treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA investigation of the safety and effectiveness of our products, our manufacturing processes and facilities, our marketing programs and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources, substantial monetary awards to trial participants or patients and a decline in our stock price. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, our partners or we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we may establish, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such 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. It is not always possible to identify and deter 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 and financial condition, including the imposition of significant criminal, civil and administrative fines or other sanctions, such as monetary penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, integrity obligations, reputational harm and the curtailment or restructuring of our operations.

We are subject to stringent and evolving U.S. and foreign laws, regulations and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to government investigations or enforcement actions (which could include civil or criminal penalties), litigation (including class claims) and mass arbitration demands; fines or penalties; or disruptions of our business operations, reputational harm, loss of revenue or profits, adverse publicity and other adverse business consequences, which could negatively affect our operating results and business.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit and share (collectively, "process") personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, sensitive third-party data, business plans, transactions, financial information and clinical trial and other health data (collectively, "sensitive data").

Our data processing activities may subject us to numerous data privacy and security obligations, such as various federal, state, local and foreign data protection laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other obligations relating to data privacy and security. In the United States, federal, state and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (*e.g.*, Section 5 of the Federal Trade Commission Act) and other similar laws (*e.g.*, wiretapping laws). For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security and transmission of protected health information. In the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct or delete certain personal data and to opt-out of certain data processing activities, such as targeted advertising, profiling and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 ("CPRA") (collectively, "CCPA"), applies to personal data of consumers, business representatives and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines of up to $7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. 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 these laws also exempt some data processed in the context of clinical trials, these developments further complicate our compliance efforts and increase compliance costs for us, the third parties we rely on and our future customers.

Outside the United States, an increasing number of laws, regulations and industry standards govern data privacy and security. For example, the European Union's General Data Protection Regulation ("EU GDPR") and the United Kingdom's GDPR ("UK GDPR") (collectively, "GDPR") and Australia's Privacy Act impose strict requirements for processing personal data. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to €20 million under the EU GDPR, £17.5 million under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or 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. In addition, we conduct and may conduct in the future clinical trials in Asia and may therefore be subject to new and emerging data privacy regimes in Asia, including South Korea's Personal Information Protection Act, Taiwan's Personal Data Protection Act, Thailand's Personal Data Protection Act and Hong Kong's Personal Data (Privacy) Ordinance.

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 United Kingdom ("UK") have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws they generally believe are inadequate. 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 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 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 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 data privacy and security laws, we are contractually subject to data privacy and security obligations and may become subject to such obligations in the future. We are also bound by other contractual obligations related to data privacy and security and our efforts to comply with such obligations may not be successful. For example, clinical trial subjects about whom we or any of our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information.

We publish privacy policies, marketing materials and other statements regarding data privacy and security. If these policies, materials or statements are found to be deceptive, unfair, deficient, lacking in transparency or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to data privacy and security (and consumers' data privacy expectations) 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, or be perceived to have failed, in our efforts to comply with our data privacy and 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. In the event of failure (or perceived failure) of us or the third parties we rely on to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (*e.g.*, investigations, fines, civil or criminal penalties, audits, inspections and similar); litigation (including class claims) and mass arbitration demands, additional reporting requirements and/or oversight, bans on processing personal data, orders to destroy or not use personal data, adverse publicity or imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class action 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 monumental 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 or financial condition, including but not limited to: loss of customers, 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.

If our information technology systems (or those of the third parties we rely on) or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits and other adverse consequences.

In the ordinary course of business, we and the third parties we rely on process sensitive data. As a result, we and the third parties we rely on face a variety of evolving threats, including but not limited to ransomware attacks, which could cause security incidents. Cyber-attacks, malicious internet-based activity, online and offline fraud and other similar activities threaten the confidentiality, integrity and availability of our sensitive data and information technology systems, and those of the third parties we rely on. Such threats are prevalent and continue to rise, are increasingly difficult to detect and come from a variety of sources, including traditional computer “hackers,” threat actors, “hacktivists,” organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties we on rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain and ability to produce, sell and distribute our services.

