

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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 001-37355

VIKING THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

46-1073877
(I.R.S. Employer
Identification Number)

9920 Pacific Heights Blvd, Suite 350
San Diego, California
(Address of Principal Executive Offices)

92121
(Zip Code)

(858) 704-4660
(Registrant's telephone number, including area code)

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

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock, par value \$0.00001 per share	VKTX	The Nasdaq Stock Market LLC

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

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

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

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

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

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date:

Class	Number of Shares Outstanding as of October 15, 2024
Common stock, \$0.00001 par value	111,436,384

VIKING THERAPEUTICS, INC.
FORM 10-Q FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2024
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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Viking Therapeutics, Inc. Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	September 30, 2024 (Unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 50,347	\$ 55,516
Short-term investments – available-for-sale	880,093	306,563
Prepaid clinical trial and preclinical study costs	4,476	2,624
Prepaid expenses and other current assets	1,733	2,522
Total current assets	936,649	367,225
Right-of-use assets	1,113	1,126
Deferred financing costs	80	106
Deposits	46	33
Total assets	<u>\$ 937,888</u>	<u>\$ 368,490</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 254	\$ 7,512
Other accrued liabilities	24,951	11,299
Lease liability, current	480	324
Total current liabilities	25,685	19,135
Lease liability, net of current portion	755	936
Total long-term liabilities	755	936
Total liabilities	26,440	20,071
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, \$0.00001 par value: 10,000,000 shares authorized at September 30, 2024 and December 31, 2023; no shares issued and outstanding at September 30, 2024 and December 31, 2023	—	—
Common stock, \$0.00001 par value: 300,000,000 shares authorized at September 30, 2024 and December 31, 2023; 111,434,821 shares issued and outstanding at September 30, 2024 and 100,113,770 shares issued and outstanding at December 31, 2023	1	1
Treasury stock at cost, no shares at September 30, 2024 and 2,193,251 shares at December 31, 2023	—	(6,795)
Additional paid-in capital	1,362,305	733,546
Accumulated deficit	(452,490)	(377,944)
Accumulated other comprehensive loss	1,632	(389)
Total stockholders' equity	911,448	348,419
Total liabilities and stockholders' equity	<u>\$ 937,888</u>	<u>\$ 368,490</u>

See accompanying notes to the unaudited consolidated financial statements.

Viking Therapeutics, Inc.
Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenues	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	22,785	18,379	70,657	43,304
General and administrative	13,771	8,886	34,026	28,238
Total operating expenses	36,556	27,265	104,683	71,542
Loss from operations	(36,556)	(27,265)	(104,683)	(71,542)
Other income (expense):				
Amortization of financing costs	(24)	(2)	(70)	(62)
Interest income, net	11,531	4,733	30,096	10,314
Realized gain on investments, net	109	—	111	—
Total other income, net	11,616	4,731	30,137	10,252
Net loss	(24,940)	(22,534)	(74,546)	(61,290)
Other comprehensive loss, net of tax:				
Unrealized gain on securities	3,902	221	2,079	305
Foreign currency translation gain (loss)	2	(86)	(58)	(108)
Comprehensive loss	<u>\$ (21,036)</u>	<u>\$ (22,399)</u>	<u>\$ (72,525)</u>	<u>\$ (61,093)</u>
Basic and diluted net loss per share	<u>\$ (0.22)</u>	<u>\$ (0.23)</u>	<u>\$ (0.69)</u>	<u>\$ (0.66)</u>
Weighted-average shares used to compute basic and diluted net loss per share	<u>110,911</u>	<u>99,846</u>	<u>108,262</u>	<u>92,481</u>

See accompanying notes to the unaudited consolidated financial statements.

Viking Therapeutics, Inc.
Consolidated Statements of Stockholders' Equity

(In thousands, except share amounts)
(Unaudited)

Three-Month Period Ended September 30, 2024

	Common Stock		Additional Paid-In	Accumul ated	Accumul ated Other Compreh ensive Income (Loss)	Treasury Stock	Total
	Shares	Amount	Capital	Deficit		Amount	
Balance at June 30, 2024	110,796, 200	\$ 1	\$ 1,350,801	\$ (427,550)	\$ (2,272)	\$ —	\$ 920,980
Employee stock-based compensation, net	—	—	8,982	—	—	—	8,982
Shares withheld related to employee tax withholding	291,835	—	—	—	—	—	—
Issuance of common stock under employee stock plans	346,786	—	2,522	—	—	—	2,522
Unrealized gain on investments	—	—	—	—	3,902	—	3,902
Unrealized currency translation gain	—	—	—	—	2	—	2
Net loss	—	—	—	(24,940)	—	—	(24,940)
Balance at September 30, 2024	111,434, 821	\$ 1	\$ 1,362,305	\$ (452,490)	\$ 1,632	\$ —	\$ 911,448

Nine-Month Period Ended September 30, 2024

	Common Stock		Additional Paid-In	Accumul ated	Accumul ated Other Compreh ensive Income (Loss)	Treasury Stock	Total
	Shares	Amount	Capital	Deficit		Amount	
Balance at December 31, 2023	100,113, 770	\$ 1	\$ 733,546	\$ (377,944)	\$ (389)	\$ (6,795)	\$ 348,419
Employee stock-based compensation, net	—	—	24,045	—	—	—	24,045
Shares withheld related to employee tax withholding	(541,876)	—	(42,101)	—	—	—	(42,101)
Issuance of common stock under employee stock plans	2,994,974	—	9,813	—	—	—	9,813
Sale of common stock, net of issuance costs	8,867,953	—	637,002	—	—	6,795	643,797
Unrealized gain on investments	—	—	—	—	2,079	—	2,079
Unrealized currency translation loss	—	—	—	—	(58)	—	(58)
Net loss	—	—	—	(74,546)	—	—	(74,546)
Balance at September 30, 2024	111,434, 821	\$ 1	\$ 1,362,305	\$ (452,490)	\$ 1,632	\$ —	\$ 911,448

See accompanying notes to the unaudited consolidated financial statements.

Viking Therapeutics, Inc.
Consolidated Statements of Stockholders' Equity

(In thousands, except share amounts)
(Unaudited)

Three-Month Period Ended September 30, 2023

	Common Stock		Additional Paid-In	Accumul- ated	Accumul- ated Other Compreh- ensive Income (Loss)	Treasury Stock	Total
	Shares	Amount	Capital	Deficit		Amount	
Balance at June 30, 2023	100,028, 828	\$ 1	\$ 724,754	\$ (330,805)	\$ (1,040)	\$ (6,795)	\$ 386,115
Employee stock-based compensation, net	—	—	4,481	—	—	—	4,481
Sale of common stock, net of issuance costs	—	—	43	—	—	—	43
Unrealized gain on investments	—	—	—	—	221	—	221
Unrealized currency translation loss	—	—	—	—	(86)	—	(86)
Net loss	—	—	—	(22,534)	—	—	(22,534)
Balance at September 30, 2023	100,028, 828	\$ 1	\$ 729,278	\$ (353,339)	\$ (905)	\$ (6,795)	\$ 368,240

Nine-Month Period Ended September 30, 2023

	Common Stock		Additional Paid-In	Accumul- ated	Accumul- ated Other Compreh- ensive Income (Loss)	Treasury Stock	Total
	Shares	Amount	Capital	Deficit		Amount	
Balance at December 31, 2022	78,257,2 58	\$ 1	\$ 445,267	\$ (292,049)	\$ (1,102)	\$ (6,795)	\$ 145,322
Employee stock-based compensation, net	—	—	12,670	—	—	—	12,670
Shares withheld related to employee tax withholding	(509,686)	—	(7,121)	—	—	—	(7,121)
Issuance of common stock under employee stock plans	2,274,75 2	—	6,580	—	—	—	6,580
	20,006,5						
Sale of common stock, net of issuance costs	04	—	271,882	—	—	—	271,882
Unrealized gain on investments	—	—	—	—	305	—	305
Unrealized currency translation loss	—	—	—	—	(108)	—	(108)
Net loss	—	—	—	(61,290)	—	—	(61,290)
Balance at September 30, 2023	100,028, 828	\$ 1	\$ 729,278	\$ (353,339)	\$ (905)	\$ (6,795)	\$ 368,240

See accompanying notes to the unaudited consolidated financial statements.

Viking Therapeutics, Inc.
Consolidated Statements of Cash Flows

(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2024	2023
Cash flows from operating activities		
Net loss	\$ (74,546)	\$ (61,290)
Adjustments to reconcile net loss to net cash used in operating activities		
Amortization of investment premiums	(13,236)	(5,500)
Amortization of financing costs	70	62
Stock-based compensation	24,045	12,670
Amortization of right-of-use assets	236	218
Realized gain on investment	(111)	—
Interest expense related to operating lease liability	27	33
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,059)	6,466
Accrued interest, net of interest receivable on maturity of investments	1,845	422
Accounts payable	(7,258)	(2,819)
Accrued expenses	13,652	(5,738)
Lease liability	(274)	(260)
Net cash used in operating activities	(56,609)	(55,736)
Cash flows from investing activities		
Purchases of investments	(976,408)	(380,770)
Proceeds from maturities of investments	416,458	165,951
Net cash used in investing activities	(559,950)	(214,819)
Cash flows from financing activities		
Public offering, net of offering costs	597,094	269,760
Value of shares withheld related to employee tax withholding	(42,101)	(7,121)
Proceeds from option exercises and Employee Stock Purchase Plan common stock issuance	9,813	6,580
ATM offering, net of fees	46,658	1,969
Net cash provided by financing activities	611,464	271,188
Net (decrease) increase in cash and cash equivalents	(5,095)	633
Cash and cash equivalents beginning of period	55,516	36,632
Effect of exchange rate changes on cash	(74)	(80)
Cash and cash equivalents end of period	<u>\$ 50,347</u>	<u>\$ 37,185</u>
Supplemental disclosure of non-cash investing and financing transactions		
Unpaid deferred public offering and other financing costs	\$ 50	\$ 50
Right-of-use asset obtained in exchange for lease obligation	<u>\$ 223</u>	<u>\$ —</u>

See accompanying notes to the unaudited consolidated financial statements.

Viking Therapeutics, Inc.
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Organization and Summary of Significant Accounting Policies

The Company

Viking Therapeutics, Inc., a Delaware corporation, together with its subsidiary (the "Company"), is a clinical-stage biopharmaceutical company focused on the development of novel therapies for metabolic and endocrine disorders. In June of 2021, the Company formed an Australian subsidiary, Viking Therapeutics, PTY LTD, so as to be able to take advantage of certain research and development reimbursements available to local Australian based research and development companies that choose to do research in Australia.

The Company was incorporated under the laws of the State of Delaware on September 24, 2012 and its principal executive offices are located in San Diego, California, with a subsidiary located in Adelaide, Australia.

Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The accompanying consolidated balance sheet as of September 30, 2024, consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2024 and 2023, consolidated statements of stockholders' equity for the three and nine months ended September 30, 2024 and 2023, and consolidated statements of cash flows for the nine months ended September 30, 2024 and 2023 are unaudited. These unaudited consolidated financial statements have been prepared in accordance with the rules and regulations of the United States Securities and Exchange Commission (the "SEC") for interim financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. These consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the accompanying notes for the year ended December 31, 2023 contained in the Annual Report on Form 10-K filed by the Company with the SEC on February 7, 2024. The unaudited interim consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and, in the opinion of management, reflect all adjustments (consisting of normal recurring adjustments) necessary to state fairly the Company's financial position as of September 30, 2024, the results of operations for the three and nine months ended September 30, 2024 and 2023, the unaudited consolidated statements of stockholders' equity for the three and nine months ended September 30, 2024 and 2023 and the unaudited consolidated statements of cash flows for the nine months ended September 30, 2024 and 2023. The December 31, 2023 consolidated balance sheet included herein was derived from the audited consolidated financial statements, but it does not include all disclosures or notes required by GAAP for complete consolidated financial statements.

The financial data and other information disclosed in these notes to the consolidated financial statements related to the three and nine months ended September 30, 2024 and 2023 are unaudited. Interim results are not necessarily indicative of results for an entire year.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the accompanying consolidated financial statements. Significant estimates made in preparing these consolidated financial statements relate to accounting for an operating lease and certain commitments. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less from the date of purchase to be cash equivalents.

Investments Available-for-Sale

Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in accumulated other comprehensive loss. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. The amortization of premiums and accretion of discounts is included in interest income. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other income (expense). The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to concentration of credit risk, consist primarily of cash and cash equivalents and marketable securities. The Company maintains deposits in federally insured depository institutions in excess of federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. Additionally, the Company has established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity.

Prepaid Clinical Trial and Preclinical Study Costs

Prepaid clinical trial and preclinical study costs represent advance payments by the Company for future clinical trial and preclinical study services to be performed by the clinical research organization and other research organizations. Such amounts are recognized as research and development expense as the related clinical trial and preclinical study services are performed.

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included in right-of-use ("ROU") assets, and lease liability obligations are included in the Company's consolidated balance sheets. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liability obligations represent its obligation to make lease payments arising from the lease. ROU assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. As the Company's leases typically do not provide an implicit rate, the Company estimates its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. The Company uses the implicit rate when readily determinable. The ROU asset also includes any lease payments made and excludes lease incentives and lease direct costs. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense is recognized on a straight-line basis over the lease term. Please refer to Note 4 for additional information.

Deferred Financing Costs

Deferred financing costs represent legal, accounting and other direct costs related to the Company's efforts to raise capital through a public or private sale of the Company's common stock. Costs related to the public sale of the Company's common stock are deferred until the completion of the applicable offering, at which time such costs are reclassified to additional paid-in-capital as a reduction of the proceeds. Costs related to the private sale of the Company's common stock are deferred until the completion of the applicable offering, at which time such costs are amortized over the term of the applicable purchase agreement.

Revenue Recognition

The Company has not recorded any revenues since its inception. However, in the future, the Company may enter into collaborative research and licensing agreements, under which the Company could be eligible for payments made in the form of upfront license fees, research funding, cost reimbursement, contingent event-based payments and/or royalties.

On January 1, 2018, the Company adopted Financial Accounting Standards Board ("FASB") Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers and all related amendments ("ASC 606" or "the revenue standard"). ASC 606 is a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. The revenue standard is based on the principle that an entity should recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve this core principle, ASC 606 provides that an entity should apply the following steps: (1) identify the contract(s) with a customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract and (5) recognize revenue when (or as) the entity satisfies a performance obligation. The revenue standard also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, and costs to obtain or fulfill contracts. The Company will apply ASC 606 prospectively to all contracts.

Research and Development Expenses

All costs of research and development are expensed in the period incurred. Research and development costs primarily consist of fees paid to contract research organizations ("CROs") and clinical trial sites, employee and consultant related expenses, which include salaries, benefits and stock-based compensation for research and development personnel, external research and development expenses incurred pursuant to agreements with third-party manufacturing organizations, facilities costs, travel costs, dues and subscriptions, depreciation and materials used in preclinical studies, clinical trials and research and development.

The Company estimates its preclinical study and clinical trial expenses based on the services it received pursuant to contracts with research institutions and CROs that conduct and manage preclinical studies and clinical trials on the Company's behalf. Clinical trial-related contracts vary significantly in length, and may be for a fixed amount based on milestones or deliverables, a variable amount based on actual costs incurred, capped at a certain limit, or a combination of these elements. The Company accrues service fees based on work performed, which relies on estimates of total costs incurred based on milestones achieved, patient enrollment and other events. The majority of the Company's service providers invoice the Company in arrears, and to the extent that amounts invoiced differ from its estimates of expenses incurred, the Company accrues for additional costs. The financial terms of these agreements vary from contract to contract and may result in uneven expenses and payment flows. Preclinical study and clinical trial expenses include:

- fees paid to CROs, consultants and laboratories in connection with preclinical studies;
- fees paid to CROs, clinical trial sites, investigators and consultants in connection with clinical trials; and
- fees paid to contract manufacturers and service providers in connection with the production, testing and packaging of active pharmaceutical ingredients and drug materials for preclinical studies and clinical trials.

Payments under some of these agreements depend on factors such as the milestones accomplished, including enrollment of certain numbers of patients, site initiation and the completion of clinical trial milestones. To date, the Company has not experienced any events requiring it to make material adjustments to its accruals for service fees. If the Company does not identify costs that it has begun to incur or if it underestimates or overestimates the level of services performed or the costs of these services, its actual expenses could differ from its estimates, which could materially affect its results of operations. Adjustments to the Company's accruals are recorded as changes in estimates become evident. Furthermore, based on amounts invoiced to the Company by its service providers, the Company may also record payments made to those providers as prepaid expenses that will be recognized as expense in future periods as services are rendered.

Related to the Company's Australian subsidiary, Viking Therapeutics, PTY LTD, the Company is eligible under the AusIndustry Research and Tax Development Tax Incentive Program to receive, and has received, cash payments from the Australian Taxation Office ("ATO"). The tax incentive is available to the Company on the basis of specific criteria with which the Company must comply related to research and development expenditures in Australia. As there is no specific GAAP guidance related to how to record this research and development tax incentive, the Company looked to International Accounting Standard ("IAS") 20 and determined that it will recognize these research and development tax incentives as contra research and development expense once received. The amounts are determined based on a cost-reimbursement basis, and the incentive is related to the Company's research and development expenditures and is due regardless of whether any Australian tax is owed.

Patent Costs

Costs related to filing and pursuing patent applications are expensed as incurred to general and administrative expense, as recoverability of such expenditures is uncertain.

Stock-Based Compensation

The Company generally uses the straight-line method to allocate compensation cost to reporting periods over each optionee's requisite service period, which is generally the vesting period, and estimates the fair value of stock-based awards or restricted stock units to employees and directors using the Black-Scholes option-valuation model (the "Black-Scholes model"). The Black-Scholes model requires the input of subjective assumptions, including volatility, the expected term and the fair value of the underlying common stock on the date of grant, among other inputs. For restricted stock and restricted stock unit awards, the Company generally uses the straight-line method to allocate compensation cost to reporting periods over the holder's requisite service period, which is generally the vesting period, and uses the fair value at grant date to value the awards. For restricted stock that vests upon the satisfaction of certain performance conditions, the Company recognizes stock-based compensation expense when it becomes probable that the performance conditions will be met. At the grant date, the Company determines the grant date fair value, as a publicly traded company, using the intrinsic value, or the closing price of the Company's common stock on the date of grant. At the point where the criteria are deemed probable of being met, the Company records stock-based compensation with a cumulative catch-up expense in the period first recognized and then on a straight-line basis over the remaining period for which the performance criteria are expected to be completed.

For the Company's 2014 Employee Stock Purchase Plan (the "2014 ESPP") and 2024 Employee Stock Purchase Plan (the "2024 ESPP"), the Company generally recognizes compensation expense for the fair value of the purchase options, as measured on the grant date, and uses the graded vesting method to allocate this compensation cost to each purchase period within the related two-year offering period. As the 2014 ESPP previously allowed, and 2024 ESPP currently allows, for up to one increase in contributions during each purchase period, if an employee elected to increase his or her contributions, the Company treated this as an accounting

modification. The pre- and post-modification values were calculated on the date of the modification, and the incremental expense is then amortized over the remaining purchase periods.

Income Taxes

The Company accounts for its income taxes using the liability method whereby deferred tax assets and liabilities are determined based on temporary differences between the basis used for financial reporting and income tax reporting purposes. Deferred income taxes are provided based on the enacted tax rates in effect at the time such temporary differences are expected to reverse. A valuation allowance is provided for deferred tax assets if it is more likely than not that the Company will not realize those tax assets through future operations.