We and the third parties we rely on are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing attacks, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, attacks enhanced or facilitated by artificial intelligence ("AI") and other similar threats.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions, such as acquisitions or integrations, could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities’ systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

In addition, our reliance on third parties, such as our CROs or other vendors, contractors or consultants, could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks and other threats to our business operations. We rely on third parties and technologies to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, clinical trials, drug discovery and development, encryption and authentication technology, employee email and other functions. We also rely on third parties to provide other products, services, parts or otherwise to operate our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If the third parties we rely on experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if the third parties we rely on fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or the supply chain of third parties we rely on have not been compromised.

While we have implemented security measures designed to protect against security incidents, including measures designed to prevent the sharing and loss of patient data in our sample collection process associated with our drug discovery and development efforts, there can be no assurance that these measures will be effective. We have taken steps designed to detect and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties we rely on). We may not, however, be able to detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to, our sensitive data or our information technology systems or those of the third parties we rely on. A security incident or other interruption could disrupt our ability (and that of the third parties we rely on) to provide our services.

We may expend significant resources or modify our business activities to try to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data.

Applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators and investors, of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

If we or a third party we rely on experiences a security incident or is perceived to have experienced a security incident, we may experience adverse consequences such as: government enforcement actions (for example, investigations, fines, penalties, audits and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; disputes with physicians, patients and our partners; monetary fund diversions; interruptions in our operations (including availability of data and interruptions and delays in our research and development work; financial loss; and other similar harms. Security incidents and attendant consequences may negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect or infer sensitive data about us from public sources, data brokers or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive data of the Company could be leaked, disclosed or revealed as a result of or in connection with the use of generative AI technologies by our personnel or our vendors.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

Our research, development and manufacturing involve the use of hazardous materials and various chemicals. We maintain quantities of various flammable and toxic chemicals in our facilities that are required for our research, development and manufacturing activities. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. We believe our procedures for storing, handling and disposing of these materials in our facilities comply with the relevant guidelines of the state of California and the Occupational Safety and Health Administration of the U.S. Department of Labor. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by applicable regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of animals and biohazardous materials. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. Although we have some environmental liability insurance covering certain of our facilities, we may not maintain adequate insurance for all environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

Environmental, social and governance matters and any related reporting obligations may impact our business.

Companies across many industries are facing increasing scrutiny related to their environmental, social and governance ("ESG") practices and reporting, both in the United States and internationally. For example, new domestic and international laws and regulations relating to ESG matters, including environmental sustainability, climate change and human capital management, are under consideration or being adopted, which may include specific, target-driven disclosure requirements or obligations. If increased ESG disclosure requirements apply to us, we may require additional investments and implementation of new practices and reporting processes, all entailing additional compliance risk regulations.

Risks Related to Ownership of Our Common Stock

Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to the ongoing development of our drug candidates or future development programs;
- results of clinical trials, or the addition, delay or termination of clinical trials or funding support by us or potential future partners;
- our execution of any collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under potential future arrangements or the termination or modification of any such potential future arrangements;
- any intellectual property infringement, misappropriation or violation lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any of our drug candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such drug candidates;
- regulatory developments affecting our drug candidates or those of our competitors; and
- changes in general market and economic conditions.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Our stock price may be volatile and purchasers of our common stock could incur substantial losses.

Our stock price has been and is likely to continue to be highly volatile. The market price for our common stock may be influenced by many factors, including the other risks described in this "Risk Factors" section and the following:

- our ability to advance zelnecirnon, tivumecirnon or other potential future drug candidates through clinical development;
- results of our preclinical studies, non-clinical studies and clinical trials for our current and future drug candidates or those of our competitors or potential future partners;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our products;
- the success of competitive products or technologies;
- introductions and announcements of new products by us, our future commercialization partners or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our products, clinical trials, manufacturing process or sales and marketing terms;
- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional technologies, products or drug candidates;
- developments concerning any future collaborations, including, but not limited to, those with our sources of manufacturing supply and our commercialization partners;
- market conditions in the pharmaceutical and biotechnology sectors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- developments, disputes or litigation matters concerning patents or other intellectual property rights, and our ability to obtain and maintain patent protection for our products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- actual or anticipated changes in earnings estimates or changes in securities analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- our failure or the failure of our competitors to meet securities analysts' projections or guidance that we or our competitors may give to the market;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcement and expectation of additional financing efforts;
- speculation in the press or investment community;
- trading volume of our common stock;
- sales of our common stock by us or our stockholders, including after the expiration of the lockup agreements entered into in connection with our public offerings;
- the concentrated ownership of our common stock;
- changes in accounting principles;

- terrorist acts, acts of war or periods of widespread civil unrest, including as a result of ongoing overseas conflicts;
- natural disasters, medical epidemics, pandemics and other calamities; and
- general economic, industry and market conditions.

In addition, the stock markets in general, and the markets for pharmaceutical, therapeutics, biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that has been often unrelated to the operating performance of the issuer, including in connection with ongoing overseas conflicts and potential future bank failures, each of which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad market and industry factors, including worsening economic or financial conditions, macroeconomic factors including inflation and rising interest rates and geopolitical instability, including instability resulting from ongoing overseas conflicts, may negatively affect the market price of our common stock, regardless of our actual operating performance. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. Substantial purchases of common stock by existing stockholders could reduce the liquidity of the trading market for our common stock and increase volatility.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and 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, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

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

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

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property rights or our common stock performance, or if our clinical studies and operating results fail to meet the expectations of the analysts, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Our principal stockholders and management own a significant percentage of our stock and are able to exert significant control over matters subject to stockholder approval.

Our executive officers and directors, together with holders of 5% or more of our capital stock and their respective affiliates, beneficially own a significant percentage of our common stock. As a result, these stockholders, if acting together, will have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction.

The interests of these stockholders may not be the same as, and may even conflict with, your interests. 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.

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

We are an "emerging growth company" as defined in the 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 not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, ("Section 404"), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We may take advantage of these provisions until December 31, 2024. 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 including not being required to comply with the auditor attestation requirements of Section 404 and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy 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.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of an exemption that allows us to delay adopting new or revised accounting standards until such time as those standards apply to private companies. As a result, we will not be subject to the same new or revised accounting standards as other public companies that comply with the public company effective dates, including but not limited to the new lease accounting standard. We may elect to take advantage of other reduced reporting requirements in future filings. As a result of these elections, the information that we provide to our stockholders may be different than you might receive from other public reporting companies. However, if we later decide to opt out of the extended period for adopting new accounting standards, we would need to disclose such decision and it would be irrevocable.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) our voting and non-voting common stock held by nonaffiliates is less than $250.0 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

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

Our ability to use our net operating loss carryforwards ("NOLs") and certain other tax attributes is conditioned upon our attaining profitability and generating U.S. federal and state taxable income. As described above under "—Risks Related to Our Business," we have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; thus, we do not know whether or when we will generate the U.S. federal or state taxable income necessary to utilize our NOLs and certain other tax attributes. Our NOLs could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. Federal NOLs generated in tax years beginning before January 1, 2018, are only permitted to be carried forward for 20 taxable years under applicable U.S. federal tax law. Under the Tax Cuts and Jobs Act (the "Tax Act"), as modified by the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") signed into law in March 2020, federal NOLs arising in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs may be limited to 80% of current year taxable income. It is uncertain if and to what extent various states will conform to the Tax Act or the CARES Act.