FASB Accounting Standards Codification Topic 740-10, *Income Taxes*, clarifies the accounting for uncertainty in income taxes recognized in the Company's consolidated financial statements in accordance with GAAP. Income tax positions must meet a more-likely-than-not recognition threshold to be recognized. Income tax positions that previously failed to meet the more-likely-than-not threshold are recognized in the first subsequent financial reporting period in which that threshold is met. Previously recognized tax positions that no longer meet the more-likely-than-not threshold are derecognized in the first subsequent financial reporting period in which that threshold is no longer met.

The Company's policy is to recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense.

Foreign Currency

The financial statements of the Company's foreign subsidiary whose functional currency is the local currency are translated into U.S. dollars for consolidation as follows: assets and liabilities at the exchange rate as of the balance sheet date, stockholders' equity at the historical rates of exchange, and income and expense amounts at the average exchange rate for the period. Translation adjustments resulting from the translation of the subsidiaries' accounts are included in "Accumulated other comprehensive loss" as equity in the consolidated balance sheet. Transactions denominated in currencies other than the applicable functional currency are converted to the functional currency at the exchange rate on the transaction date. At period end, monetary assets and liabilities are remeasured to the functional currency using exchange rates in effect at the balance sheet date. Non-monetary assets and liabilities are remeasured at historical exchange rates. Gains and losses resulting from foreign currency transactions are included within "Comprehensive loss" in the consolidated statement of operations and comprehensive loss. For the three months ended September 30, 2024, foreign currency transaction gain amounted to \$2,000. For the three months ended September 30, 2023, foreign currency transaction loss amounted to \$86,000. For the nine months ended September 30, 2024 and 2023, foreign currency transaction loss amounted to \$58,000 and \$108,000, respectively.

Comprehensive Loss

The Company's comprehensive loss consists of net loss and foreign currency translation adjustments arising from the consolidation of the Company's foreign subsidiary.

Net Loss per Common Share

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, the Company currently does not have any deemed common share equivalents; therefore, its basic and diluted net loss per share calculations are the same.

The following table presents the computation of basic and diluted net loss per common share (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Numerator:				
Net loss attributable to common stockholders	\$ (24,940)	\$ (22,534)	\$ (74,546)	\$ (61,290)
Denominator:				
Weighted-average common shares outstanding	111,093,799	100,028,828	108,445,522	92,664,250
Less: Weighted-average shares subject to repurchase	(183,095)	(183,095)	(183,095)	(183,095)
Denominator for basic and diluted net loss per share	<u>110,910,704</u>	<u>99,845,733</u>	<u>108,262,427</u>	<u>92,481,155</u>
Net loss per share:				
Basic and diluted	<u>\$ (0.22)</u>	<u>\$ (0.23)</u>	<u>\$ (0.69)</u>	<u>\$ (0.66)</u>

Potentially dilutive securities that are not included in the calculation of diluted net loss per share because their effect is anti-dilutive are as follows (in common equivalent shares):

	As of September 30,	
	2024	2023
Restricted stock units	2,537,352	2,855,656
Common stock subject to repurchase	183,095	183,095
Common stock options	4,864,642	5,243,807
	<u>7,585,089</u>	<u>8,282,558</u>

Segments

The Company operates in only one segment. Management uses cash flows as the primary measure to manage its business and does not segment its business for internal reporting or decision-making purposes.

2. Investments in Marketable Securities

The Company's investment strategy is focused on capital preservation. The Company invests in instruments that meet the credit quality standards outlined in the Company's investment policy. This policy also limits the amount of credit exposure to any one issue or type of instrument. As of each of September 30, 2024 and December 31, 2023, the Company's investments were in government money market funds, certificates of deposit, commercial paper, corporate debt securities and government debt securities. There were no sales of available-for-sale securities during the three and nine months ended September 30, 2024 or during the year ended December 31, 2023.

Investments classified as available-for-sale as of September 30, 2024 consisted of the following (in thousands):

As of September 30, 2024	Amortized Cost	Gross Unrealized Gains ⁽¹⁾	Gross Unrealized Losses ⁽¹⁾	Aggregate Estimated Fair Value
Commercial paper ⁽²⁾	\$ 14,550	\$ —	\$ —	\$ 14,550
Corporate debt securities ⁽²⁾	690,756	1,954	(138)	692,572
Government debt securities ⁽²⁾	172,810	241	(80)	172,971
	<u>\$ 878,116</u>	<u>\$ 2,195</u>	<u>\$ (218)</u>	<u>\$ 880,093</u>

(1) Unrealized gains and losses on available-for-sale securities are included as a component of comprehensive loss. At September 30, 2024, there were 270 securities in an unrealized gain position and there were 58 securities in an unrealized loss position. The unrealized gains were less than \$100,000 individually and \$2.2 million in the aggregate. The unrealized losses were less than \$42,000 individually and \$218,000 in the aggregate. The Company does not intend to sell these investments and it is not more likely than not that the Company will be required to sell these investments before recovery of their amortized cost basis, which may be at maturity. The Company reviews its investments to identify and evaluate investments that have an indication of possible other-than-temporary impairment. Factors considered in determining whether a loss is other-than-temporary include the length of time and extent to which fair value has been less than the cost basis, the financial condition and near-term prospects of the investee, and the Company's intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value.

(2) At September 30, 2024, none of these securities were classified as cash and cash equivalents on the Company's consolidated balance sheet, and \$189.8 million of the corporate debt securities were scheduled to mature outside of one year at the time of purchase.

Investments classified as available-for-sale as of December 31, 2023 consisted of the following (in thousands):

As of December 31, 2023	Amortized Cost	Gross Unrealized Gains ⁽¹⁾	Gross Unrealized Losses ⁽¹⁾	Aggregate Estimated Fair Value
Commercial paper ⁽²⁾	\$ 24,226	\$ —	\$ —	\$ 24,226
Corporate debt securities ⁽²⁾	168,564	148	(128)	168,584
Government debt securities ⁽²⁾	113,871	8	(126)	113,753
	<u>\$ 306,661</u>	<u>\$ 156</u>	<u>\$ (254)</u>	<u>\$ 306,563</u>

(1) Unrealized gains and losses on available-for-sale securities are included as a component of comprehensive loss. At December 31, 2023, there were 49 securities in an unrealized gain position and 115 securities in an unrealized loss position. The unrealized gains were less than \$37,000 individually and \$158,000 in the aggregate. The unrealized losses were less than \$23,000 individually and \$258,000 in the aggregate. None of these securities have been in a continuous unrealized loss or unrealized gain position for more than 12 months. The Company does not intend to sell these investments and it is not more likely than not that the Company will be required to sell these investments before recovery of their amortized cost basis, which may be at maturity. The Company reviews its investments to identify and evaluate investments that have an indication of possible other-than-temporary impairment. Factors considered in determining whether a loss is other-than-temporary include the length of time and extent to which fair value has been less than the cost basis, the financial condition and near-term prospects of the investee, and the Company's intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value.

(2) At December 31, 2023, none of these securities were classified as cash and cash equivalents on the Company's consolidated balance sheet and none of the corporate debt securities were scheduled to mature outside of one year at the time of purchase.

3. Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, investments and accounts payable. The carrying amounts reported in the accompanying consolidated balance sheets for cash and cash equivalents and accounts payable approximate fair value because of the short-term maturity of those instruments. Fair value measurements are classified and disclosed in one of the following three categories:

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

Level 2 —Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices 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 assets or liabilities.

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

As of September 30, 2024 and December 31, 2023, all of the Company's financial assets that were subject to fair value measurements were valued using observable inputs. The Company's financial assets valued based on Level 1 inputs consist of money market funds. The Company's financial assets valued based on Level 2 inputs consist of certificates of deposit, commercial paper, corporate debt securities and government debt securities, which consist of investments in highly rated investment-grade corporations.

The Company's investment strategy is focused on capital preservation. The Company invests in instruments that meet the credit quality standards outlined in the Company's investment policy. This policy also limits the amount of credit exposure to any one issue or type of instrument. As of September 30, 2024, the Company's investments were in government money market funds, commercial paper, corporate debt securities and government debt securities.

The fair values of the Company's financial instruments are presented below (in thousands):

Fair Value Measurements at September 30, 2024				
	Total	Level 1	Level 2	Level 3
Financial assets carried at fair value:				
Cash equivalents:	\$ 35,841	\$ 35,841	\$ —	\$ —
Short-term investments				
Commercial paper, available-for-sale	14,550	—	14,550	—
Corporate debt securities, available-for-sale	692,572	—	692,572	—
Government debt securities, available-for-sale	172,971	—	172,971	—
Total financial assets	<u>\$ 915,934</u>	<u>\$ 35,841</u>	<u>\$ 880,093</u>	<u>\$ —</u>

Fair Value Measurements at December 31, 2023				
	Total	Level 1	Level 2	Level 3
Financial assets carried at fair value:				
Cash equivalents:	\$ 40,479	\$ 16,411	\$ 24,068	\$ —
Short-term investments				
Commercial paper, available-for-sale	24,226	—	24,226	—
Corporate debt securities, available-for-sale	168,584	—	168,584	—
Government debt securities, available-for-sale	113,753	—	113,753	—
Total financial assets	<u>\$ 347,042</u>	<u>\$ 16,411</u>	<u>\$ 330,631</u>	<u>\$ —</u>

4. Operating Leases – ROU Assets and Lease Liability Obligations

The Company has an operating lease (the “Office Lease”), which is for office space under a lease that commenced on March 1, 2022 and expires on July 31, 2027 (the “Term”). Below is a summary of the Company’s ROU assets and lease liabilities as of September 30, 2024 and December 31, 2023 (in thousands, except for years and %):

	September 30, 2024	December 31, 2023
Right-of-use assets	\$ 1,113	\$ 1,126
Lease liability obligations, current	\$ 480	\$ 324
Lease liability obligations, less current portion	755	936
Total lease liability obligations	\$ 1,235	\$ 1,260
Weighted-average remaining lease term	2.60 years	3.58 years
Weighted-average discount rate	3.70 %	3.00 %

During the three and nine months ended September 30, 2024, the Company recognized \$97,000 and \$268,000 in operating lease expenses, respectively, which are included in operating expenses in the Company’s consolidated statement of operations and comprehensive loss.

During the three and nine months ended September 30, 2023, the Company recognized \$84,000 and \$255,000 in operating lease expenses, respectively, which are included in operating expenses in the Company’s consolidated statement of operations and comprehensive loss.

Approximate future minimum lease payments for the Company’s ROU assets over the remaining lease period as of September 30, 2024 are as follows (in thousands):

Remainder of 2024	\$ 127
2025	521
2026	418
2027	227
Total minimum lease payments	\$ 1,293
Less: amount representing interest	\$ (58)
Total lease liability obligations	\$ 1,235

The Office Lease provides the Company with an option to extend the term of the Office Lease for a period of five years beyond the Term. If the option is exercised, the renewal term will be upon the same terms and conditions as the original Term, except that the base rent will be equal to the prevailing market rate as determined pursuant to the terms of the Office Lease. The option to extend the Term was not recognized as part of the Company’s lease liability and right-of-use assets.

5. Stockholders’ Equity

Preferred Stock

The Company is authorized to issue up to 10,000,000 shares of preferred stock, \$0.00001 par value per share, with no shares of preferred stock outstanding as of September 30, 2024 and December 31, 2023. The Company’s Board of Directors is authorized to designate the terms and conditions of any preferred stock the Company may issue without further action by the stockholders of the Company.

Common Stock

The Company is authorized to issue up to 300,000,000 shares of common stock, \$0.00001 par value per share.

In February 2014, the Company entered into a stock purchase agreement with one of its founders. The agreement provided for the purchase of 1,000,000 shares of the Company’s common stock at a price per share of \$0.01 in exchange for future services to be

rendered to the Company as measured by certain performance criteria. The shares were subject to a repurchase option and were to vest in two tranches of 500,000 shares each, upon achievement of the performance target or upon a triggering event as defined.

The Company determined that the fair value of the unrecognized expense was \$168,000 at February 20, 2014, the grant date. In May 2015, the Company repurchased 633,810 of these shares at a purchase price of \$0.00001 per share. In connection with the repurchase, the Company entered into an amendment to the stock purchase agreement to provide that the remaining 366,190 shares would continue to vest in two tranches of 183,095 shares each, upon achievement of the performance target or upon a triggering event as defined. The pro rata grant date fair value of the unrecognized expense is \$62,000. In October 2015, a triggering event became probable of occurrence and was deemed achieved in October 2016 and 183,095 shares vested at that time; therefore, the Company recorded \$31,000 of stock-based compensation expense through December 31, 2016. No similar expense was recognized during the nine months ended September 30, 2024 or 2023. The Company will continue to reassess at each reporting period whether it is probable that the performance target will be achieved, and if and when it is deemed probable, the Company will begin to record compensation expense using the fair value to determine stock-based compensation expense in its financial statements over the period the Company estimates the performance target will actually be achieved.

On July 28, 2021, the Company entered into an At-The-Market Equity Offering Sales Agreement (the "ATM Agreement"), with Stifel, Nicolaus & Company, Incorporated, Truist Securities, Inc. and H.C. Wainwright & Co. LLC (collectively, the "Agents"), pursuant to which the Company could offer and sell, from time to time, through or to the Agents, as sales agent or principal (the "ATM Offering"), shares of the Company's common stock (the "ATM Shares"). Any ATM Shares offered and sold in the ATM Offering were to be issued pursuant to a universal Shelf Registration Statement on Form S-3 (File No. 333-258231) (the "2021 Shelf Registration Statement") and the 424(b) prospectus supplement relating to the ATM Offering dated August 11, 2021. From its inception through the expiration of the 2021 Shelf Registration Statement in July 2023, 1,587,404 shares of the Company's common stock were sold pursuant to the ATM Offering for aggregate net proceeds to the Company of approximately \$13.6 million.

On March 10, 2022, the Company's Board of Directors authorized a stock repurchase program effective March 18, 2022, whereby the Company could purchase up to \$50.0 million in shares of its common stock over a period of up to two years (the "Repurchase Program"). The Repurchase Program was to be carried out at the discretion of a committee of the Company's Board of Directors through open market purchases, one or more Rule 10b5-1 trading plans, block trades and in privately negotiated transactions. Through March 18, 2024, the termination date of the Repurchase Program, an aggregate of 729,034 shares of the Company's common stock were repurchased by the Company under the Repurchase Program. Shares repurchased by the Company under the Repurchase Program were held in treasury and reissued by the Company as part of the March 2024 Offering (as defined below).

On April 3, 2023, the Company completed an underwritten public offering of its common stock (the "April 2023 Offering") pursuant to the 2021 Shelf Registration Statement. In the April 2023 Offering, the Company sold an aggregate of 19,828,300 shares of its common stock at a public offering price of \$14.50 per share, which included the exercise in full by the underwriters of their option to purchase 2,586,300 additional shares of common stock. Upon the closing of the April 2023 Offering, the Company received net proceeds of \$270.0 million, after deducting underwriting discounts, commissions and other offering expenses.

On July 26, 2023, the Company filed an automatic universal shelf registration statement on Form S-3 (File No. 333-273460) as a well-known seasoned issuer as defined in Rule 405 under the Securities Act of 1933, as amended, which became effective upon filing (the "2023 Shelf Registration Statement"). The 2023 Shelf Registration Statement allows the Company to offer an indeterminate amount of securities, including equity securities, debt securities, warrants, rights, units and depositary shares, from time to time as described in the 2023 Shelf Registration Statement. The specific terms of any offering under the 2023 Shelf Registration Statement will be established at the time of such offering. The 2023 Shelf Registration Statement will expire on July 26, 2026.

On July 26, 2023, the Company entered into an Amendment No. 1 to At-The-Market Equity Offering Sales Agreement (the "ATM Agreement Amendment") with Stifel, Nicolaus & Company, Incorporated, Truist Securities, Inc., H.C. Wainwright & Co. LLC and BTIG, LLC. Pursuant to the ATM Agreement Amendment, BTIG, LLC was added as a sales agent for the ATM Offering and the ATM Agreement was amended to provide that the ATM Offering could be conducted off of registration statements on Form S-3 subsequently filed by the Company. Any ATM Shares offered and sold in the ATM Offering will now be issued pursuant to the 2023 Shelf Registration Statement and the prospectus relating to the ATM Offering, dated July 26, 2023, that was included in the 2023 Shelf Registration Statement (the "ATM Prospectus"). The 2023 Shelf Registration Statement will expire on July 26, 2026. From the date of the ATM Prospectus through September 30, 2024, 1,426,303 shares of the Company's common stock were sold pursuant to the ATM Offering and, as of September 30, 2024, the Company may sell shares of its common stock for remaining gross proceeds of up to \$151.9 million from time to time pursuant to the ATM Prospectus.

On March 4, 2024, the Company completed an underwritten public offering of its common stock (the "March 2024 Offering") pursuant to the 2023 Shelf Registration Statement. In the March 2024 Offering, the Company sold an aggregate of 7,441,650 shares of its common stock at a public offering price of \$85.00 per share, which included the exercise in full by the underwriters of their option to purchase 970,650 additional shares of common stock. Of the shares sold, 2,193,251 were issued out of the Company's treasury

shares. Upon the closing of the March 2024 Offering, the Company received net proceeds of \$597.1 million, after deducting underwriting discounts, commissions and other offering expenses.

During the nine months ended September 30, 2024 and 2023, the Company issued 166,816 and 95,357 shares of its common stock pursuant to the 2014 ESPP, respectively, and did not issue any shares of its common stock pursuant to the 2024 ESPP.

6. Stock-Based Compensation

The Company generally uses the straight-line method to allocate compensation cost to reporting periods over each optionee's requisite service period, which is generally the vesting period, and estimates the fair value of stock-based awards or restricted stock units to employees and directors using the Black-Scholes option-valuation model. The Black-Scholes model requires the input of subjective assumptions, including volatility, the expected term and the fair value of the underlying common stock on the date of grant, among other inputs. For restricted stock and restricted stock unit awards, the Company generally uses the straight-line method to allocate compensation cost to reporting periods over the holder's requisite service period, which is generally the vesting period, and uses the fair value at grant date to value the awards. For restricted stock that vests upon the satisfaction of certain performance conditions, the Company recognizes stock-based compensation expense when it becomes probable that the performance conditions will be met. At the grant date, the Company determines the grant date fair value, as a publicly traded company, using the intrinsic value, or the closing price of its common stock on the date of grant. At the point where the criteria are deemed probable of being met, the Company records stock-based compensation with a cumulative catch-up expense in the period first recognized and then on a straight-line basis over the remaining period for which the performance criteria are expected to be completed.

For the 2014 ESPP and 2024 ESPP, the Company generally recognizes compensation expense for the fair value of the purchase options, as measured on the grant date, and uses the graded vesting method to allocate this compensation cost to each purchase period within the related two-year offering period. As the 2014 ESPP previously allowed, and the 2024 ESPP currently allows, for up to one increase in contributions during each purchase period, then as an employee elects to increase their contributions, the Company treats this as an accounting modification. The pre- and post-modification values are calculated on the date of the modification, and the incremental expense is then amortized over the remaining purchase periods.