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), a corporation that undergoes an "ownership change," generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, is subject to limitations on its ability to utilize its pre-change NOLs and certain other pre-change tax attributes (such as research and development tax credits) to offset post-change taxable income. Our existing NOLs and certain other tax attributes may be subject to substantial limitations arising from previous ownership changes, if any, and if we undergo an ownership change, our ability to utilize NOLs and certain other tax attributes could be further limited by Sections 382 and 383 of the Code. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change. Our NOLs and certain other tax attributes may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs and certain other tax attributes.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New tax laws, statutes, rules, regulations or ordinances could be enacted at any time. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted differently, changed, repealed or modified at any time. Any such enactment, interpretation, change, repeal or modification could adversely affect us, possibly with retroactive effect. For instance, the recently enacted IRA imposes, among other rules, a 15% minimum tax on the book income of certain large corporations and a 1% excise tax on certain corporate stock repurchases. In addition, for certain research and experimental expenses incurred in tax years beginning after December 31, 2021, the Tax Act requires the capitalization and amortization of such expenses over five years if incurred in the United States and fifteen years if incurred outside the United States, rather than deducting such expenses currently. There have been legislative proposals to repeal or defer the capitalization requirement, including legislation recently passed by the U.S. House of Representatives that would restore the deductibility of research and experimental expenses incurred in the United States (but not research and experimental expenses incurred outside the United States); however, there can be no assurance that such requirement will be repealed, deferred or otherwise modified. Changes in corporate tax rates, the realization of our net deferred tax assets, the taxation of foreign earnings and the deductibility of expenses under the Tax Act, as amended by the CARES Act or any future tax reform legislation, could have a material impact on the value of our deferred tax assets, result in significant one-time charges and increase our future tax expenses.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We may incur significant costs from class action litigation due to the volatility of our stock.

Our stock price may fluctuate for many reasons, including as a result of public announcements regarding the progress of our drug discovery and development efforts and our drug candidates, the development efforts of future partners or competitors, the addition or departure of our key personnel, variations in our quarterly operating results and changes in market valuations of biopharmaceutical and biotechnology companies. This risk is especially relevant to us because biopharmaceutical and biotechnology companies have experienced significant stock price volatility in recent years. When the market price of a stock has been volatile, holders of that stock have occasionally brought securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit is without merit, we could incur substantial costs defending the lawsuit. The lawsuit could also divert the time and attention of our management.

Anti-takeover provisions in our 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 management.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may delay or prevent an acquisition of our company or a change in our management. In addition, 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. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include:

- a prohibition on actions by our stockholders by written consent;
- a requirement that special meetings of stockholders, which our company is not obligated to call more than once per calendar year, be called only by the chair of our board of directors, our chief executive officer or our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors;
- advance notice requirements for election to our board of directors and for proposing matters that can be acted upon at stockholder meetings;
- division of our board of directors into three classes, serving staggered terms of three years each; and
- the authority of the board of directors to issue preferred stock with such terms as the board of directors may determine.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, as amended, 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. These provisions would apply even if the proposed merger or acquisition could be considered beneficial by some stockholders.

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

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

(1) any derivative action or proceeding brought on our behalf;

(2) any action asserting a breach of fiduciary duty owed by any of our directors, officers, employees or agents to us or our stockholders;

(3) any action asserting a claim against us or any of our directors, officers or other employees arising under any provisions of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; or

(4) any action asserting a claim against us or any of our directors, officers or other employees governed by the internal affairs doctrine.

These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act or the rules and regulations thereunder. However, these provisions apply to Securities Act claims and Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce a duty or liability created by the Securities Act or the rules and regulations thereunder. Accordingly, there is uncertainty as to whether a court would enforce such provisions, and our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

Our amended and restated certificate of incorporation further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. For the avoidance of doubt, this provision is intended to benefit, and may be enforced by, us, our officers and directors, the underwriters to any offering giving rise to such complaint and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and the provisions may not be enforced by a court in those other jurisdictions.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

We have filed the exhibits listed on the accompanying Exhibit Index, which is incorporated herein by reference.

Exhibit Number	Description	Incorporated by Reference			
		Schedule Form	File Number	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation	8-K	001-38997	3.1	11/04/19
3.2	Amended and Restated Bylaws	8-K	001-38997	3.2	11/04/19
10.1*+	Non-Employee Director Compensation Policy				
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
32.1*†	Certification of Principal Executive Officer 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				
101.SCH*	Inline XBRL Taxonomy Extension Schema Document With Embedded Linkbase Documents				
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)				

* Filed herewith.
+ Indicates management contract or compensatory plan or arrangement.
† The certifications attached as Exhibit 32.1 to this Quarterly Report on Form 10-Q are not deemed filed with the SEC and are not to be incorporated by reference into any filing of RAPT Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

SIGNATURES

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

Date: May 9, 2024

RAPT Therapeutics, Inc.

By: /s/ Brian Wong, M.D., Ph.D.
Brian Wong
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ Rodney Young
Rodney Young
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 10.1

RAPT Therapeutics, Inc.

Non-Employee Director Compensation Policy

March 27, 2024

Each member of the Board of Directors (the "***Board***") of RAPT Therapeutics, Inc. (the "***Company***") who is a non-employee director of the Company (each such member, a "***Non-Employee Director***") will receive the compensation described in this Non-Employee Director Compensation Policy (the "***Director Compensation Policy***") for his or her Board service.

The Director Compensation Policy will be effective as of March 27, 2024 (the "***Effective Date***"). The Director Compensation Policy may be amended at any time in the sole discretion of the Board.

A Non-Employee Director may decline all or a portion of his or her compensation by giving notice to the Company prior to the date cash is to be paid or equity awards are to be granted, as the case may be.

Annual Cash Compensation

Commencing at the beginning of the first calendar quarter following the Effective Date, each Non-Employee Director will receive the cash compensation set forth below for service on the Board. The annual cash compensation amounts will be payable in equal quarterly installments, in arrears no later than 30 days following the end of each quarter in which the service occurred, prorated for any partial quarter of service. All annual cash fees are vested upon payment. In addition, each Non-Employee Director may elect to receive all of the annual cash compensation set forth below that the Non-Employee Director is eligible to earn in the form of stock options granted pursuant to the Company's 2019 Equity Incentive Plan, as amended from time to time, or any successor plan (the "***Plan***") subject to the terms and conditions as set forth below.

1. Annual Board Service Retainer:

(a) All Non-Employee Directors: $40,000
(b) Chair of the Board (as applicable): $30,000 (in addition to above)

2. Annual Committee Member Service Retainer:

- Member of the Audit Committee: $12,500
- Member of the Compensation Committee: $7,500
- Member of the Nominating and Corporate Governance Committee: $5,000

3. Annual Committee Chair Service Retainer (in lieu of Committee Member Service Retainer):

(a) Chair of the Audit Committee: $25,000
(b) Chair of the Compensation Committee: $15,000
(c) Chair of the Nominating and Corporate Governance Committee: $10,000

Timing of Elections Regarding Annual Cash Compensation; Time and Form of Payment

1. *Current Non-Employee Directors*: If a Non-Employee Director's service as a Non-Employee Director commences prior to the beginning of a fiscal year, then the Non-Employee Director must make an

election, prior to the beginning of such fiscal year, to receive the Non-Employee Director's (i) Annual Board Service Retainer(s) for such fiscal year and (ii) any Annual Committee Member Service Retainer(s) or Annual Committee Chair Service Retainer(s) that is or may become payable for such fiscal year (each, a "***Retainer***") in the form of either cash or stock options. The Retainer(s) will be paid or granted as follows:

- *Cash*: If the Non-Employee Director elects to receive the Retainers in cash, the Retainers will be paid in the form of cash in arrears in equal installments over the applicable number of fiscal quarters during such fiscal year, with payment occurring on the last day of the applicable fiscal quarter (i.e., March 31st, June 30th, September 30th or December 31st).

- *Stock Options*: If the Non-Employee Director elects to receive the Retainers in the form of stock options, such stock options will automatically, and without further action by the Board or Committee of the Board, be granted on the last business day in March of such fiscal year. Any such award will vest as follows: (i) 25% will vest on the last day of the first fiscal quarter during such fiscal year; and (ii) 25% will vest on the last day of each subsequent fiscal quarter during such fiscal year, provided that the Non-Employee Director is in service as a Director on the first day of the fiscal quarter of the applicable scheduled vesting date. Notwithstanding the foregoing, if the Non-Employee Director becomes a member of a Committee, Chair of a Committee or Chair of the Board after the last business day in March of such fiscal year, then the portion (if any) of his or her Annual Committee Member Service Retainer, Annual Committee Chair Service Retainer or Chair of the Board Service Retainer, as applicable, that is to be granted in the form of stock options will automatically, and without further action by the Board or Committee of the Board, be granted on the third business day after the date that the Non-Employee Director becomes a member of a Committee, Chair of a Committee or Chair of the Board, as applicable. Any such award will vest in equal installments as follows: (i) the first installment will vest on the last day of the fiscal quarter of the date of grant; and (ii) any remaining installment(s) will vest on the last day of any subsequent fiscal quarter(s) during such fiscal year, provided that the Non-Employee Director is in service as a Director on the first day of the fiscal quarter of the applicable scheduled vesting date.