2014 Plan. The Company's 2014 Equity Incentive Plan (the "2014 Plan") provided that the compensation committee of the Company's Board of Directors (the "Compensation Committee") could grant or issue stock options, stock appreciation rights, restricted shares, restricted stock units and unrestricted shares, deferred share units, performance and cash-settled awards and dividend equivalent rights to participants under the 2014 Plan. Initially, a total of 1,527,770 shares of the Company's common stock were reserved for issuance pursuant to the 2014 Plan. The 2014 Plan provided that the number of shares available for issuance under the 2014 Plan would, unless otherwise determined by the Company's Board of Directors or the Compensation Committee, be automatically increased on January 1 of each year commencing on January 1, 2016 and ended on (and including) January 1, 2024, in an amount equal to 3.5% of the total number of shares of the Company's common stock outstanding on December 31 of the preceding calendar year. The shares of common stock deliverable pursuant to awards under the 2014 Plan are authorized but unissued shares of the Company's common stock, or shares of the Company's common stock that the Company otherwise holds in treasury or in trust. The 2014 Plan provided that any shares of the Company's common stock underlying awards that are settled in cash or otherwise expire, or are forfeited, terminated or cancelled (including pursuant to an exchange program established by the Compensation Committee) prior to the issuance of stock would again be available for issuance under the 2014 Plan. In addition, shares of the Company's common stock that are withheld (or not issued) in payment of the exercise price or taxes relating to an award, and shares of the Company's common stock equal to the number surrendered in payment of any exercise price or withholding taxes relating to an award, would again be available for issuance under the 2014 Plan. As of December 31, 2023, there were 5,939,750 shares of the Company's common stock available for issuance and, effective January 1, 2024, an additional 3,503,981 shares of the Company's common stock were added to the number of shares reserved for issuance under the 2014 Plan in accordance with the terms of the 2014 Plan.

2024 Plan. On May 21, 2024, the Company's stockholders approved the Viking Therapeutics, Inc. 2024 Equity Incentive Plan (the "2024 Plan"), which replaces the 2014 Plan. No further awards have been or will be made under the 2014 Plan since May 21, 2024. The number of shares of common stock initially authorized for issuance pursuant to the 2024 Plan is equal to (a) 12,000,000 shares of common stock, plus (b) up to a maximum of 7,674,614 shares of common stock subject to outstanding stock options or other equity awards previously granted under the 2014 Plan that will become available for future issuance under the 2024 Plan to the extent that, after May 21, 2024, any such equity award terminates or expires prior to exercise or settlement, is not issued because the award is settled in cash, is forfeited because of the failure to vest or is reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price.

2014 ESPP. Initially, a total of 458,331 shares of the Company's common stock were reserved for issuance pursuant to the 2014 ESPP. The 2014 ESPP provided that the number of shares available for issuance under the 2014 ESPP would, unless otherwise determined by the Company's Board of Directors or the Compensation Committee, be automatically increased on January 1 of each year commencing on January 1, 2016 and ended on (and including) January 1, 2024, in an amount equal to 1% of the total number of shares of the Company's common stock outstanding on December 31 of the preceding calendar year. The shares of common stock available for purchase pursuant to the 2014 ESPP were authorized but unissued shares of the Company's common stock, shares of the Company's common stock that the Company otherwise held in treasury or shares of the Company's common stock that were purchased on the open market in arms' length transactions in accordance with applicable securities laws. Shares of the Company's common stock were offered for purchase under the 2014 ESPP as determined by the Compensation Committee through a series of successive offerings that each had a term of 24 months and consisted of four consecutive purchase periods of six months each. As of December 31, 2023, there were 4,251,444 shares of the Company's common stock available for issuance and, effective January 1, 2024, an additional 1,001,137 shares of the Company's common stock were added to the number of shares reserved for issuance under the 2014 ESPP in accordance with the terms of the 2014 ESPP. On May 20, 2024, 166,816 shares of the Company's common stock were purchased by participants of the 2014 ESPP.

2024 ESPP. On May 21, 2024, the Company's stockholders approved the Viking Therapeutics, Inc. 2024 Employee Stock Purchase Plan (the "2024 ESPP"), which replaces the 2014 ESPP. No further shares have been or will be issued to participants under the 2014 ESPP since May 21, 2024. The maximum number of shares of the Company's common stock that may be issued under the 2024 ESPP will not exceed 5,500,000 shares for issuance pursuant to purchases under the 2024 ESPP. The shares of common stock available for purchase pursuant to the 2024 ESPP are authorized but unissued shares of the Company's common stock, shares of the Company's common stock that the Company otherwise held in treasury or shares of the Company's common stock that are purchased on the open market in arms' length transactions in accordance with applicable securities laws. Shares of the Company's common stock will be offered for purchase under the 2024 ESPP as determined by the Compensation Committee through a series of successive offerings that each had a term of 24 months and consisted of four consecutive purchase periods of six months each. Prior to the commencement of any future offering under the 2024 ESPP, the Compensation Committee may determine that the current offering shall end, may commence a new offering on the first day after the end of such terminal purchase period (or any desired later date), and may decide that future offerings will consist of one or more consecutive purchase periods, each to be of such duration as determined by the Compensation Committee; however, no offering will exceed 27 months and no purchase period will exceed one year. Each employee of the Company who (1) is an employee on the first date of any offering under the 2024 ESPP, (2) is customarily scheduled to work for more than 20 hours per week and more than five months per calendar year, and (3) meets such other criteria as may be determined by the Compensation Committee (consistent with Section 423 of the Internal Revenue Code of 1986, as amended), is eligible to participate in the 2024 ESPP for each purchase period within such offering. The purchase price per share of the Company's common stock under the 2024 ESPP may not be less than, and will initially be equal to, the lesser of: (1) 85% of the fair market value per share of the Company's common stock on the first day of the offering, or (2) 85% of the fair market value per share of the Company's common stock on the date the purchase right is exercised, which will be the last day of the applicable purchase period.

During the three and nine months ended September 30, 2024 and 2023, the Company recognized the following stock-based compensation expense (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Stock-based compensation expense by type of award:				
Stock options	\$ 3,467	\$ 1,320	\$ 8,148	\$ 4,311
Restricted stock and restricted stock units	5,440	2,699	14,879	7,251
Employee stock purchase plan	75	462	1,018	1,108
Total stock-based compensation expense included in expenses	<u>\$ 8,982</u>	<u>\$ 4,481</u>	<u>\$ 24,045</u>	<u>\$ 12,670</u>
Stock-based compensation expense by line item:				
Research and development expenses	\$ 3,016	\$ 1,145	\$ 7,062	\$ 3,571
General and administrative expenses	5,966	3,336	16,983	9,099
Total stock-based compensation expense included in expenses	<u>\$ 8,982</u>	<u>\$ 4,481</u>	<u>\$ 24,045</u>	<u>\$ 12,670</u>

The following table sets forth the Company's unrecognized stock-based compensation expense by type of award and the weighted-average period over which that expense is expected to be recognized (in thousands, except for years):

	As of September 30, 2024	
Type of award:	Unrecognized Expense, Net of Estimated Forfeitures	Weighted-average Recognition Period (in years)
Stock options	\$ 20,272	2.72
Restricted stock and restricted stock units	\$ 16,195	1.69

The following table is a summary of restricted stock activity during the nine months ended September 30, 2024:

	Shares of Restricted Stock	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2023	183,095	\$ 0.17
Granted	—	\$ —
Vested	—	\$ —
Forfeited	—	\$ —
Repurchased	—	\$ —
Unvested at September 30, 2024	183,095	\$ 0.17

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

	Shares Subject to Restricted Stock Units	Weighted-Average Grant Date Value
Unvested at December 31, 2023	2,855,656	\$ 7.32
Granted	1,310,533	\$ 17.40
Vested	(1,551,003)	\$ 8.68
Forfeited	—	\$ —
Cancelled	(77,834)	\$ 7.77
Unvested at September 30, 2024	2,537,352	\$ 11.68

The Company issues performance-based restricted stock units ("PRSU awards"). These awards are issued to certain of its employees and the shares subject to these PRSU awards will vest upon the Company achieving certain milestones over a four-year period, with any then-unvested portion of the PRSU awards to be cancelled on the four-year anniversary of the applicable grant date. At the grant date, the Company determines the grant date fair value, as a publicly traded company, using the intrinsic value, or the closing price of the Company's common stock on the date of grant. At the point where the criteria are deemed probable of being met, the Company records stock-based compensation with a cumulative catch-up expense in the period first recognized and then on a straight-line basis over the remaining period for which the performance criteria are expected to be completed.

In January 2020, the Company issued 244,000 PRSU awards to several of its employees, which are reflected in the above table summarizing restricted stock unit activity. The shares subject to these PRSU awards vested upon the Company achieving certain milestones, with 100% of the shares subject to the PRSU awards vesting upon the achievement of three of the milestones over a four-year period, with any then-unvested portion of the PRSU awards to be cancelled on the four-year anniversary of the grant date. As of January 4, 2024, the date of cancellation, 77,834 PRSU awards were cancelled, 10,500 PRSU awards had been forfeited, and two of the milestones had been met, resulting in the Company recording cumulative stock-based compensation expense of \$1.2 million.

In January 2021, the Company issued 205,500 PRSU awards to several of its employees, which are reflected in the above table summarizing restricted stock unit activity. The shares subject to these PRSU awards shall vest upon the Company achieving certain milestones, with 100% of the shares subject to the PRSU awards vesting upon the achievement of three of the milestones over a four-year period and 133.3% of the shares subject to the PRSU awards vesting upon the achievement of all four milestones over a four-year period, with any then-unvested portion of the PRSU awards to be cancelled on the four-year anniversary of the grant date. As of September 30, 2024, 10,000 PRSU awards had been forfeited, two of the four milestones had been met and the remaining two were deemed improbable of achievement, resulting in the Company recording cumulative stock-based compensation expense of \$800,000 through September 30, 2024 and stock-based compensation expense of \$(191,000) during the nine months ended September 30, 2024.

In January 2022, the Company issued 657,000 PRSU awards to several of its employees, which are reflected in the above table summarizing restricted stock unit activity. The shares subject to these PRSU awards shall vest upon the Company achieving certain milestones, with 100% of the shares subject to the PRSU awards vesting upon the achievement of three of the milestones over a four-year period and 133.3% of the shares subject to the PRSU awards vesting upon the achievement of all four milestones over a four-year period, with any then-unvested portion of the PRSU awards to be cancelled on the four-year anniversary of the grant date. As of September 30, 2024, no PRSU awards had been forfeited, three of the four milestones had been met and the remaining one was deemed improbable of achievement, resulting in the Company recording cumulative stock-based compensation expense of \$3.2 million through September 30, 2024 and stock-based compensation expense of \$(709,000) during the nine months ended September 30, 2024.

In January 2023, the Company issued 920,000 PRSU awards to several of its employees, which are reflected in the above table summarizing restricted stock unit activity. The shares subject to these PRSU awards shall vest upon the Company achieving certain milestones, with 100% of the shares subject to the PRSU awards vesting upon the achievement of three of the milestones over a four-year period and 133.3% of the shares subject to the PRSU awards vesting upon the achievement of all four milestones over a four-year period, with any then-unvested portion of the PRSU awards to be cancelled on the four-year anniversary of the grant date. As of September 30, 2024, no PRSU awards had been forfeited, two of the four milestones had been met and the remaining two were deemed probable of achievement, resulting in the Company recording cumulative stock-based compensation expense of \$7.9 million through September 30, 2024 and stock-based compensation expense of \$2.9 million during the nine months ended September 30, 2024.

In January 2024, the Company issued 677,500 PRSU awards to several of its employees, which are reflected in the above table summarizing restricted stock unit activity. The shares subject to these PRSU awards shall vest upon the Company achieving certain milestones, with 100% of the shares subject to the PRSU awards vesting upon the achievement of three of the milestones over a four-year period and 133.3% of the shares subject to the PRSU awards vesting upon the achievement of all four milestones over a four-year period, with any then-unvested portion of the PRSU awards to be cancelled on the four-year anniversary of the grant date. As of September 30, 2024, no PRSU awards had been forfeited, one of the four milestones had been met and the remaining three were deemed probable of achievement, resulting in the Company recording stock-based compensation expense of \$9.5 million during the nine months ended September 30, 2024.

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

	Shares Subject to Stock Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Options outstanding at December 31, 2023	5,248,682	\$ 6.79	7.10	62,210,000
Granted	1,197,200	\$ 22.39		
Exercised	(1,568,990)	\$ 6.00		
Forfeited	(12,250)	\$ 9.93		
Cancelled	—	\$ —		
Options outstanding at September 30, 2024	<u>4,864,642</u>	\$ 10.87	7.51	255,374,000
Options exercisable at September 30, 2024	<u>1,983,233</u>	\$ 7.64	6.18	110,485,000

The Company received \$9.8 million and \$6.6 million in cash proceeds from option exercises and ESPP common stock issuances during the nine months ended September 30, 2024 and 2023, respectively.

Compensation cost for stock options granted to employees is based on the estimated grant date fair value and is recognized ratably over the vesting period of the applicable option. The estimated per share weighted average fair value of stock options granted to employees during the nine months ended September 30, 2024 was \$16.22.

As stock-based compensation expense recognized is based on options ultimately expected to vest, the fair value of each employee option grant during the nine months ended September 30, 2024 was estimated on the date of grant using the Black-Scholes model with the following weighted average assumptions:

Nine Months Ended September 30, 2024		
Expected volatility	82.86	%
Expected term (in years)	6.10	
Risk-free interest rate	3.86	%
Expected dividend yield	0	%

Expected Volatility. The expected volatility rate used to value stock option grants is based on the volatility of the Company's historical share prices.

Expected Term. The Company elected to utilize the "simplified" method for "plain vanilla" options to value stock option grants. Under this approach, the weighted-average expected life is presumed to be the average of the vesting term and the contractual term of the option.

Risk-free Interest Rate. The risk-free interest rate assumption was based on zero-coupon U.S. Treasury instruments that had terms consistent with the expected term of the Company's stock option grants.

Expected Dividend Yield. The Company has never declared or paid any cash dividends and does not presently plan to pay cash dividends in the foreseeable future.

Forfeitures are accounted for as actual forfeitures occur.

Since the Company had a net operating loss carryforward as of September 30, 2024, no excess tax benefits for the tax deductions related to stock-based awards were recognized in the consolidated statements of operations and comprehensive loss.

7. Commitments and Contingencies

On November 15, 2021, the Company entered into the Office Lease with One Pacific Heights LLC. The Office Lease is for approximately 7,940 rentable square feet of space located at 9920 Pacific Heights Blvd, Suite 350, San Diego, California 92121 (the "Premises"). The Premises are now the Company's corporate headquarters.

Monthly base rent payments due under the Office Lease for the Premises are \$28,187, subject to annual increases of 3.0% during the Term. Under the Office Lease, the Company is responsible for certain charges for common area maintenance and other costs, including utility expenses, and the Office Lease provides for abatement of rent during certain periods and escalating rent payments throughout the Term.

The Office Lease provides the Company with an option to extend the term of the Office Lease for a period of five years beyond the Term. If the option is exercised, the renewal term will be upon the same terms and conditions as the original Term, except that the base rent will be equal to the prevailing market rate as determined pursuant to the terms of the Office Lease.

8. Subsequent Events

The Company has evaluated all subsequent events through the date of the filing of this Quarterly Report on Form 10-Q with the SEC, to ensure that this filing includes appropriate disclosure of events both recognized in the consolidated financial statements as of September 30, 2024, and events which occurred subsequent to September 30, 2024, but were not recognized in the consolidated financial statements. The Company has determined that there were no subsequent events which required recognition, adjustment to or disclosure in the consolidated financial statements.

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

This Quarterly Report on Form 10-Q contains "forward-looking statements" as defined in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, in connection with the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially and adversely from those expressed or implied by such forward-looking statements. Such forward-looking statements include estimates of our expenses, future revenue, capital requirements and our needs for additional financing; statements regarding our ability to develop, acquire and advance drug candidates into, and successfully complete, clinical trials and preclinical studies; statements concerning new product candidates; risks and uncertainties associated with our research and development activities, including our clinical trials and preclinical studies; our expectations regarding the potential market size and the size of the patient populations for our drug candidates, if approved for commercial use, and our ability to serve such markets; statements regarding our ability to maintain and establish collaborations or obtain additional funding; statements regarding developments and projections relating to our competitors and our industry and other matters that do not relate strictly to historical facts or statements of assumptions underlying any of the foregoing. These statements are often identified by the use of words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may" or "will," the negative versions of these terms and similar expressions or variations. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Such forward-looking statements are subject to risks, uncertainties and other factors that could cause actual results and the timing of certain events to differ materially and adversely from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included elsewhere in this Quarterly Report on Form 10-Q and in our other Securities and Exchange Commission, or SEC, filings. Furthermore, such forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q. We undertake no obligation to update any forward-looking statements to reflect events or circumstances occurring after the date of such statements.

Throughout this Quarterly Report on Form 10-Q, unless the context otherwise requires, the terms "Viking," "we," "us" and "our" in this Quarterly Report on Form 10-Q refer to Viking Therapeutics, Inc. and its subsidiary.

Overview

We are a clinical-stage biopharmaceutical company focused on the development of novel, first-in-class or best-in-class therapies for metabolic and endocrine disorders.

In January 2022, we announced the initiation of a Phase 1 single ascending dose, or SAD, and multiple ascending dose, or MAD, clinical trial of VK2735, a novel dual agonist of the glucagon-like peptide 1, or GLP-1, and glucose-dependent insulintropic polypeptide, or GIP, receptors. VK2735 is in development for the potential treatment of various metabolic disorders.

On March 28, 2023, we announced the completion of the Phase 1 trial. The study was a randomized, double-blind, placebo-controlled, SAD and MAD study in healthy adults. The primary objectives of the study included evaluation of the safety and tolerability of single and multiple doses of VK2735 delivered subcutaneously and the identification of VK2735 doses suitable for further clinical development. Study investigators also evaluated the pharmacokinetics of single and multiple doses of VK2735. Based upon the results from this Phase 1 study, in September 2023, we initiated the VENTURE study, a Phase 2 clinical trial of VK2735 in patients with obesity.

The Phase 2 VENTURE study is a randomized, double-blind placebo-controlled study to evaluate the safety, tolerability, pharmacokinetics and weight loss efficacy of VK2735, administered subcutaneously, once weekly. The 13-week study will enroll adults who are obese (BMI $\geq$ 30 kg/m²) or adults who are overweight (BMI $\geq$ 27kg/m²) with at least one weight-related co-morbidity condition. The primary endpoint of the study is the percent change in body weight from baseline to week 13, with secondary and exploratory endpoints evaluating a range of additional safety and efficacy measures. In October 2023, we announced completion of patient enrollment in the Phase 2 VENTURE study and on February 27, 2024, we announced that patients receiving weekly doses of VK2735 demonstrated statistically significant reductions in mean body weight after 13 weeks, ranging up to 14.7% from baseline. Patients receiving VK2735 also demonstrated statistically significant reductions in mean body weight relative to placebo, ranging up to 13.1%. Based on written feedback received from the U.S. Food and Drug Administration, or the FDA, we plan to advance the subcutaneous formulation of VK2735 into Phase 3 development.

On March 28, 2023, we announced the initiation of a Phase 1 clinical study to evaluate a novel oral formulation of VK2735. The study, which is an extension of our recently completed Phase 1 evaluation of subcutaneously administered VK2735, is evaluating daily oral doses for 28 days. On March 26, 2024, we announced that the 28-day MAD study results highlighted positive signs of clinical activity following treatment with oral VK2735. Cohorts receiving VK2735 demonstrated dose-dependent reductions in mean body weight from baseline, ranging up to approximately 5.3%. Based on these Phase 1 results, we plan to initiate a Phase 2 trial with the oral formulation of VK2735 in obesity later in 2024.