2. *New Non-Employee Directors*: If a Non-Employee Director's service as a Non-Employee Director commences on or after the beginning of a fiscal year, then the Non-Employee Director must make an election, within 30 days following the commencement of such service, with respect to his or her Retainers that are or may become payable for such fiscal year; provided, however, that (a) such election will be applicable only to the portion of the applicable Retainer payable for any fiscal quarter during such fiscal year that begins after the date of such election, and (b) no such election may be made if such service commences during the final fiscal quarter of such fiscal year. Each such Retainer will be paid or granted as follows:

- *Cash*: If the Non-Employee Director elects to receive the Retainers in cash, Retainers with respect to any fiscal quarter during such fiscal year that begins after the date of such election will be paid in the form of cash in arrears in equal installments over the applicable number of fiscal quarters during such fiscal year, with payment occurring on the last day of the applicable fiscal quarter.

- *Stock Options*: If the Non-Employee Director elects to receive the Retainers in the form of stock options, with respect to any fiscal quarter during such fiscal year that begins after the date of such election, such stock options will automatically, and without further action by the Board or Committee of the Board, be granted on the first business day of the first fiscal quarter that begins after the date of such election. Any such award will vest in equal installments as follows: (i) the first installment will vest on the last day of the fiscal quarter of the date of grant;

and (ii) any remaining installment(s) will vest on the last day of any subsequent fiscal quarter(s) during such fiscal year, provided that the Non-Employee Director is in service as a Director on the first day of the fiscal quarter of the applicable scheduled vesting date. Notwithstanding the foregoing, if the Non-Employee Director becomes a member of a Committee, Chair of a Committee or Chair of the Board after the first business day of the first fiscal quarter that begins after the date of such election, then the portion (if any) of his or her Annual Committee Member Service Retainer, Annual Committee Chair Service Retainer or Chair of the Board Service Retainer, as applicable, that is to be granted in the form of stock options, will automatically, and without further action by the Board or Committee of the Board, be granted on the third business day after the date that the Non-Employee Director becomes a member of a Committee, Chair of a Committee or Chair of the Board, as applicable. Any such award will vest in equal installments as follows: (i) the first installment will vest on the last day of the fiscal quarter of the date of grant; and (ii) any remaining installment(s) will vest on the last day of any subsequent fiscal quarter(s) during such fiscal year, provided that the Non-Employee Director is in service as a Director on the first day of the fiscal quarter of the applicable scheduled vesting date.

Terms of Elections Regarding Annual Cash Compensation:

- Once an election is submitted for a fiscal year, it will be irrevocable with respect to such fiscal year.
- A Non-Employee Director must submit a new election for each fiscal year.
- Elections with respect to a Non-Employee Director's Retainers must be allocated 100% in either cash or stock options. A Non-Employee Director may not make an election to receive cash or stock options with respect to an individual Retainer or any portion thereof.

Terms of Stock Options Granted Pursuant to Elections:

- Any stock options granted pursuant to a Non-Employee Director's election will be granted under the Plan and will be subject to the terms and conditions of (i) this Director Compensation Policy, (ii) the Plan and (iii) the form stock option grant notices and agreements approved by the Board for the grant of such awards to Non-Employee Directors.
- The actual number of shares subject to any stock options granted pursuant to this Director Compensation Policy and a Non-Employee Director's election to receive the Retainers in the form of stock options will be determined by dividing the Retainers by the "fair value" of a share of the Company's common stock on the last business day in March of the fiscal year in which the stock option is granted, determined using a Black-Scholes model based on the average closing price of the Company's common stock over the 30 calendar days prior to the grant date and with such number of shares rounded down to the nearest whole share.
- The shares subject to any stock options granted pursuant to a Non-Employee Director's election will vest in installments subject to the Non-Employee Director's Continuous Service (as defined in the Plan) through such vesting dates on the terms specified above; provided, however, that all unvested shares subject to such stock options will accelerate and vest in full upon a Change in Control (as defined in the Plan), subject in each case to the Non-Employee Director's Continuous Service as of immediately prior to the Change in Control.
- Any stock options granted pursuant to this Director Compensation Policy will be Nonstatutory Stock Options (as defined in the Plan), will have an exercise price per share equal to 100% of the Fair Market