Our most advanced clinical program's drug candidate, VK2809, is an orally available, tissue and receptor-subtype selective agonist of the thyroid hormone receptor beta, or TR β . In November 2019, we initiated the VOYAGE study, a Phase 2b clinical trial of VK2809 in patients with biopsy-confirmed non-alcoholic steatohepatitis, or MASH/NASH.

The VOYAGE study is a randomized, double-blind, placebo-controlled, multicenter trial designed to assess the efficacy, safety and tolerability of VK2809 in patients with biopsy-confirmed MASH/NASH and fibrosis ranging from stages F1 to F3. The primary endpoint of the study will evaluate the relative change in liver fat content, as assessed by magnetic resonance imaging, proton density fat fraction, or MRI-PDFF, from baseline to week 12 in subjects treated with VK2809 as compared to placebo. Secondary objectives include evaluation of histologic changes assessed by hepatic biopsy after 52 weeks of dosing.

In January 2023, we announced completion of patient enrollment in the VOYAGE study and in May 2023 we reported that the VOYAGE study successfully achieved its primary endpoint, with patients receiving VK2809 experiencing statistically significant reductions in liver fat content from baseline to Week 12 as compared to placebo.

In June 2024, we announced positive 52-week histologic data from the VOYAGE study with up to 75% of patients treated with VK2809 achieving MASH/NASH resolution with no worsening of fibrosis as compared to 29% for placebo ($p=0.0001$), up to 57% of VK2809-treated patients achieving ≥ 1 -stage improvement in fibrosis with no worsening of MASH/NASH as compared to 34% for placebo ($p<0.05$) and up to 48% of VK2809-treated patients achieving both resolution of MASH/NASH and a ≥ 1 -stage improvement in fibrosis as compared to 20% for placebo ($p=0.01$). Adverse events, including GI-related adverse events were similar among VK2809-treated patients vs. placebo at week 52 and consistent with prior data reported at week 12.

VK2809 has been evaluated in eight completed clinical studies, which enrolled more than 400 subjects. No serious adverse events, or SAEs, have been observed in subjects receiving VK2809 in these completed studies, and overall tolerability remains encouraging. In addition, the compound has been evaluated in chronic toxicity studies of up to 12 months in duration.

We are also developing VK0214, which is also an orally available, tissue and receptor-subtype selective agonist of TR β for X-linked adrenoleukodystrophy, or X-ALD, a rare X-linked, inherited neurological disorder characterized by a breakdown in the protective barriers surrounding brain and nerve cells. The disease, for which there is no approved treatment, is caused by mutations in a peroxisomal transporter of very long chain fatty acids, or VLCFA, known as ABCD1. As a result, transporter function is impaired and patients are unable to efficiently metabolize VLCFA. The TR β receptor is known to regulate expression of an alternative VLCFA transporter, known as ABCD2. Various preclinical models have demonstrated that increased expression of ABCD2 can lead to normalization of VLCFA metabolism. Preliminary data suggest that VK0214 stimulates ABCD2 expression in an in vitro model and reduces VLCFA levels in an in vivo model of X-ALD.

In June 2021, we initiated a Phase 1b clinical trial of VK0214 in patients with X-ALD. This trial was a multi-center, randomized, double-blind, placebo-controlled study in adult male patients with the adrenomyeloneuropathy, or AMN, form of X-ALD. The study enrolled patients across three cohorts: placebo, VK0214 20 mg daily, and VK0214 40 mg daily.

The primary objectives of the study were to evaluate the safety and tolerability of VK0214 administered once-daily over a 28-day dosing period. Secondary objectives included an evaluation of the pharmacokinetics of VK0214 following 28 days of dosing in this population. An exploratory objective was to evaluate the effects of VK0214 on plasma levels of very long-chain fatty acids, or VLCFAs, in subjects with AMN. In October 2024, we announced results from the Phase 1b clinical trial, which showed VK0214 to be safe and well-tolerated following once-daily dosing over the 28-day study period. In addition, significant reductions were observed in plasma levels of VLCFAs and other lipids, as compared to placebo.

Other clinical programs include VK5211, an orally available, non-steroidal selective androgen receptor modulator, or SARM. In November 2017, we announced positive top-line results from a Phase 2 proof-of-concept clinical trial in 108 patients recovering from non-elective hip fracture surgery. Top-line data showed that the trial achieved its primary endpoint, demonstrating statistically significant, dose dependent increases in lean body mass, less head, following treatment with VK5211 as compared to placebo. The study also achieved certain secondary endpoints, demonstrating statistically significant increases in appendicular lean body mass and total lean body mass for all doses of VK5211, compared to placebo. VK5211 demonstrated encouraging safety and tolerability in this study, with no drug-related SAEs reported. Our intent is to continue to pursue partnering or licensing opportunities for VK5211 prior to conducting additional clinical studies.

We were incorporated under the laws of the State of Delaware on September 24, 2012. Since our incorporation, we have devoted most of our efforts towards conducting certain clinical trials and preclinical studies related to our VK2735, VK2809, VK0214, VK5211 and the dual amylin and calcitonin receptor agonist programs and towards raising capital and building infrastructure. We obtained exclusive worldwide rights to VK2809, VK0214 and VK5211 and certain other assets pursuant to an exclusive license agreement with Ligand Pharmaceuticals Incorporated, or Ligand. The terms of this license agreement are detailed in the Master License Agreement with Ligand, which we entered into on May 21, 2014, as amended, or the Master License Agreement. A summary of the Master

License Agreement can be found under the heading “Agreements with Ligand—Master License Agreement” under Part I, “Item 1. Business” of our Annual Report on Form 10-K filed with the SEC on February 7, 2024.

Financial Operations Overview

Revenues

To date, we have not generated any revenue. We do not expect to receive any revenue from any drug candidates that we develop unless and until we obtain regulatory approval for, and commercialize, our drug candidates or enter into collaborative agreements with third parties.

Research and Development Expenses

During the year ended December 31, 2023, we incurred \$63.8 million in research and development expense primarily related to our efforts in conducting the VK2735 Phase 2 VENTURE clinical trial, the VK2735 Phase 1 clinical trial, VK2809 Phase 2b VOYAGE clinical trial and the VK0214 Phase 1b clinical trial. During the nine months ended September 30, 2024, we incurred \$70.7 million to research and development expense primarily related to our efforts in continuing our Phase 1 SAD and MAD clinical trial of VK2735 for the treatment of various metabolic disorders, our efforts in preparing for the commencement of a Phase 3 clinical trial for subcutaneous VK2735 in obesity, our efforts in concluding the VK2809 Phase 2b VOYAGE clinical trial and our efforts related to concluding our Phase 1b clinical trial of VK0214 in patients with X-ALD. We expect that our ongoing research and development expenses will consist of costs incurred for the development of our drug candidates, including, but not limited to:

- employee- and consultant-related expenses, which will include salaries, benefits and stock-based compensation, and certain consultant fees and travel expenses;
- expenses incurred under agreements with investigative sites and CROs, which will conduct a substantial portion of our research and development activities, including studies in obesity, MASH/NASH and X-ALD, on our behalf;
- payments to third-party manufacturers, which will produce our active pharmaceutical ingredients and finished drug products;
- license fees paid to third parties for use of their intellectual property; and
- facilities, depreciation and other allocated expenses, which will include direct and allocated expenses for rent and maintenance of facilities and equipment, depreciation of leasehold improvements, equipment and laboratory and other supplies.

We expense all research and development costs as incurred.

The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming and the successful development of our drug candidates is highly uncertain. Our future research and development expenses will depend on the clinical success of each of our drug candidates, as well as ongoing assessments of the commercial potential of such drug candidates. In addition, we cannot forecast with any degree of certainty which drug candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. We expect to incur increased research and development expenses in the future as we continue our efforts towards advancing our VK2735, VK2809, and VK0214 programs and seek to advance our additional programs.

General and Administrative Expenses

Our general and administrative expenses have generally increased year-over-year as we have hired additional employees, issued additional equity awards, which has resulted in increased stock-based compensation expense, implemented certain systems to increase efficiency, and incurred additional costs for insurance, legal and accounting related to operating as a public company. We expect that our general and administrative expenses will continue to increase in the future in order to support our expected increase in research and development activities, including increased salaries and other related costs, stock-based compensation and consulting fees for executive, finance, accounting and business development functions. We also expect general and administrative expenses to increase as a result of additional costs associated with being a public company, including expenses related to continued compliance with the rules and regulations of the SEC and The Nasdaq Stock Market LLC, additional insurance expenses, investor relations activities and other administration and professional services. Other significant costs are expected to include legal fees relating to patent and corporate matters, facility costs not otherwise included in research and development expenses, and fees for accounting and other consulting services.

Other Income (Expense)

Other income (expense) includes interest income earned from our cash, cash equivalents and short-term investments.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these 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 revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments related to our preclinical, nonclinical and clinical development costs and drug manufacturing costs, which we consider to be critical accounting estimates. We base our estimates on 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.

Our significant accounting policies are more fully described in Note 1 and Note 3 to our consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Results of Operations

Comparison of the Three Months Ended September 30, 2024 and 2023

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended September 30, 2024 and 2023 (in thousands, except % change).

	Three Months Ended September 30,		\$	%
	2024	2023	Change	Change
Research and development expenses	\$ 22,785	\$ 18,379	\$ 4,406	24.0%

The increase in research and development expenses during the three months ended September 30, 2024 as compared to the same period in 2023 was primarily due to increased expenses related to manufacturing for our drug candidates, stock-based compensation, salaries and benefits and regulatory services, partially offset by decreased expenses related to preclinical studies and clinical studies.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended September 30, 2024 and 2023 (in thousands, except % change).

	Three Months Ended September 30,		\$	%
	2024	2023	Change	Change
General and administrative expenses	\$ 13,771	\$ 8,886	\$ 4,885	55.0%

The increase in general and administrative expenses during the three months ended September 30, 2024 as compared to the same period in 2023 was primarily due to increased expenses related to stock-based compensation, legal and patent services, services provided by third-party consultants and insurance.

Other income (expense)

The following table summarizes our other income (expense) for the three months ended September 30, 2024 and 2023 (in thousands, except % change).

	Three Months Ended September 30,		\$	%
	2024	2023	Change	Change
Total other income, net	\$ 11,616	\$ 4,731	\$ 6,885	145.5%

Other income (expense) recognized during the three months ended September 30, 2024 and 2023 consisted primarily of interest income, partially offset by expense relating to the amortization of certain financing costs.

Comparison of the Nine Months Ended September 30, 2024 and 2023

Research and Development Expenses

The following table summarizes our research and development expenses for the nine months ended September 30, 2024 and 2023 (in thousands, except % change).

	Nine Months Ended September 30,		\$	%
	2024	2023	Change	Change
Research and development expenses	\$ 70,657	\$ 43,304	\$ 27,353	63.2%

The increase in research and development expenses during the nine months ended September 30, 2024 as compared to the same period in 2023 was primarily due to increased expenses related to manufacturing for our drug candidates, clinical studies, stock-based compensation, preclinical studies and salaries and benefits.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the nine months ended September 30, 2024 and 2023 (in thousands, except % change).

	Nine Months Ended September 30,		\$	%
	2024	2023	Change	Change
General and administrative expenses	\$ 34,026	\$ 28,238	\$ 5,788	20.5%

The increase in general and administrative expenses during the nine months ended September 30, 2024 as compared to the same period in 2023 was primarily due to increased expenses related to stock-based compensation, salaries and benefits, services provided by third-party consultants and insurance, partially offset by decreased expenses related to legal and patent services.

Other income (expense)

The following table summarizes our other income (expense) for the nine months ended September 30, 2024 and 2023 (in thousands, except % change).

	Nine Months Ended September 30,		\$	%
	2024	2023	Change	Change
Total other income, net	\$ 30,137	\$ 10,252	\$ 19,885	194.0%

Other income (expense) recognized during the nine months ended September 30, 2024 and 2023 consisted primarily of interest income, partially offset by expense relating to the amortization of certain financing costs.

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations and have not generated any revenues since our inception. As of September 30, 2024, we had cash, cash equivalents and short-term investments of \$930.4 million. As such, we believe our cash, cash equivalents and short-term investments will be sufficient to fund our operations through at least December 31, 2025, which is more than one year after the date of our filing of this Form 10-Q.

Our primary use of cash is to fund operating expenses, which to date have consisted of the cost to obtain the license of intellectual property from Ligand, certain research and development expenses related to furthering the development of VK2735, VK2809, VK0214 and VK5211, and general and administrative expenses. Since we have not generated any revenues to date, we have incurred operating losses since our inception. Cash used to fund operating expenses is impacted by the timing of payment of these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

On July 28, 2021, we entered into an At-The-Market Equity Offering Sales Agreement, or the ATM Agreement, with Stifel, Nicolaus & Company, Incorporated, Truist Securities, Inc. and H.C. Wainwright & Co. LLC, collectively, the Agents, pursuant to which we could offer and sell, from time to time, through or to the Agents, as sales agent or principal, or the ATM Offering, shares of our common stock having an aggregate offering price of up to \$125.0 million, or the ATM Shares. Any ATM Shares offered and sold in the ATM Offering were to be issued pursuant to a universal Shelf Registration Statement on Form S-3 (File No. 333-258231), or the 2021 Shelf Registration Statement, and the 424(b) prospectus supplement relating to the ATM Offering dated August 11, 2021. From its inception through the expiration of the 2021 Shelf Registration Statement in July 2023, 1,587,404 shares of our common stock were sold pursuant to the ATM Offering for aggregate net proceeds to us of approximately \$13.6 million.

On April 3, 2023, we completed an underwritten public offering of our common stock, or the April 2023 Offering, pursuant to the 2021 Shelf Registration Statement. In the April 2023 Offering, we sold an aggregate of 19,828,300 shares of our common stock at a public offering price of \$14.50 per share, which included the exercise in full by the underwriters of their option to purchase 2,586,300 additional shares of common stock. Upon the closing of the April 2023 Offering, we received gross proceeds of \$287.5 million.

On March 10, 2022, our board of directors authorized a stock repurchase program, or the Repurchase Program, effective March 18, 2022, whereby we could purchase up to \$50.0 million in shares of our common stock over a period of up to two years. The Repurchase Program was carried out at the discretion of a committee of our board of directors through open market purchases, one or more Rule 10b5-1 trading plans, block trades and in privately negotiated transactions. Through March 18, 2024, the termination date of the Repurchase Program, we repurchased an aggregate of 729,034 shares of our common stock under the Repurchase Program. Shares repurchased by us under the Repurchase Program were held in treasury and reissued by us as part of the March 2024 Offering (as defined below).

On July 26, 2023, we filed an automatic universal shelf registration statement on Form S-3 (File No. 333-273460) as a well-known seasoned issuer as defined in Rule 405 under the Securities Act of 1933, as amended, which became effective upon filing, or the 2023 Shelf Registration Statement. The 2023 Shelf Registration Statement allows us to offer an indeterminate amount of securities, including equity securities, debt securities, warrants, rights, units and depositary shares, from time to time as described in the 2023 Shelf Registration Statement. The specific terms of any offering under the 2023 Shelf Registration Statement will be established at the time of such offering. The 2023 Shelf Registration Statement will expire on July 26, 2026.

On July 26, 2023, we entered into an Amendment No. 1 to At-The-Market Equity Offering Sales Agreement, or the ATM Agreement Amendment, with Stifel, Nicolaus & Company, Incorporated, Truist Securities, Inc., H.C. Wainwright & Co. LLC and BTIG, LLC. Pursuant to the ATM Agreement Amendment, BTIG, LLC was added as a sales agent for the ATM Offering and the ATM Agreement was amended to provide that the ATM Offering could be conducted off of registration statements on Form S-3 subsequently filed by us. Any ATM Shares offered and sold in the ATM Offering will now be issued pursuant to the 2023 Shelf Registration Statement and the prospectus relating to the ATM Offering, dated July 26, 2023, that was included in the 2023 Shelf Registration Statement, or the ATM Prospectus. The 2023 Shelf Registration Statement will expire on July 26, 2026. From the date of the ATM Prospectus through September 30, 2024, 1,426,303 shares of our common stock were sold pursuant to the ATM Offering and, as of September 30, 2024, we may sell shares of our common stock for remaining gross proceeds of up to \$151.9 million from time to time pursuant to the ATM Prospectus.

On March 4, 2024, we completed an underwritten public offering of our common stock, or the March 2024 Offering, pursuant to the 2023 Shelf Registration Statement. In the March 2024 Offering, we sold an aggregate of 7,441,650 shares of our common stock at a public offering price of \$85.00 per share, which included the exercise in full by the underwriters of their option to purchase 970,650 additional shares of common stock. Upon the closing of the March 2024 Offering, we received net proceeds of \$597.1 million.

The following table summarizes our cash flows for the periods indicated below (in thousands):

	Nine Months Ended September 30,	
	2024	2023
Cash used in operating activities	\$ (56,609)	\$ (55,736)
Cash used in investing activities	\$ (559,950)	\$ (214,819)
Cash provided by financing activities	\$ 611,464	\$ 271,188

Cash Used in Operating Activities

During the nine months ended September 30, 2024, cash used in operating activities of \$56.6 million primarily reflected our net losses for the period, adjusted by non-cash charges such as stock-based compensation, amortization of investment premiums, amortization of right-of-use assets, realized gain on investment, amortization of financing costs, and interest expense related to operating lease liabilities as well as changes in our working capital accounts, primarily consisting of an increase in accrued expenses and accrued interest, net of interest received on maturity of investments, partially offset by decreases in accounts payable, prepaid expenses and other assets and lease liability.

During the nine months ended September 30, 2023, cash used in operating activities of \$55.7 million primarily reflected our net losses for the period, adjusted by non-cash charges such as stock-based compensation, amortization of investment premiums, amortization of right-of-use assets, amortization of financing costs, and interest expense related to operating lease liabilities as well as changes in our working capital accounts, primarily consisting of an increase in accrued interest, net of interest received on maturity of investments, partially offset by a decrease in prepaid expenses and other assets and decreases in accounts payable, accrued expenses and lease liability.

Cash Used in Investing Activities

During the nine months ended September 30, 2024, cash used in investing activities of \$560.0 million resulted primarily from the purchase of investments of \$976.4 million, partially offset by the proceeds of maturities of investments of \$416.5 million.

During the nine months ended September 30, 2023, cash used in investing activities of \$214.8 million resulted primarily from the purchase of investments of \$380.8 million, partially offset by the proceeds of maturities of investments of \$166.0 million.

Cash Provided by Financing Activities

During the nine months ended September 30, 2024, cash provided by financing activities was \$611.5 million, which consisted primarily of proceeds from the issuance of common stock, net of discount, of \$597.1 million in the March 2024 Offering, proceeds from certain option exercises and 2014 ESPP common stock issuance of \$9.8 million and proceeds from the ATM Offering, net of fees, of \$46.7 million, partially offset by value of shares withheld to cover taxes of \$42.1 million.

During the nine months ended September 30, 2023, cash provided by financing activities was \$271.2 million, which consisted primarily of proceeds from the issuance of common stock, net of discount, of \$269.8 million in the April 2023 Offering, proceeds from certain option exercises and 2014 ESPP common stock issuance of \$6.6 million and proceeds from the ATM Offering, net of fees of \$2.0 million, partially offset by value of shares withheld to cover taxes of \$7.1 million.

Future Funding Requirements

As of the date of this Quarterly Report on Form 10-Q and based upon our current operating plan, we believe that we have sufficient capital to fund our operating and capital requirements for at least the next 12 months. We anticipate, however, that we will continue to generate losses for the foreseeable future, and we expect the losses to increase materially as we continue the development of, and seek regulatory approvals for, our drug candidates, and seek to commercialize any drugs for which we receive regulatory approval. We will need to raise additional capital to fund our operations and complete our ongoing and planned clinical trials. We expect to finance future cash needs through public or private equity or debt offerings, however, funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market drug candidates that we would otherwise prefer to develop and market ourselves.

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

- the scope, rate of progress, results and costs of our clinical trials, preclinical studies and other related activities;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- the timing of, and the costs involved in, obtaining regulatory approvals for any of our current or future drug candidates;
- the number and characteristics of the drug candidates we seek to develop or commercialize;
- the cost of manufacturing clinical supplies, and establishing commercial supplies, of our drug candidates;

- the cost of commercialization activities if any of our current or future drug candidates are approved for sale, including marketing, sales and distribution costs;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- the amount of revenue, if any, received from commercial sales of our drug candidates, should any of our drug candidates receive marketing approval; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing possible patent claims, including litigation costs and the outcome of any such litigation.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Financial Instruments

As part of our investment portfolio, we own financial instruments that are sensitive to market risks. The investment portfolio is used to preserve our capital, provide adequate liquidity and earn returns commensurate with our risk appetite. We invest in instruments that meet the credit quality standards outlined in our investment policy, which also limits the amount of credit exposure to any one issue or type of instrument. These instruments principally include securities issued by the U.S. government and its agencies, investment-grade corporate bonds and commercial paper, and money market funds. These investments are denominated in U.S. Dollars and none are held for trading purposes.

All of our interest-bearing securities are subject to interest rate risk and could change in value if interest rates fluctuate. Substantially all of our investment portfolio consists of marketable securities with active secondary or resale markets to help ensure portfolio liquidity, and we have implemented guidelines limiting the term-to-maturity of our investment instruments. Since we account for these securities as available-for-sale, no gains or losses are realized due to changes in the fair value of our investments unless we sell our investments prior to maturity or incur a credit loss. Due to the conservative nature of these instruments, we do not believe that the fair value of our investments has a material exposure to interest rate risk.

While we are exposed to global interest rate fluctuations, our investment portfolio is most affected by fluctuations in U.S. interest rates, which affect the interest earned on our cash, cash equivalents and marketable securities. Interest income generated from the Company's cash, cash equivalents, and short-term investments – available-for-sale will vary with the general level of interest rates.

(in thousands)	September 30, 2024	December 31, 2023
Cash and cash equivalents	\$ 50,347	\$ 55,516
Short-term investments – available-for-sale	\$ 880,093	\$ 306,563
Total	<u>\$ 930,440</u>	<u>\$ 362,079</u>

Based on the above balances at September 30, 2024, if short-term interest rates increased or decreased by 10%, or 46 basis points, for the remainder of the year, annual interest income, including interest earned on short-term investments – available-for-sale, would increase or decrease by approximately \$1.4 million.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. As required by Rule 13a-15(b) or Rule 15d-15(b) promulgated by the SEC under the Exchange Act, we carried out an evaluation, under

the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on the foregoing, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Quarterly Report on Form 10-Q at the reasonable assurance level.

Changes in Internal Control

There has been no change in our internal control over financial reporting during the three months ended September 30, 2024 that has materially affected, or is 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 be party to lawsuits in the ordinary course of business. We are not presently a party to any legal proceedings, the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business, operating results or financial condition.

In December 2022, we filed suit against Ascleitis Bioscience Co., Ltd., Gannex Pharma Co., Ltd., Ascleitis Pharmaceuticals Co., Ltd., Ascleitis Pharma Inc., and Jinzi Jason Wu, or the Ascleitis Defendants, in the Southern District of California, San Diego division, alleging, among other things: (1) violation of the Defend Trade Secrets Act; (2) violation of the California Uniform Trade Secrets Act; (3) breach of contract; (4) breach of the implied covenant of good faith and fair dealing; and (5) tortious interference with contract. In a related action, we also filed suit against the same Ascleitis Defendants in the International Trade Commission, or the ITC, for unlawful and unfair methods of competition. These legal proceedings arise at least in part from the misappropriation of our trade secrets.

On October 3, 2024, the ITC's Chief Administrative Law Judge issued a Notice of his determination in favor of Viking. The ruling states that Ascleitis Defendants misappropriated our trade secrets while under a Confidential Disclosure Agreement ("CDA") and engaged in discovery misconduct, warranting monetary and non-monetary sanctions. We plan to continue to vigorously pursue, as necessary, all of our legal remedies in these litigations, including through any appeals processes that the Ascleitis Defendants may initiate.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this Quarterly Report on Form 10-Q, before making a decision to invest in our common stock. The risks and uncertainties described below may not be the only ones we face. If any of the risks actually occur, our business, financial condition and results of operations could be materially and adversely affected. In that event, the trading price of our common stock could decline, and you could lose part or all of your investment.

Risk factors marked with an asterisk () below include a change from or an update to the risk factors included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on February 7, 2024.*

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q and our other filings with the SEC before making an investment decision regarding our common stock.

Risk Factor Summary

- We are a clinical-stage company, have a limited operating history and are expected to incur significant operating losses during the next stages of our corporate development.
- We are substantially dependent on technologies we licensed from Ligand Pharmaceuticals Incorporated, or Ligand, and if we lose the license to such technologies or our master license agreement with Ligand, or the Master License Agreement, is terminated for any reason, our ability to develop existing and new drug candidates would be harmed, and our business, financial condition and results of operations would be materially and adversely affected.
- We are dependent on the success of one or more of our current drug candidates and we cannot be certain that any of them will receive regulatory approval or be commercialized.
- If development of our drug candidates does not produce favorable results, we and our collaborators, if any, may be unable to commercialize these products.
- Delays in the commencement or completion of clinical trials could result in increased costs to us and delay our ability to establish strategic collaborations.
- We intend to rely on third parties to conduct our preclinical studies and clinical trials and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business, financial condition and results of operations could be substantially harmed.

- If our competitors have drug candidates that are approved faster, are marketed more effectively, are better tolerated, have a more favorable safety profile or are demonstrated to be more effective than ours, our commercial opportunity may be reduced or eliminated.
- Unstable market and economic conditions may have serious adverse consequences on our business and financial condition.
- We may not be successful in obtaining or maintaining necessary rights to our drug candidates through acquisitions and in-licenses.
- If we fail to comply with our obligations in the agreements under which we in-license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.

Risks Relating to Our Business

***We are a clinical-stage company, have a limited operating history and are expected to incur significant operating losses during the next stages of our corporate development.**

We are a clinical-stage company. Since our incorporation in September 2012, our operations have been limited to raising capital, building infrastructure, obtaining the worldwide rights to certain technology from Ligand Pharmaceuticals Incorporated, or Ligand, and planning, preparing and conducting preclinical studies and clinical trials of our drug candidates, including VK2735 subcutaneous, VK2809, VK5211 and VK0612, which are currently in Phase 2 clinical development, VK2735, for which we continue to conduct an oral Phase 1 SAD/MAD clinical trial, and VK0214, for which we recently completed a Phase 1b clinical trial, as well as the diacylglycerol acyltransferase-1, or DGAT-1, erythropoietin receptor, or EPOR, and our dual amylin and calcitonin receptor agonist, or DACRA, programs, which are each currently in preclinical development. We have not yet demonstrated an ability to obtain marketing approval for any of our drug candidates or successfully overcome the risks and uncertainties frequently encountered by companies in the biopharmaceutical industry. We also have not generated any revenue to date, and we continue to incur significant research and development and other expenses. As of September 30, 2024, we had an accumulated deficit of \$452.5 million. For the foreseeable future, we expect to continue to incur losses, which will increase significantly from historical levels as we expand our drug development activities, seek potential partnering opportunities and/or regulatory approvals for our drug candidates and begin to commercialize them if they are approved by the U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or EMA, or comparable foreign authorities. Even if we succeed in partnering or developing and commercializing one or more drug candidates, we may never become profitable. If we fail to achieve or maintain profitability, it would adversely affect the value of our common stock.

We are substantially dependent on technologies we licensed from Ligand Pharmaceuticals Incorporated, or Ligand, and if we lose the license to such technologies or our master license agreement with Ligand, or the Master License Agreement, is terminated for any reason, our ability to develop existing and new drug candidates would be harmed, and our business, financial condition and results of operations would be materially and adversely affected.

Our business is substantially dependent upon technology licensed from Ligand. Pursuant to the Master License Agreement, we have been granted exclusive worldwide rights to VK2809, VK0214, VK5211, VK0612 and preclinical programs for metabolic disorders and anemia. Selective androgen receptor modulators, such as the one used in our VK5211 program, are key compounds used by us in the development and commercialization of our drug candidates. Most of the intellectual property related to our drug candidates is currently owned by Ligand, and we have the rights to use such intellectual property pursuant to the Master License Agreement. Therefore, our ability to develop and commercialize our drug candidates depends entirely on the effectiveness and continuation of the Master License Agreement. If we lose the right to license any of these key compounds, our ability to develop existing and new drug candidates would be harmed.

Ligand has the right to terminate the Master License Agreement under certain circumstances, including, but not limited to: (1) in the event of our insolvency or bankruptcy, (2) if we do not pay an undisputed amount owing under the Master License Agreement when due and fail to cure such default within a specified period of time, or (3) if we default on certain of our material obligations and fail to cure the default within a specified period of time.

***We are dependent on the success of one or more of our current drug candidates and we cannot be certain that any of them will receive regulatory approval or be commercialized.**

We have spent significant time, money and effort on the licensing and development of our core metabolic and endocrine disease assets, VK2735, VK2809, VK0214, VK5211, VK0612 and our earlier-stage assets, our DGAT-1, EPOR and DACRA programs. To date, no pivotal clinical trials designed to provide clinically and statistically significant proof of efficacy, or to provide sufficient

evidence of safety to justify approval, have been completed with any of our drug candidates. All of our drug candidates will require additional development, including clinical trials as well as further preclinical studies to evaluate their toxicology, carcinogenicity and pharmacokinetics and optimize their formulation, and regulatory clearances before they can be commercialized. Positive results obtained during early development do not necessarily mean later development will succeed or that regulatory clearances will be obtained. Our drug development efforts may not lead to commercial drugs, either because our drug candidates fail to be safe and effective or because we have inadequate financial or other resources to advance our drug candidates through the clinical development and approval processes. If any of our drug candidates fail to demonstrate safety or efficacy at any time or during any phase of development, we would experience potentially significant delays in, or be required to abandon, development of the drug candidate.

We do not anticipate that any of our current drug candidates will be eligible to receive regulatory approval from the FDA, EMA or comparable foreign authorities and begin commercialization for a number of years, if ever. Even if we ultimately receive regulatory approval for any of these drug candidates, we or our potential future partners, if any, may be unable to commercialize them successfully for a variety of reasons. These include, for example, the availability of alternative treatments, lack of cost-effectiveness, the cost of manufacturing the product on a commercial scale and competition with other drugs. The success of our drug candidates may also be limited by the prevalence and severity of any adverse side effects. If we fail to commercialize one or more of our current drug candidates, we may be unable to generate sufficient revenues to attain or maintain profitability, and our financial condition and stock price may decline.

***If development of our drug candidates does not produce favorable results, we and our collaborators, if any, may be unable to commercialize these products.**

To receive regulatory approval for the commercialization of our core metabolic and endocrine disease assets, VK2735, VK2809, VK0214, VK5211, VK0612 and our earlier-stage assets, our DGAT-1, EPOR and DACRA programs, or any other drug candidates that we may develop, adequate and well-controlled clinical trials must be conducted to demonstrate safety and efficacy in humans to the satisfaction of the FDA, EMA and comparable foreign authorities. In order to support marketing approval, these agencies typically require successful results in one or more Phase 3 clinical trials, which our current drug candidates have not yet reached and may never reach. The development process is expensive, can take many years and has an uncertain outcome. Failure can occur at any stage of the process. We may experience numerous unforeseen events during, or as a result of, the development process that could delay or prevent commercialization of our current or future drug candidates, including the following:

- clinical trials may produce negative or inconclusive results;
- preclinical studies conducted with drug candidates during clinical development to, among other things, evaluate their toxicology, carcinogenicity and pharmacokinetics and optimize their formulation may produce unfavorable results;
- patient recruitment and enrollment in clinical trials may be slower than we anticipate;
- costs of development may be greater than we anticipate;
- our drug candidates may cause undesirable side effects that delay or preclude regulatory approval or limit their commercial use or market acceptance, if approved;
- collaborators who may be responsible for the development of our drug candidates may not devote sufficient resources to these clinical trials or other preclinical studies of these candidates or conduct them in a timely manner; or
- we may face delays in obtaining regulatory approvals to commence one or more clinical trials.

Success in early development does not mean that later development will be successful because, for example, drug candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy despite having progressed through initial clinical trials.

In February 2024, we reported positive top-line results from the VENTURE Phase 2 clinical trial for VK2735 in patients with obesity. In May 2023, we reported positive top-line results from the VOYAGE Phase 2b clinical trial for VK2809 and in June 2024, we announced positive 52-week histologic data from the VOYAGE study. In late 2017, we reported positive top-line results from a Phase 2 clinical trial for VK5211. In October 2024, we reported positive data from our Phase 1b clinical trial of VK0214 in patients with X-ALD. However, there is no guarantee that the results of our Phase 2 clinical trials for VK2735 or VK2809 or our Phase 1b clinical trial for VK2014 will be repeated for our other drug candidates or lead to other positive outcomes. As a company, we have conducted only a limited number of clinical trials and preclinical studies for our drug candidates. Therefore, we have limited experience in conducting clinical trials for our drug candidates. Since our experience with our drug candidates is limited, we will need to train our existing personnel and hire additional personnel in order to successfully administer and manage our clinical trials and other studies as planned, which may result in delays in completing such planned clinical trials and preclinical studies. Moreover, to date, our drug candidates have been tested in less than the number of patients that will likely need to be studied to obtain regulatory approval. The data collected

from clinical trials with larger patient populations may not demonstrate sufficient safety and efficacy to support regulatory approval of these drug candidates.

We currently do not have strategic collaborations in place for clinical development of any of our current drug candidates. Therefore, in the future, we or any potential future collaborative partner will be responsible for establishing the targeted endpoints and goals for development of our drug candidates. These targeted endpoints and goals may be inadequate to demonstrate the safety and efficacy levels required for regulatory approvals. Even if we believe data collected during the development of our drug candidates are promising, such data may not be sufficient to support marketing approval by the FDA, EMA or comparable foreign authorities. Further, data generated during development can be interpreted in different ways, and the FDA, EMA or comparable foreign authorities may interpret such data in different ways than us or our collaborators. Our failure to adequately demonstrate the safety and efficacy of our drug candidates would prevent our receipt of regulatory approval, and ultimately the potential commercialization of these drug candidates.

Since we do not currently possess the resources necessary to independently develop and commercialize the majority of our drug candidates, we may seek to enter into collaborative agreements to assist in the development and potential future commercialization of some or all of these assets as a component of our strategic plan. However, our discussions with potential collaborators may not lead to the establishment of collaborations on acceptable terms, if at all, or it may take longer than expected to establish new collaborations, leading to development and potential commercialization delays, which would adversely affect our business, financial condition and results of operations.

We expect to continue to incur significant research and development expenses, which may make it difficult for us to attain profitability.

We expect to expend substantial funds in research and development, including preclinical studies and clinical trials of our drug candidates, and to manufacture and market any drug candidates in the event they are approved for commercial sale. We also may need additional funding to develop or acquire complementary companies, technologies and assets, as well as for working capital requirements and other operating and general corporate purposes. Moreover, our planned increases in staffing will dramatically increase our costs in the near and long-term.

However, our spending on current and future research and development programs and drug candidates for specific indications may not yield any commercially viable products. Due to our limited financial and managerial resources, we must focus on a limited number of research programs and drug candidates and on specific indications. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Because the successful development of our drug candidates is uncertain, we are unable to precisely estimate the actual funds we will require to develop and potentially commercialize them. In addition, we may not be able to generate sufficient revenue, even if we are able to commercialize any of our drug candidates, to become profitable.

***Given our lack of current cash inflows, it is expected that we may need to raise additional capital; however, it may be unavailable to us or, even if capital is obtained, may cause dilution or place significant restrictions on our ability to operate our business.**

Since we will be unable to generate sufficient, if any, cash inflows to fund our operations for the foreseeable future, we may need to seek additional equity or debt financing to provide the capital required to maintain or expand our operations. As of September 30, 2024, we had cash, cash equivalents and investments totaling \$930.4 million. There can be no assurance that we will be able to raise sufficient additional capital on acceptable terms or at all. If such additional financing is not available on satisfactory terms, or is not available in sufficient amounts, we may be required to delay, limit or eliminate the development of business opportunities and our ability to achieve our business objectives, our competitiveness, and our business, financial condition and results of operations may be materially adversely affected. In addition, we may be required to grant rights to develop and market drug candidates that we would otherwise prefer to develop and market ourselves. Our inability to fund our business could lead to the loss of your investment. Our future capital requirements will depend on many factors, including, but not limited to:

- the scope, rate of progress, results and cost of our clinical trials, preclinical studies and other related activities; our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the timing of, and the costs involved in, obtaining regulatory approvals for any of our current or future drug candidates;
- the number and characteristics of the drug candidates we seek to develop or commercialize;
- the cost of manufacturing clinical supplies, and establishing commercial supplies, of our drug candidates;

- the cost of commercialization activities if any of our current or future drug candidates are approved for sale, including marketing, sales and distribution costs;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- the amount of revenue, if any, received from commercial sales of our drug candidates, should any of our drug candidates receive marketing approval; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing possible patent claims, including litigation costs and the outcome of any such litigation.

On July 26, 2023, we filed an automatic universal shelf registration statement on Form S-3 (File No. 333-273460) with the SEC as a well-known seasoned issuer as defined in Rule 405 under the Securities Act of 1933, as amended, which became effective upon filing, or the 2023 Shelf Registration Statement. The 2023 Shelf Registration Statement allows us to offer an indeterminate amount of securities, including equity securities, debt securities, warrants, rights, units and depositary shares, from time to time as described in the 2023 Shelf Registration Statement. The specific terms of any offering under the 2023 Shelf Registration Statement will be established at the time of such offering under a separate prospectus supplement, which will be filed with the SEC at the time of any offering. The 2023 Shelf Registration Statement will expire on July 26, 2026.

The 2023 Shelf Registration Statement includes a prospectus, or the ATM Prospectus, pursuant to which we may offer and sell, from time to time, through or to Stifel, Nicolaus & Company, Incorporated, Truist Securities, Inc., H.C. Wainwright & Co. LLC and BTIG, LLC, or, collectively, the ATM Agents, as sales agent(s) or principal(s), shares of our common stock having an aggregate offering price of up to \$200.0 million, or the ATM Offering. Any shares offering and sold in ATM Offering will be issued pursuant to the ATM Prospectus and the At-The-Market Equity Offering Sales Agreement, dated July 28, 2021, as amended on July 26, 2023, among us and the ATM Agents. As of September 30, 2024, we may sell shares of our common stock for remaining gross proceeds of up to \$151.9 million from time to time pursuant to the ATM Prospectus.