Value (as defined in the Plan) of the Company's common stock on the date of grant and will have a term of ten years from the date of grant (subject to earlier termination in connection with the Non-Employee Director's termination of service or certain corporate transactions and in accordance with the terms of the Plan). Any such stock option will become exercisable when vested and the vested portion of any such stock option will remain exercisable in accordance with the stock option grant notice and agreement governing the stock option.

EQUITY COMPENSATION

Equity awards will be granted under the Plan. All stock options granted under the Director Compensation Policy will be Nonstatutory Stock Options, with a term of ten years from the date of grant (subject to earlier termination upon a termination of the Non-Employee Director's Continuous Service (as defined in the Plan)) and an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of a share of the Company's common stock on the date of grant.

1. Automatic Equity Grants.

(a) Initial Grant for New Directors. Without any further action of the Board, each person who, after the Effective Date, is elected or appointed for the first time to be a Non-Employee Director will automatically, upon the date of his or her initial election or appointment to be a Non-Employee Director, be granted a Nonstatutory Stock Option to purchase shares of Company common stock with a value of $400,000, determined using a Black-Scholes valuation methodology based on the average closing price of the Company's common stock over the 30 calendar days prior to the grant date and with such number of shares rounded down to the nearest whole share (the "***Initial Grant***"). Each Initial Grant will vest in a series of three successive equal annual installments over the three-year period measured from the date of grant, subject to the Non-Employee Director's Continuous Service through each applicable vesting date.

(b) Annual Grant. Without any further action of the Board, at the close of business on the date of each annual meeting of the Company's stockholders (each, an "***Annual Meeting***") following the Effective Date, each person who is then a Non-Employee Director will automatically be granted a Nonstatutory Stock Option to purchase shares of Company common stock with a value of $200,000, determined using a Black-Scholes valuation methodology based on the average closing price of the Company's common stock over the 30 calendar days prior to the grant date and with such number of shares rounded down to the nearest whole share (the "***Annual Grant***"). Each Annual Grant will vest monthly in twelve equal installments, subject to the Non-Employee Director's Continuous Service through the vesting date.

2. Change in Control. Notwithstanding the foregoing vesting schedules, for each Non-Employee Director who remains in Continuous Service with the Company until immediately prior to the closing of a Change in Control (as defined in the Plan), the shares subject to his or her then-outstanding equity awards that were granted pursuant to the Director Compensation Policy will become fully vested immediately prior to the closing of such Change in Control.

3. Remaining Terms. The remaining terms and conditions of each stock option, including transferability, will be as set forth in the Company's standard Option Agreement, in the form adopted from time to time by the Board.

EXPENSES

The Company will reimburse Non-Employee Directors for ordinary, necessary and reasonable out-of-pocket travel expenses to cover in-person attendance at and participation in Board and committee meetings; *provided*, that the Non-Employee Director timely submits to the Company appropriate documentation substantiating such expenses in accordance with the Company's travel and expense policy, as in effect from time to time.

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Brian Wong, certify that:

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

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

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

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

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

   b) Designed such internal control over financial reporting or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: May 9, 2024

By: /s/ Brian Wong
Brian Wong
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Rodney Young, certify that:

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

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

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

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

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

   b) Designed such internal control over financial reporting or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: May 9, 2024

By: /s/ Rodney Young
Rodney Young
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Brian Wong, Chief Executive Officer of RAPT Therapeutics, Inc. (the "Company"), and Rodney Young, Chief Financial Officer of the Company, each hereby certifies that, to the best of his or her knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended March 31, 2024, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 9, 2024

In Witness Whereof, the undersigned have set their hands hereto as of the 9th day of May, 2024

/s/ Brian Wong
Brian Wong
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Rodney Young
Rodney Young
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of RAPT Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.