On March 4, 2024, we completed an underwritten public offering of our common stock, or the March 2024 Offering, pursuant to the 2023 Shelf Registration Statement. In the March 2024 Offering, we sold an aggregate of 7,441,650 shares of our common stock at a public offering price of \$85.00 per share, which included the exercise in full by the underwriters of their option to purchase 970,650 additional shares of common stock. Upon the closing of the March 2024 Offering, we received net proceeds of \$597.1 million, after deducting underwriting discounts, commissions and other offering expenses.

If we raise additional capital by issuing equity securities, the percentage ownership of our existing stockholders may be reduced, and accordingly these stockholders may experience substantial dilution. We may also issue equity securities that provide for rights, preferences and privileges senior to those of our common stock. Given our need for cash and that equity issuances are the most common type of fundraising for companies like ours, the risk of dilution is particularly significant for stockholders of our company.

Our drug candidates may cause undesirable side effects that could delay or prevent their regulatory approval or commercialization or have other significant adverse implications on our business, financial condition and results of operations.

Undesirable side effects observed in clinical trials or in supportive preclinical studies with our drug candidates could interrupt, delay or halt their development and could result in the denial of regulatory approval by the FDA, EMA or comparable foreign authorities for any or all targeted indications or adversely affect the marketability of any such drug candidates that receive regulatory approval. In turn, this could eliminate or limit our ability to commercialize our drug candidates.

Our drug candidates may exhibit adverse effects in preclinical toxicology studies and adverse interactions with other drugs. There are also risks associated with additional requirements the FDA, EMA or comparable foreign authorities may impose for marketing approval with regard to a particular disease.

Our drug candidates may require a risk management program that could include patient and healthcare provider education, usage guidelines, appropriate promotional activities, a post-marketing observational study, and ongoing safety and reporting mechanisms, among other requirements. Prescribing could be limited to physician specialists or physicians trained in the use of the drug, or could be limited to a more restricted patient population. Any risk management program required for approval of our drug candidates could potentially have an adverse effect on our business, financial condition and results of operations.

Undesirable side effects involving our drug candidates may have other significant adverse implications on our business, financial condition and results of operations. For example:

- we may be unable to obtain additional financing on acceptable terms, if at all;

- our collaborators may terminate any development agreements covering these drug candidates;
- if any development agreements are terminated, we may determine not to further develop the affected drug candidates due to resource constraints and may not be able to establish additional collaborations for their further development on acceptable terms, if at all;
- if we were to later continue the development of these drug candidates and receive regulatory approval, earlier findings may significantly limit their marketability and thus significantly lower our potential future revenues from their commercialization;
- we may be subject to product liability or stockholder litigation; and
- we may be unable to attract and retain key employees.

In addition, if any of our drug candidates receive marketing approval and we or others later identify undesirable side effects caused by the product:

- regulatory authorities may withdraw their approval of the product, or we or our partners may decide to cease marketing and sale of the product voluntarily;
- we may be required to change the way the product is administered, conduct additional clinical trials or preclinical studies regarding the product, change the labeling of the product, or change the product's manufacturing facilities; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product and could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from generating significant revenues from the sale of the product.

Our efforts to discover drug candidates beyond our current drug candidates may not succeed, and any drug candidates we recommend for clinical development may not actually begin clinical trials.

We intend to continue to use our technology, including our licensed technology, knowledge and expertise to develop novel drugs to address some of the world's most widespread and costly chronic diseases. We intend to expand our existing pipeline of core assets by advancing drug compounds from current ongoing discovery programs into clinical development. However, the process of researching and discovering drug compounds is expensive, time-consuming and unpredictable. Data from our current preclinical programs may not support the clinical development of our lead compounds or other compounds from these programs, and we may not identify any additional drug compounds suitable for recommendation for clinical development. Moreover, any drug compounds we recommend for clinical development may not demonstrate, through preclinical studies, indications of safety and potential efficacy that would support advancement into clinical trials. Such findings would potentially impede our ability to maintain or expand our clinical development pipeline. Our ability to identify new drug compounds and advance them into clinical development also depends upon our ability to fund our research and development operations, and we cannot be certain that additional funding will be available on acceptable terms, or at all.

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

Because we have limited financial and managerial resources, we must focus on a limited number of research programs and product candidates and on specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications 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 discovery and preclinical development programs and product candidates for specific indications may not yield any commercially viable products. In addition, our projections of both the number of people who have the targeted indications, as well as the subset of people with these disorders who have the potential to benefit from treatment with our product candidates, are based on estimates. If any of our estimates are inaccurate, the market opportunities for any of our product candidates could be significantly diminished and have an adverse material impact on our business. Additionally, the potentially addressable patient population for our product candidates may be limited, or may not be amenable to treatment with our product candidates.

Delays in the commencement or completion of clinical trials could result in increased costs to us and delay our ability to establish strategic collaborations.

Delays in the commencement or completion of clinical trials could significantly impact our drug development costs. We do not know whether planned clinical trials will begin on time or be completed on schedule, if at all. The commencement of clinical trials can be delayed for a variety of reasons, including, but not limited to, delays related to:

- obtaining regulatory approval to commence one or more clinical trials;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- manufacturing sufficient quantities of a drug candidate or other materials necessary to conduct clinical trials, as well as receiving the supplies and materials needed to conduct our clinical trials, including interruptions in global shipping that may affect the transport of clinical materials;
- obtaining institutional review board approval to conduct one or more clinical trials at a prospective site;
- recruiting and enrolling patients to participate in one or more clinical trials, especially as patients may be reluctant or unable to visit clinical sites, or may delay seeking treatment for chronic conditions;
- the failure of our collaborators to adequately resource our drug candidates due to their focus on other programs or as a result of general market conditions;
- recruiting clinical site investigators, clinical site staff and potential closure of clinical facilities; and
- changes in regulations, which may require us to change the ways in which our clinical trials are conducted.

In addition, once a clinical trial has begun, it may be suspended or terminated by us, our collaborators, the institutional review boards or data safety monitoring boards charged with overseeing our clinical trials, the FDA, EMA or comparable foreign authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- inspection of the clinical trial operations or clinical trial site by the FDA, EMA or comparable foreign authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues; or
- lack of adequate funding to continue the clinical trial.

If we experience delays in the completion or termination of any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to commence product sales and generate product revenues from any of our product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs and slow down our product candidate development and approval process. Delays in completing our clinical trials could also allow our competitors to obtain marketing approval before we do or shorten the patent protection period during which we may have the exclusive right to commercialize our product candidates. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Results of earlier clinical trials may not be predictive of the results of later-stage clinical trials.

The results of preclinical studies and early clinical trials of product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy results despite having progressed through preclinical studies and initial clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier studies. Similarly, our future clinical trial results may not be successful for these or other reasons.

This drug candidate development risk is heightened by any changes in the planned clinical trials compared to the completed clinical trials. As product candidates are developed through preclinical to early to late stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and methods of administration, are altered along the way in an effort to optimize processes and results. While these types of changes are common and

are intended to optimize the product candidates for late stage clinical trials, approval and commercialization, such changes carry the risk that they will not achieve these intended objectives.

Any of these changes could make the results of our planned clinical trials or other future clinical trials we may initiate less predictable and could cause our product candidates to perform differently, including causing toxicities, which could delay completion of our clinical trials, delay approval of our product candidates and/or jeopardize our ability to commence product sales and generate revenues.

If we experience delays in the enrollment of patients in our clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product 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. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. For example, the COVID-19 pandemic previously negatively impacted our ability to recruit and enroll patients for our clinical trials, as they may have been reluctant or unable to visit clinical sites, or may have delayed seeking treatment for chronic conditions.

If we fail to enroll and maintain the number of patients for which the clinical trial was designed, the statistical power of that clinical trial may be reduced, which would make it harder to demonstrate that the product candidate being tested in such clinical trial is safe and effective. Additionally, enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Our inability to enroll a sufficient number of patients for any of our current or future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

We intend to rely on third parties to conduct our preclinical studies and clinical trials and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business, financial condition and results of operations could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party CROs, medical institutions, clinical investigators and contract laboratories to monitor and manage data for our licensed ongoing preclinical and clinical programs. Nevertheless, we maintain responsibility for ensuring that each of our clinical trials and preclinical studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with current requirements on good manufacturing practices, or cGMP, good clinical practices, or GCP, and good laboratory practice, or GLP, which are a collection of laws and regulations enforced by the FDA, EMA or comparable foreign authorities for all of our drug candidates in clinical development. Regulatory authorities enforce these regulations through periodic inspections of preclinical study and clinical trial sponsors, principal investigators, preclinical study and clinical trial sites, and other contractors. If we or any of our CROs or vendors fail to comply with applicable regulations, the data generated in our preclinical studies and clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign authorities may require us to perform additional preclinical studies and clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products produced consistent with cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the development and regulatory approval processes.

If any of our relationships with these third-party CROs, medical institutions, clinical investigators or contract laboratories terminate, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements, or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. CROs may also generate higher costs than anticipated. As a result, our business, financial condition, results of operations and the commercial prospects for our drug candidates could be materially and adversely affected, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding additional CROs, medical institutions, clinical investigators or contract laboratories involves additional cost and requires management's time and focus. In addition, there is a natural transition period when a new CRO commences work replacing a

previous CRO. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business, financial condition or results of operations.

In addition, our CROs may need to make certain adjustments to the operation of our trials in an effort to ensure the monitoring and safety of patients and minimize risks to trial integrity during the pandemic in accordance with the guidance issued by the FDA on March 18, 2020 and generally, and may need to make further adjustments in the future. Many of these adjustments are new and untested, may not be effective, and may have unforeseen effects on the enrollment, progress and completion of these trials and the findings from these trials.

Our drug candidates are subject to extensive regulation under the FDA, EMA or comparable foreign authorities, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals to commercialize our drug candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, export, marketing and distribution of our drug candidates are subject to extensive regulation by the FDA and other U.S. regulatory agencies, EMA or comparable authorities in foreign markets. In the U.S., neither we nor our collaborators are permitted to market our drug candidates until we or our collaborators receive approval of a new drug application, or an NDA, from the FDA or receive similar approvals abroad. The process of obtaining these approvals is expensive, often takes many years, and can vary substantially based upon the type, complexity and novelty of the drug candidates involved. Approval policies or regulations may change and may be influenced by the results of other similar or competitive products, making it more difficult for us to achieve such approval in a timely manner or at all. For example, the FDA has released draft guidance regarding clinical trials for drug candidates treating diabetes that may result in more stringent requirements for the clinical trials and regulatory approval of such drug candidates. This and any future guidance that may result from recent FDA advisory panel discussions on the topic of diabetes, non-alcoholic steatohepatitis, or MASH/NASH, and other metabolic indications, may make it more expensive to develop and commercialize such drug candidates for such indications. Such increased expense could make it more difficult to obtain favorable terms in the collaborative arrangements we require to maximize the value of our programs seeking to develop new drug candidates for diabetes. In addition, as a company, we have not previously filed NDAs with the FDA or filed similar applications with other foreign regulatory agencies. This lack of experience may impede our ability to obtain FDA or other foreign regulatory agency approval in a timely manner, if at all, for our drug candidates for which development and commercialization is our responsibility.

Despite the time and expense invested, regulatory approval is never guaranteed. The FDA, EMA or comparable foreign authorities can delay, limit or deny approval of a drug candidate for many reasons, including:

- a drug candidate may not be deemed safe or effective;
- agency officials of the FDA, EMA or comparable foreign authorities may not find the data from non-clinical or preclinical studies and clinical trials generated during development to be sufficient;
- the FDA, EMA or comparable foreign authorities may not approve our third-party manufacturers' processes or facilities; or
- the FDA, EMA or a comparable foreign authority may change its approval policies or adopt new regulations.

Our inability to obtain these approvals would prevent us from commercializing our drug candidates.

Even if our drug candidates receive regulatory approval in the U.S., we may never receive approval or commercialize our products outside of the U.S.

In order to market any products outside of the U.S., we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the U.S. as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay seeking or obtaining such approval would impair our ability to develop foreign markets for our drug candidates.

Even if any of our drug candidates receive regulatory approval, our drug candidates may still face future development and regulatory difficulties.

If any of our drug candidates receive regulatory approval, the FDA, EMA or comparable foreign authorities may still impose significant restrictions on the indicated uses or marketing of the drug candidates or impose ongoing requirements for potentially costly post-approval studies and trials. In addition, regulatory agencies subject a product, its manufacturer and the manufacturer's facilities to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, our collaborators or us, including requiring withdrawal of the product from the market. Our drug candidates will also be subject to ongoing FDA, EMA or comparable foreign authorities' requirements for the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. If our drug candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or other notices of possible violations;
- impose civil or criminal penalties or fines or seek disgorgement of revenue or profits;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us or our collaborators;
- withdraw any regulatory approvals;
- impose restrictions on operations, including costly new manufacturing requirements, or shut down our manufacturing operations; or
- seize or detain products or require a product recall.

The FDA, EMA and comparable foreign authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA, EMA and comparable foreign authorities strictly regulate the promotional claims that may be made about prescription products, such as our drug candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA, EMA or comparable foreign authorities as reflected in the product's approved labeling. If we receive marketing approval for our drug candidates for our proposed indications, physicians may nevertheless use our products for their patients in a manner that is inconsistent with the approved label, if the physicians personally believe in their professional medical judgment that our products could be used in such manner. However, if we are found to have promoted our products for any off-label uses, the federal government could levy civil, criminal or administrative penalties, and seek fines against us. Such enforcement has become more common in the industry. The FDA, EMA or comparable foreign authorities could also request that we enter into a consent decree or a corporate integrity agreement or seek a permanent injunction against us under which specified promotional conduct is monitored, changed or curtailed. If we cannot successfully manage the promotion of our drug candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business, financial condition and results of operations.

***If our competitors have drug candidates that are approved faster, are marketed more effectively, are better tolerated, have a more favorable safety profile or are demonstrated to be more effective than ours, our commercial opportunity may be reduced or eliminated.**

The biopharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including commercial biopharmaceutical enterprises, academic institutions, government agencies and private and public research institutions. Any drug candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical studies, clinical trials, regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our competitors may succeed in developing technologies and therapies that are more effective, better tolerated or less costly than any which we are developing, or that would render our drug candidates obsolete and noncompetitive. Even if we obtain regulatory approval for any of our drug candidates, our competitors may succeed in obtaining regulatory approvals for their products earlier than we do. We will also face competition from these third parties in recruiting and retaining qualified scientific and management

personnel, in establishing clinical trial sites and patient registration for clinical trials, and in acquiring and in-licensing technologies and products complementary to our programs or advantageous to our business.

The key competitive factors affecting the success of each of our drug candidates, if approved, are likely to be its efficacy, safety, tolerability, frequency and route of administration, convenience and price, the level of branded and generic competition and the availability of coverage and reimbursement from government and other third-party payors.

VK2735

VK2735, if approved, will compete against therapies that are already approved and marketed for obesity, including Semaglutide (Wegovy®) and liraglutide (Saxenda®) from Novo Nordisk A/S, and tirzepatide (Zepbound™) from Eli Lilly and Company. We are also aware of several programs targeting obesity that are in the late development stage that will compete against VK2735, if approved, including CagriSema from Novo Nordisk A/S, orforglipron and retatrutide from Eli Lilly and Company, and survodutide (BI 456906) from Boehringer Ingelheim International GmbH. In addition, we are aware of active programs at Altimune, Inc., Amgen Inc., AstraZeneca, BioAge Labs, Inc., Biophytis SA, D&D Pharmatech, Inc., ERX Pharmaceuticals Inc., F. Hoffmann-La Roche Ltd, Gubra, Hanmi Pharmaceutical Co., Ltd., Kailera Therapeutics Inc., Kallyope Inc., Metsera, Inc., Pfizer Inc., Regeneron Pharmaceuticals Inc., Rivus Pharmaceuticals Inc., Scholar Rock, Inc., Structure Therapeutics Inc., Terns Pharmaceuticals, Inc., Ventyx Biosciences, Inc., and Zealand Pharma A/S.

VK2809

Resmetirom (Rezdiffra™), another agonist of the thyroid hormone receptor beta, or TRβ, from Madrigal Pharmaceuticals, Inc., is the only therapy currently approved in the U.S. for the treatment of non-alcoholic steatohepatitis. In addition, we are aware of numerous development-stage programs targeting this disease, including arachidyl amido cholanoic acid from Galmed Pharmaceuticals Ltd., belaepectin from Galectin Therapeutics Inc., lanifibranor from Inventiva S.A., semaglutide from Novo Nordisk A/S, efruxifermin (AKR-001) from Akero Therapeutics, Inc., firsocostat (GS-0976) and cilofexor (GS-9674) from Gilead Sciences, Inc., tirzepatide from Eli Lilly and Company, ervogastat (PF-06865571) and clesacostat (PF-05221304) from Pfizer Inc., pegozafermin (BIO89-100) from 89bio, Inc., denifanstat (TVB-2640) from Sagimet Biosciences Inc., efocipegtrutide (HM15211) from Hanmi Pharmaceutical Co., Ltd., survodutide (BI 456906) from Boehringer Ingelheim International GmbH, ION224 from Ionis Pharmaceuticals, Inc., rencofilstat (CRV431) from Hepion Pharmaceuticals, Inc., HTD1801 from HighTide Therapeutics Inc., GSK4532990 (ARO-HSD) from GlaxoSmithKline plc., ALN-HSD from Alnylam Pharmaceuticals, Inc./ Regeneron Pharmaceuticals Inc., efinopegdutide (MK-6024) from Merck & Co., Inc., and pemvidutide (ALT-801) from Altimune, Inc. In addition, we are aware of active programs at Aligos Therapeutics, Inc., Arrowhead Pharmaceuticals, Inc., Asclelis Biopharmaceutical, AstraZeneca PLC, Boston Pharmaceuticals Inc., ChemomAb Ltd., CohBar, Inc., Corcept Therapeutics Inc., CytoDyn Inc., D&D Pharmatech, Inc., Durect Corporation, Enyo Pharma SA, Inc., Future Medicine Co., Ltd., Galecto, Inc., Hepagene Therapeutics, Inc., Kowa Company, Ltd., MediciNova Inc., NorthSea Therapeutics BV, Poxel SA, Rivus Pharmaceuticals Inc., Seal Rock Therapeutics, Inc., Theratechnologies Inc., Yuhan Corporation, and Cadila Healthcare Limited (a.k.a. Zydus Cadila).

VK0214

In the U.S., there are currently no marketed therapies for the treatment of X-ALD. Hematopoietic stem cell therapy has been used to treat the most severe form of X-ALD, cerebral adrenoleukodystrophy, or CALD. More recently, gene therapy has been shown to be effective in CALD, and elivaldogene autotemcel from bluebird bio, Inc., has received accelerated approval by the FDA (to slow the progression of neurologic dysfunction in boys 4-17 years of age with early, active CALD), and approval by the European Commission (for patients less than 18 years of age with early CALD without a matched sibling donor). However, both treatments are invasive, requiring surgical intervention, and these do not appear to have an effect on the most pervasive form of X-ALD, adrenomyeloneuropathy, or AMN. There are several experimental therapies that are in various stages of clinical development for X-ALD by companies, including Minoryx Therapeutics S.L., Neuraxpharm Group, Poxel SA, and Spur Therapeutics, Inc., which may be competitive with VK0214, if approved.

VK5211

In the U.S., there are currently no marketed therapies for the maintenance or improvement of lean body mass, bone mineral density or physical function in patients recovering from non-elective hip fracture surgery. However, VK5211, if approved, will face competition from experimental therapies that are in various stages of clinical development for conditions characterized by muscle wasting by companies including Biophytis SA, MyMD Pharmaceuticals, Inc., and Pluri Inc. (formerly Pluristem Therapeutics Inc.). In addition, nutritional and growth hormone-based therapies are sometimes used in patients experiencing muscle wasting.

We, or any future collaborators, may not be able to obtain orphan drug designation or orphan drug exclusivity for our product candidates.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. While we received orphan drug designation from the FDA for VK0214 for the treatment X-ALD in December 2016, we, or any future collaborators, may not be granted orphan drug designations for our product candidates in the U.S. or in other jurisdictions.

Even if we, or any future collaborators, obtain orphan drug designation for a product candidate, we, or they, may not be able to obtain orphan drug exclusivity for that product candidate. Generally, a product with orphan drug designation only becomes entitled to orphan drug exclusivity if it receives the first marketing approval for the indication for which it has such designation, in which case the FDA or the EMA will be precluded from approving another marketing application for the same drug for that indication for the applicable exclusivity period. The applicable exclusivity period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we, or any future collaborators, obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because FDA has taken the position that, under certain circumstances, another drug with the same active moiety can be approved for the same condition. Specifically, the FDA's regulations provide that it can approve another drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs and limit supply of our drug candidates.

The process of manufacturing our drug candidates is complex, highly regulated and subject to several risks. For example, the process of manufacturing our drug candidates is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing processes for any of our drug candidates could result in reduced production yields, product defects and other supply disruptions. If microbial, viral, or other contaminations are discovered in our drug candidates or in the manufacturing facilities in which our drug candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. In addition, the manufacturing facilities in which our drug candidates are made could be adversely affected by equipment failures, labor shortages, natural disasters, epidemics, pandemics, power failures and numerous other factors.

In addition, any adverse developments affecting manufacturing operations of our drug candidates may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls, or other interruptions in the supply of our drug candidates. We also may need to take inventory write-offs and incur other charges and expenses for drug candidates that fail to meet specifications, undertake costly remediation efforts, or seek costlier manufacturing alternatives.

We rely completely on third parties to manufacture our preclinical and clinical drug supplies, and our business, financial condition and results of operations could be harmed if those third parties fail to provide us with sufficient quantities of drug product, or fail to do so at acceptable quality levels or prices.

We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture our preclinical and clinical drug supplies for use in our clinical trials, and we lack the resources and the capability to manufacture any of our drug candidates on a clinical or commercial scale. We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our drug candidates for our clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture our drugs, and there may be a need to identify alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our drug candidates for our clinical trials, and, if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a drug candidate to complete such clinical trial, any significant delay or discontinuity in the supply of a drug candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our drug candidates, which could harm our business, financial condition and results of operations.

We and our contract manufacturers are subject to significant regulation with respect to manufacturing our drug candidates. The manufacturing facilities on which we rely may not continue to meet regulatory requirements.

All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for our drug candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our drug candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of an NDA or marketing authorization application, or MAA, on a timely basis and must adhere to GLP and cGMP regulations enforced by the FDA, EMA or comparable foreign authorities through their facilities inspection program. Some of our contract manufacturers may not have produced a commercially approved pharmaceutical product and therefore may not have obtained the requisite regulatory authority approvals to do so. The facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our drug candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our drug candidates or any of our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we oversee the contract manufacturers, we cannot control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly or time consuming for us or a third party to implement, and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business, financial condition and results of operations.

If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA, EMA or comparable foreign authorities can impose regulatory sanctions including, among other things, refusal to approve a pending application for a drug candidate, withdrawal of an approval, or suspension of production. As a result, our business, financial condition and results of operations may be materially and adversely affected.

Additionally, if supply from one manufacturer is interrupted, an alternative manufacturer would need to be qualified through an NDA supplement or MAA variation, or equivalent foreign regulatory filing, which could result in further delay. The regulatory agencies may also require additional studies or trials if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause us to incur higher costs and could cause the delay or termination of clinical trials, regulatory submissions, required approvals, or commercialization of our drug candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed, or we could lose potential revenue.

Any collaboration arrangement that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our current and potential future drug candidates.

We may seek collaboration arrangements with biopharmaceutical companies for the development or commercialization of our current and potential future drug candidates. To the extent that we decide to enter into collaboration agreements, we will face significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time-consuming to negotiate, execute and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we choose to enter into such arrangements, and the terms of the arrangements may not be favorable to us. If, and when, we collaborate with a third party for development and commercialization of a drug candidate, we can expect to relinquish some or all of the control over the future success of that drug candidate to the third party. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations.

Disagreements between parties to a collaboration arrangement can lead to delays in developing or commercializing the applicable drug candidate and can be difficult to resolve in a mutually beneficial manner. In some cases, collaborations with biopharmaceutical

companies and other third parties are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect our business, financial condition and results of operations.

If we are unable to develop our own commercial organization or enter into agreements with third parties to sell and market our drug candidates, we may be unable to generate significant revenues.

We do not have a sales and marketing organization, and we have no experience as a company in the sales, marketing and distribution of pharmaceutical products. If any of our drug candidates are approved for commercialization, we may be required to develop our sales, marketing and distribution capabilities, or make arrangements with a third party to perform sales and marketing services. Developing a sales force for any resulting product or any product resulting from any of our other drug candidates is expensive and time-consuming and could delay any product launch. We may be unable to establish and manage an effective sales force in a timely or cost-effective manner, if at all, and any sales force we do establish may not be capable of generating sufficient demand for our drug candidates. To the extent that we enter into arrangements with collaborators or other third parties to perform sales and marketing services, our product revenues are likely to be lower than if we marketed and sold our drug candidates independently. If we are unable to establish adequate sales and marketing capabilities, independently or with others, we may not be able to generate significant revenues and may not become profitable.

The commercial success of our drug candidates depends upon their market acceptance among physicians, patients, healthcare payors and the medical community.

Even if our drug candidates obtain regulatory approval, our products, if any, may not gain market acceptance among physicians, patients, healthcare payors and the medical community. The degree of market acceptance of any of our approved drug candidates will depend on a number of factors, including:

- the effectiveness of our approved drug candidates as compared to currently available products;
- patient willingness to adopt our approved drug candidates in place of current therapies;
- our ability to provide acceptable evidence of safety and efficacy;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- restrictions on use in combination with other products;
- availability of alternative treatments;
- pricing and cost-effectiveness assuming either competitive or potential premium pricing requirements, based on the profile of our drug candidates and target markets;
- effectiveness of our or our partners' sales and marketing strategy;
- our ability to obtain sufficient third-party coverage or reimbursement; and
- potential product liability claims.

In addition, the potential market opportunity for our drug candidates is difficult to precisely estimate. Our estimates of the potential market opportunity for our drug candidates include several key assumptions based on our industry knowledge, industry publications, third-party research reports and other surveys. Independent sources have not verified all of our assumptions. If any of these assumptions proves to be inaccurate, then the actual market for our drug candidates could be smaller than our estimates of our potential market opportunity. If the actual market for our drug candidates is smaller than we expect, our product revenue may be limited, it may be harder than expected to raise funds and it may be more difficult for us to achieve or maintain profitability. If we fail to achieve market acceptance of our drug candidates in the U.S. and abroad, our revenue will be limited and it will be more difficult to achieve profitability.

If we fail to obtain and sustain an adequate level of reimbursement for our potential products by third-party payors, potential future sales would be materially adversely affected.

There will be no viable commercial market for our drug candidates, if approved, without reimbursement from third-party payors. Reimbursement policies may be affected by future healthcare reform measures. We cannot be certain that reimbursement will be available for our current drug candidates or any other drug candidate we may develop. Additionally, even if there is a viable

commercial market, if the level of reimbursement is below our expectations, our anticipated revenue and gross margins will be adversely affected.

Third-party payors, such as government or private healthcare insurers, carefully review and increasingly question and challenge the coverage of and the prices charged for drugs. Reimbursement rates from private health insurance companies vary depending on the company, the insurance plan and other factors. Reimbursement rates may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. There is a current trend in the U.S. healthcare industry toward cost containment.

Large public and private payors, managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Such third-party payors, including Medicare, may question the coverage of, and challenge the prices charged for, medical products and services, and many third-party payors limit coverage of or reimbursement for newly approved healthcare products. In particular, third-party payors may limit the covered indications. Cost-control initiatives could decrease the price we might establish for products, which could result in product revenues being lower than anticipated. We believe our drugs will be priced significantly higher than existing generic drugs and consistent with current branded drugs. If we are unable to show a significant benefit relative to existing generic drugs, Medicare, Medicaid and private payors may not be willing to provide reimbursement for our drugs, which would significantly reduce the likelihood of our products gaining market acceptance.

We expect that private insurers will consider the efficacy, cost-effectiveness, safety and tolerability of our potential products in determining whether to approve reimbursement for such products and at what level. Obtaining these approvals can be a time consuming and expensive process. Our business, financial condition and results of operations would be materially adversely affected if we do not receive approval for reimbursement of our potential products from private insurers on a timely or satisfactory basis. Limitations on coverage could also be imposed at the local Medicare carrier level or by fiscal intermediaries. Medicare Part D, which provides a pharmacy benefit to Medicare patients as discussed below, does not require participating prescription drug plans to cover all drugs within a class of products. Our business, financial condition and results of operations could be materially adversely affected if Part D prescription drug plans were to limit access to, or deny or limit reimbursement of, our drug candidates or other potential products.

Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country-by-country basis. In many countries, the product cannot be commercially launched until reimbursement is approved. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. The negotiation process in some countries can exceed 12 months. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products to other available therapies. If the prices for our potential products are reduced or if governmental and other third-party payors do not provide adequate coverage and reimbursement of our drugs, our future revenue, cash flows and prospects for profitability will suffer.

Current and future legislation may increase the difficulty and cost of commercializing our drug candidates and may affect the prices we may obtain if our drug candidates are approved for commercialization.

In the U.S. and some foreign jurisdictions, there have been a number of adopted and proposed legislative and regulatory changes regarding the healthcare system that could prevent or delay regulatory approval of our drug candidates, restrict or regulate post-marketing activities and affect our ability to profitably sell any of our drug candidates for which we obtain regulatory approval.

In the U.S., the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, changed the way Medicare covers and pays for pharmaceutical products. Cost reduction initiatives and other provisions of this legislation could limit the coverage and reimbursement rate that we receive for any of our approved products. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the PPACA, was enacted. The PPACA was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The PPACA increased manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate amount for both branded and generic drugs and revised the definition of "average manufacturer price," or AMP, which may also increase the amount of Medicaid drug rebates manufacturers are required to pay to states. The legislation also expanded Medicaid drug rebates and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the rebates due on those drugs. The Centers for Medicare & Medicaid Services, or CMS, which administers the Medicaid Drug Rebate Program, also has proposed to expand Medicaid rebates to the utilization that occurs in the territories of the U.S., such as

Puerto Rico and the Virgin Islands. Further, beginning in 2011, the PPACA imposed a significant annual fee on companies that manufacture or import branded prescription drug products and required manufacturers to provide a discount, equal to 70% off, effective as of 2019, the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the “donut hole.” Legislative and regulatory proposals have been introduced at both the state and federal level to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. We also expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our drug candidates, if approved for commercialization.

In Europe, the United Kingdom withdrew from the European Union on January 31, 2020, and entered into a transition period that expired on December 31, 2020. A significant portion of the previous regulatory framework in the United Kingdom was derived from the regulations of the European Union. In 2021, the United Kingdom’s Medicines and Healthcare products Regulatory Agency, or MHRA, and the European Medicines Agency, or EMA, released guidance explaining the new regulatory framework. We cannot predict the consequences or impact that the new regulatory framework will have on our future operations, if any, in these jurisdictions.

In addition, on August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022, which, among other things, includes policies that are designed to have a direct impact on drug prices and reduce drug spending by the federal government, which took effect in 2023. Under the Inflation Reduction Act, Congress authorized Medicare beginning in 2026 to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars. This provision is limited in terms of the number of pharmaceuticals whose prices can be negotiated in any given year and it only applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years. Drugs and biologics that have been approved for a single rare disease or condition are categorically excluded from price negotiation. Further, the new legislation provides that if pharmaceutical companies raise prices in Medicare faster than the rate of inflation, they must pay rebates back to the government for the difference. The new law also caps Medicare out-of-pocket drug costs at an estimated \$4,000 a year in 2024 and, thereafter beginning in 2025, at \$2,000 a year.

Changes in government funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, properly administer drug innovation, or prevent our product candidates from being developed or commercialized, which could negatively impact our business, financial condition and results of operations.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including budget and funding levels, ability to hire and retain key personnel, and statutory, regulatory and policy changes. In addition, there may be delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government or contractor personnel. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

In December 2016, the 21st Century Cures Act was signed into law. This legislation is designed to advance medical innovation and empower the FDA with the authority to directly hire positions related to drug and device development and review. However, government proposals to reduce or eliminate budgetary deficits may include reduced allocations to the FDA and other related government agencies. These budgetary pressures may result in a reduced ability by the FDA to perform its roles, including the related impact to academic institutions and research laboratories whose funding is fully or partially dependent on both the level and timing of funding from government sources.

Disruptions at the FDA and other agencies may also slow the time necessary for our product candidates to be reviewed or approved by necessary government agencies, which could adversely affect our business, financial condition and results of operations.

We are subject to “fraud and abuse” and similar laws and regulations, and a failure to comply with such regulations or prevail in any litigation related to noncompliance could harm our business, financial condition and results of operations.

In the U.S., we are subject to various federal and state healthcare “fraud and abuse” laws, including anti-kickback laws, false claims laws and other laws intended, among other things, to reduce fraud and abuse in federal and state healthcare programs. The federal Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer, or a party acting on its behalf, to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce the referral of business, including the purchase, order or prescription of a particular drug, or other good or service for which payment in whole or in part may be made under

a federal healthcare program, such as Medicare or Medicaid. Although we seek to structure our business arrangements in compliance with all applicable requirements, these laws are broadly written, and it is often difficult to determine precisely how the law will be applied in specific circumstances. Accordingly, it is possible that our practices may be challenged under the federal Anti-Kickback Statute.

The federal False Claims Act prohibits anyone from, among other things, knowingly presenting or causing to be presented for payment to the government, including the federal healthcare programs, claims for reimbursed drugs or services that are false or fraudulent, claims for items or services that were not provided as claimed, or claims for medically unnecessary items or services. Under the Health Insurance Portability and Accountability Act of 1996, we are prohibited from knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services to obtain money or property of any healthcare benefit program. Violations of fraud and abuse laws may be punishable by criminal or civil sanctions, including penalties, fines or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the government under the federal False Claims Act as well as under the false claims laws of several states.

Many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not just governmental payors. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties.

Neither the government nor the courts have provided definitive guidance on the application of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. If we are found in violation of one of these laws, we could be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from governmental funded federal or state healthcare programs and the curtailment or restructuring of our operations. If this occurs, our business, financial condition and results of operations may be materially adversely affected.

If we face allegations of noncompliance with the law and encounter sanctions, our reputation, revenues and liquidity may suffer, and any of our drug candidates that are ultimately approved for commercialization could be subject to restrictions or withdrawal from the market.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to generate revenues from any of our drug candidates that are ultimately approved for commercialization. If regulatory sanctions are applied or if regulatory approval is withdrawn, our business, financial condition and results of operations will be adversely affected. Additionally, if we are unable to generate revenues from product sales, our potential for achieving profitability will be diminished and our need to raise capital to fund our operations will increase.

***Compliance with global privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.**

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, virtually every jurisdiction in which we operate has established its own data security and privacy frameworks with which we must comply. For example, the collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, the EU, including personal health data, is subject to the EU General Data Protection Regulation, or the GDPR, which took effect across all member states of the European Economic Area, or the EEA, in May 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. In addition, the GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, which includes the United States and, as a result, increases the scrutiny that clinical trial sites located in the EEA should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the United States. The GDPR also permits data protection authorities to require destruction of

improperly gathered or used personal information and/or impose substantial fines for violations of the GDPR, which can be up to 4% of global revenues or €20 million, whichever is greater, and it also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR provides that EU member states may make their own additional laws and regulations limiting the processing of personal data, including genetic, biometric or health data.

The European Data Protection Board continues to release guidelines for industries and impose fines related to the GDPR, some of which have been very significant. To improve coordination among EU supervisory authorities, the European Commission has proposed a new regulation that would help to streamline enforcement of the GDPR in cross-border cases. Meanwhile, there continues to be persistent uncertainty relating to the transfer of personal data from Europe to the U.S., or other non-adequate countries, following the Schrems II decision. On July 10, 2023, the European Commission adopted its adequacy decision on the EU-U.S. Data Privacy Framework, or DPF. The decision, which took effect on the day of its adoption, concludes that the United States ensures an adequate level of protection for personal data transferred from the EEA to companies certified to the DPF. However, it remains too soon to tell how the future of Privacy Shield 2.0 will evolve and what impact it will have on our international activities. At least one challenge to the DPF is pending before the Court of Justice of the European Union.

Further, Brexit has led and could also lead to legislative and regulatory changes that may increase our compliance costs. As of January 1, 2021 and the expiry of transitional arrangements agreed to between the UK and the EU, data processing in the UK is governed by a UK version of the GDPR (combining the GDPR and the Data Protection Act 2018), exposing us to two parallel regimes, each of which authorizes similar fines and other potentially divergent enforcement actions for certain violations. On June 28, 2021, the European Commission adopted an Adequacy Decision for the UK, allowing for the relatively free exchange of personal information between the EU and the UK (as the UK correspondingly allows transfers back to the EU). However, the European Commission may suspend the Adequacy Decision if it considers that the UK no longer provides for an adequate level of data protection. A bill to amend the existing UK framework has been reintroduced (in a different form) by the new UK Government and was announced as a bill which will be introduced into Parliament at the King's Speech on July 17, 2024. At this time, there is no specific clarity on the provisions of the bill, or the extent to which it will amend the UK framework, beyond general descriptions on its intended purpose.

Similar actions are either in place or under way in the United States. There are a broad variety of data protection laws that are applicable to our activities, and a wide range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. The Federal Trade Commission and state Attorneys General all are aggressive in reviewing privacy and data security protections for consumers. New laws also are being considered at both the state and federal levels and several states have passed comprehensive privacy laws. For example, the California Consumer Privacy Act, or the CCPA, which went into effect on January 1, 2020, is creating similar risks and obligations as those created by the GDPR, though the CCPA does exempt certain clinical trial data. The California Privacy Rights Act, or the CPRA, which went into effect on January 1, 2023, amended and expanded the CCPA, and also created a new state agency that is vested with authority to implement and enforce the CCPA and the CRPA. The CCPA and the CRPA may increase our compliance costs and potential liability, and we cannot yet predict the impact of the CCPA or the CRPA on our business. Similar laws passed in Virginia, Colorado, Connecticut, and Utah took effect in 2023. Additionally, Delaware, Florida, Indiana, Iowa, Montana, Oregon, Tennessee, Texas and others have adopted privacy laws, which took or will take effect from July 1, 2024 through 2026. Some state laws also minimize what data can be collected from consumers and how businesses may use and disclose it. These state privacy laws also require businesses to make disclosures to consumers about data collection, use and sharing practices. In addition, some of these laws (including the CPRA), along with other standalone health privacy laws, subject health-related information to additional safeguards and disclosures and some specifically regulate consumer health data, such as the Washington My Health My Data Act, which became effective in 2023 and 2024. Additionally, a broad range of legislative measures also have been introduced at the federal level. Accordingly, failure to comply with federal and state laws (both those currently in effect and future legislation) regarding privacy and security of personal information could expose us to fines and penalties under such laws. There also is the threat of consumer class actions related to these laws and the overall protection of personal data.

Given the breadth and depth of changes in data protection obligations, preparing for and complying with these requirements is rigorous and time intensive and requires significant resources and a review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, CROs, contractors or consultants that process or transfer personal data collected in the EU. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business, and could lead to government enforcement actions, private litigation and significant fines and penalties against us and could have a material adverse effect on our business, financial condition or results of operations. Similarly, failure to comply with federal and state laws regarding privacy and security of personal information could expose us to fines and penalties under such laws. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. If we fail to comply with these laws, we could be subject to civil or criminal liabilities, other remedial measures and legal expenses, be precluded from developing, manufacturing and selling certain products outside the United States or be required to develop and implement costly compliance programs, which could adversely affect our business, results of operations and financial condition.

Our operations are subject to anti-corruption laws, including the U.S. Foreign Corrupt Practices Act, or the FCPA, the U.K. Bribery Act 2010, or the Bribery Act, and other anti-corruption laws that apply in countries where we do business and may do business in the future. The FCPA, the Bribery Act and these other laws generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. Compliance with the FCPA, in particular, is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

We may in the future operate in jurisdictions that pose a high risk of potential FCPA or Bribery Act violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA, the Bribery Act or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. If we expand our operations outside of the United States, we will need to dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United States, the United Kingdom and authorities in the EU, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as Trade Control Laws. In addition, various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, we will be required to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA, the Bribery Act or other legal requirements, including Trade Control Laws. If we are not in compliance with the FCPA, the Bribery Act and other anti-corruption laws or Trade Control Laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions. Any investigation of any potential violations of the FCPA, the Bribery Act, other anti-corruption laws or Trade Control Laws by United States, United Kingdom or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

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

In some countries, particularly member states of the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we, or our future collaborators, may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. 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 product candidate approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

***If we fail to retain current members of our senior management and scientific personnel, or to attract and keep additional key personnel, we may be unable to successfully develop or commercialize our drug candidates.**

Our success depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. As of September 30, 2024, we had thirty-three full-time employees, one part-time employee and a small number of consultants, which may make us more reliant on our individual employees than companies with a greater number of employees. The loss of any of our key personnel could delay or prevent the development of our drug candidates. These personnel are "at-will" employees and may terminate their employment with us at any time; however, our current executive officer has agreed to provide us with at least 60 days' advance notice of resignation pursuant to his employment agreement with us. The replacement of key personnel likely would involve significant time and costs, and may significantly delay or prevent the achievement of our business objectives. We do not maintain "key person" insurance on any of our employees.

From time to time, our management seeks the advice and guidance of certain scientific advisors and consultants regarding clinical and regulatory development programs and other customary matters. These scientific advisors and consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our scientific advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

Competition for qualified personnel is intense, especially in the greater San Diego, California area where we have a substantial presence and need for highly skilled personnel. We may not be successful in attracting qualified personnel to fulfill our current or future needs. Competitors and others have in the past attempted, and are likely in the future to attempt, to recruit our employees. While our employees are required to sign standard agreements concerning confidentiality and ownership of inventions, we generally do not have employment contracts or non-competition agreements with any of our personnel. In addition, we may experience employee turnover as a result of the ongoing "great resignation" occurring throughout the U.S. economy, which has impacted job market dynamics. New hires require training and take time before they achieve full productivity. New employees may not become as productive as we expect, and we may be unable to hire or retain sufficient numbers of qualified individuals. The loss of the services of any of our key personnel, the inability to attract or retain highly qualified personnel in the future or delays in hiring such personnel, particularly senior management and other technical personnel, could materially and adversely affect our business, financial condition and results of operations.

We will need to increase the size of our organization and may not successfully manage our growth.

We are a clinical-stage biopharmaceutical company with a small number of employees, and our management systems currently in place are not likely to be adequate to support our future growth plans. Our ability to grow and to manage our growth effectively will require us to hire, train, retain, manage and motivate additional employees and to implement and improve our operational, financial and management systems. These demands also may require the hiring of additional senior management personnel or the development of additional expertise by our senior management personnel. Hiring a significant number of additional employees, particularly those at the management level, would increase our expenses significantly. Moreover, if we fail to expand and enhance our operational, financial and management systems in conjunction with our potential future growth, it could have a material adverse effect on our business, financial condition and results of operations.

We are exposed to product liability, non-clinical and clinical liability risks which could place a substantial financial burden upon us, should lawsuits be filed against us.

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical formulations and products. In addition, the use in our clinical trials of pharmaceutical products and the subsequent sale of these products by us or our potential collaborators may cause us to bear a portion of or all product liability risks. A successful liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations.

We currently maintain product liability insurance; however, there can be no assurance that we will be able to continue to maintain such insurance, and we may be unable to obtain replacement product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Our research and development activities involve the use of hazardous materials, which subject us to regulation, related costs and delays and potential liabilities.

Our research and development activities involve the controlled use of hazardous materials, chemicals and various radioactive compounds, and we will need to develop additional safety procedures for the handling and disposing of hazardous materials. 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 biohazardous 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.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract, including our CROs and other business partners, are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations or the operations of our CROs and other business partners, and could result in a material disruption of our drug development and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of drug development or clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We have experienced cybersecurity incidents in the past and expect that we will experience cybersecurity incidents in the future. If we were to experience a significant cybersecurity breach of our information systems or data, the costs associated with the investigation, remediation and potential notification of the breach to counter-parties and data subjects could be material. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our development programs and the development of our drug candidates could be delayed.

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

We are exposed to the risk of employee or consultant fraud or other misconduct. Misconduct by our employees or consultants could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards, 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 commissions, customer incentive programs and other business arrangements. Employee and consultant misconduct also could 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 such 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 be in compliance 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 adverse effect on our business, financial condition and results of operations, and result in the imposition of significant fines or other sanctions against us.

Business disruptions such as natural disasters could seriously harm our future revenues and financial condition and increase our costs and expenses.

Our corporate headquarters are located in greater San Diego, California, a region known for seismic activity. In addition, one of our third-party manufacturers is located in the southeastern part of the United States, an area subject to hurricanes and related natural disasters. Our suppliers may also experience a disruption in their business as a result of natural or man-made disasters. A significant natural or man-made disaster, such as an earthquake, prolonged or repeated power outage, hurricane, flood, fire, drought or other extreme weather events and changing weather patterns, which are increasing in frequency due to the impacts of climate change, could severely damage or destroy our headquarters or facilities or the facilities of our manufacturers or suppliers, which could have a material and adverse effect on our business, financial condition and results of operations. In addition, terrorist acts or acts of war targeted at the U.S., and specifically the greater San Diego, California region, as well as the ongoing conflict between Ukraine and Russia and the global impact of restrictions and sanctions imposed on Russia and the Israel-Hamas war, could cause damage or disruption to us, our employees, facilities, partners and suppliers, which could have a material adverse effect on our business, financial condition and results of operations.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of products, drug candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near-

and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our business, financial condition and results of operations. For example, these transactions may 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 develop acquired products, drug candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for any of these transactions;
- higher-than-expected transaction and integration costs;
- write-downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses or product lines with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses or product lines due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks, and could have a material adverse effect on our business, financial condition and results of operations.

Our employment agreements with our officers and certain other employees may require us to pay severance benefits to any of those persons who are terminated in connection with a change in control of our company, which could harm our financial condition or results.

Our officers and certain employees are parties to employment agreements that contain change in control and severance provisions in the event of a termination of employment in connection with a change in control of our company providing for cash payments for severance and other benefits and acceleration of vesting of stock options and shares of restricted stock. The accelerated vesting of options and shares of restricted stock could result in dilution to our existing stockholders and lower the market price of our common stock. The payment of these severance benefits could harm our financial condition and results. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

***Investors' expectations of our performance relating to environmental, social and governance factors may impose additional costs and expose us to new risks.**

There is an increasing focus from certain investors, employees, regulators and other stakeholders concerning corporate responsibility, specifically related to environmental, social and governance, or ESG, factors. Some investors and investor advocacy groups may use these factors to guide investment strategies and, in some cases, investors may choose not to invest in our company if they believe our policies relating to corporate responsibility are inadequate. Third-party providers of corporate responsibility ratings and reports on companies have increased to meet growing investor demand for measurement of corporate responsibility performance, and a variety of organizations currently measure the performance of companies on such ESG topics, and the results of these assessments are widely publicized. Investors, particularly institutional investors, use these ratings to benchmark companies against their peers and if we are perceived as lagging with respect to ESG initiatives, certain investors may engage with us to improve ESG disclosures or performance and may also make voting decisions, or take other actions, to hold us and our board of directors accountable. In addition, the criteria by which our corporate responsibility practices are assessed may change, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. If we elect not to or are unable to satisfy such new criteria, investors may conclude that our policies with respect to corporate responsibility are inadequate.

We may face reputational damage in the event our corporate responsibility initiatives or objectives do not meet the standards set by our investors, stockholders, lawmakers, listing exchanges or other constituencies, or if we are unable to achieve an acceptable ESG or sustainability rating from third-party rating services. A low ESG or sustainability rating by a third-party rating service could also result in the exclusion of our common stock from consideration by certain investors who may elect to invest with our competition instead. Ongoing focus on corporate responsibility matters by investors and other parties as described above may impose additional costs or

expose us to new risks. Any failure or perceived failure by us in this regard could have a material adverse effect on our reputation and on our business, share price, financial condition, or results of operations, including the sustainability of our business over time.

In addition, on March 6, 2024, the SEC finalized new rules for public companies that will require extensive climate-related disclosures and significant analysis of the impact of climate-related issues on our business strategy, results of operations, and financial condition, or the SEC Climate Disclosure Rules, and extensive attestation requirements. The new rules require disclosure of, among other things and to the extent material, our climate-related risks and opportunities, greenhouse gas emissions inventory, climate-related targets and goals, and financial impacts of physical and transition risks. Subsequently, in April 2024, the SEC issued an order staying implementation of the SEC Climate Disclosure Rules pending the resolution of certain challenges. Nonetheless, our legal, accounting, and other compliance expenses may increase significantly, and compliance efforts may divert management time and attention as we prepare for the potential implementation of the SEC Climate Disclosure Rules, and such expenses, efforts and diversions of management time and attention may be even greater if the SEC Climate Disclosure Rules ultimately go into effect. We may also be exposed to legal or regulatory action or claims as a result of these new regulations. Separately, the SEC has also announced that it is scrutinizing existing climate-change related disclosures in public filings, increasing the potential for enforcement if the SEC were to allege our existing climate disclosures are misleading or deficient. All of these risks could have a material adverse effect on our business, financial position, and/or stock price.

The impact of the Russian invasion of Ukraine and the Israel-Hamas war on the global economy, energy supplies and raw materials is uncertain, but may prove to negatively impact our business and operations.

The short and long-term implications of Russia's invasion of Ukraine and the Israel-Hamas war are difficult to predict at this time. We continue to monitor any adverse impact that the outbreak of war in Ukraine, the subsequent institution of sanctions against Russia by the United States and several European and Asian countries, and the Israel-Hamas war may have on the global economy in general, on our business and operations and on the businesses and operations of our suppliers and other third parties with which we conduct business. For example, a prolonged conflict in Ukraine or Israel may result in increased inflation, escalating energy prices and constrained availability, and thus increasing costs, of raw materials. We will continue to monitor this fluid situation and develop contingency plans as necessary to address any disruptions to our business operations as they develop. To the extent the wars in Ukraine or Israel may adversely affect our business as discussed above, it may also have the effect of heightening many of the other risks described herein. Such risks include, but are not limited to, adverse effects on macroeconomic conditions, including inflation; disruptions to our global technology infrastructure, including through cyberattack, ransom attack, or cyber-intrusion; adverse changes in international trade policies and relations; disruptions in global supply chains; and constraints, volatility, or disruption in the capital markets, any of which could negatively affect our business and financial condition.

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

Our business, financial condition and results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, service providers, manufacturers or other partners and there is a risk that one or more would not survive or be able to meet their commitments to us under such circumstances. As widely reported, global credit and financial markets have experienced volatility and disruptions in the past several years and especially in 2020, 2021 and 2022 due to the impacts of the COVID-19 pandemic, and, more recently, the ongoing conflict between Ukraine and Russia and the global impact of restrictions and sanctions imposed on Russia, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. Moreover, the global impacts of the Israel-Hamas war are still unknown. There can be no assurances that further deterioration in credit and financial markets and confidence in economic conditions will not occur. For example, U.S. debt ceiling and budget deficit concerns have increased the possibility of additional credit-rating downgrades and economic slowdowns, or a recession in the United States. Although U.S. lawmakers passed legislation to raise the federal debt ceiling on multiple occasions, including a suspension of the federal debt ceiling in June 2023, ratings agencies have lowered or threatened to lower the long-term sovereign credit rating on the United States. The impact of this or any further downgrades to the U.S. government's sovereign credit rating or its perceived creditworthiness could adversely affect the U.S. and global financial markets and economic conditions. Absent further quantitative easing by the Federal Reserve, these developments could cause interest rates and borrowing costs to rise, which may negatively impact our results of operations or financial condition. Moreover, disagreement over the federal budget has caused the U.S. federal government to shut down for periods of time. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Risks Relating to Our Intellectual Property

***We may not be successful in obtaining or maintaining necessary rights to our drug candidates through acquisitions and in-licenses.**

We currently have intellectual property rights to develop our drug candidates through a license from Ligand. As of September 30, 2024, we owned or co-owned 139 patent applications and 32 patents. Because our programs require the use of proprietary rights held by Ligand, the growth of our business will likely depend in part on our ability to maintain and exploit these proprietary rights. In addition, we may need to acquire or in-license additional intellectual property in the future. We may be unable to acquire or in-license any compositions, methods of use, processes or other intellectual property rights from third parties that we identify as necessary for our drug candidates. We face competition with regard to acquiring and in-licensing third-party intellectual property rights, including from a number of more established companies. These established companies may have a competitive advantage over us due to their size, cash 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 intellectual property rights to us. We also may be unable to acquire or in-license third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

We may enter into collaboration agreements with U.S. and foreign academic institutions to accelerate development of our current or future preclinical drug candidates. Typically, these agreements include an option for us to negotiate a license to the institution's intellectual property rights resulting from the collaboration. Even with such an option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to license rights from a collaborating institution, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our desired program.

If we are unable to successfully obtain required third-party intellectual property rights or maintain our existing intellectual property rights, including if our patent applications do not result in the issuance of patents, we may need to abandon development of the related program and our business, financial condition and results of operations could be materially and adversely affected.

If we fail to comply with our obligations in the agreements under which we in-license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.

The Master License Agreement is important to our business and we expect to enter into additional license agreements in the future. The Master License Agreement imposes, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under these agreements, or if we file for bankruptcy, we may be required to make certain payments to the licensor, we may lose the exclusivity of our license, or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. Additionally, the milestone and other payments associated with these licenses could materially and adversely affect our business, financial condition and results of operations.

Pursuant to the terms of the Master License Agreement, Ligand may terminate the Master License Agreement under certain circumstances, including, but not limited to: (1) in the event of our insolvency or bankruptcy, (2) if we do not pay an undisputed amount owing under the Master License Agreement when due and fail to cure such default within a specified period of time, or (3) if we default on certain of our material obligations and fail to cure the default within a specified period of time. If the Master License Agreement is terminated in its entirety or with respect to a specific licensed program for any reason, among other consequences, all licenses granted to us under the Master License Agreement (or with respect to the specific licensed program) will terminate and we may be requested to assign and transfer to Ligand certain regulatory documentation and regulatory approvals related to the licensed programs (or those related to the specific licensed program), and we may be required to wind down any ongoing clinical trials with respect to the licensed programs (or those related to the specific licensed program). Additionally, Ligand may require us to assign to Ligand the trademarks owned by us relating to the licensed programs (or those related to the specific licensed program), and we would be obligated to grant to Ligand a license under any patent rights and know-how controlled by us to the extent necessary to make, have made, import, use, offer to sell and sell the licensed programs (or those related to the specific licensed program) anywhere in the world at a royalty rate in the low single digits.

In some cases, patent prosecution of our licensed technology may be controlled solely by the licensor. If our licensor fails to obtain and maintain patent or other protection for the proprietary intellectual property we in-license, then we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In certain cases, we may control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise regarding intellectual property subject to a licensing agreement, including, but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;

- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
- the priority of invention of patented technology.

If disputes over intellectual property and other rights that we have in-licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected drug candidates. If we fail to comply with any such obligations to our licensor, such licensor may terminate their licenses to us, in which case we would not be able to market products covered by these licenses. The loss of our license with Ligand, and potentially other licenses that we enter into in the future, would have a material adverse effect on our business.

We may be required to pay milestones and royalties to Ligand in connection with our use of the licensed technology under the Master License Agreement, which could adversely affect the overall profitability for us of any products that we may seek to commercialize.

Under the terms of the Master License Agreement, we may be obligated to pay Ligand up to an aggregate of approximately \$1.54 billion in development, regulatory and sales milestones. We will also be required to pay Ligand single-digit royalties on future worldwide net product sales. These royalty payments could adversely affect the overall profitability for us of any products that we may seek to commercialize.

We may not be able to protect our proprietary or licensed technology in the marketplace.

We depend on our ability to protect our proprietary or licensed technology. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. Our success depends in large part on our ability, Ligand's and any future licensor's or licensee's ability to obtain and maintain patent protection in the U.S. and other countries with respect to our proprietary or licensed technology and products. We currently in-license most of our intellectual property rights to develop our drug candidates and may in-license additional intellectual property rights in the future. Under the terms of the Master License Agreement, Ligand has the first right to file, prosecute and maintain the patents subject to the Master License Agreement in its name. We cannot be certain that patent enforcement activities by our current or future licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. We also cannot be certain that our current or future licensors will allocate sufficient resources or prioritize their or our enforcement of such patents. Even if we are not a party to these legal actions, an adverse outcome could prevent us from continuing to license intellectual property that we may need to operate our business, which would have a material adverse effect on our business, financial condition and results of operations.

We believe we will be able to obtain, through prosecution of patent applications covering technology licensed from others, adequate patent protection for our proprietary drug technology, including those related to our in-licensed intellectual property. If we are compelled to spend significant time and money protecting or enforcing our licensed patents and future patents we may own, designing around patents held by others or licensing or acquiring, potentially for large fees, patents or other proprietary rights held by others, our business, financial condition and results of operations may be materially and adversely affected. If we are unable to effectively protect the intellectual property that we own or in-license, other companies may be able to offer the same or similar products for sale, which could materially adversely affect our business, financial condition and results of operations. The patents of others from whom we may license technology, and any future patents we may own, may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing the same or similar products or limit the length of term of patent protection that we may have for our products.

***Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection for licensed patents, pending patent applications and potential future patent applications and patents could be reduced or eliminated for non-compliance with these requirements.**

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or patent applications will be due to be paid to the U.S. Patent and Trademark Office, or the USPTO, and various governmental patent agencies outside of the U.S. in several stages over the lifetime of the applicable patent and/or patent application. The USPTO and various non-U.S.

governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. 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. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If this occurs with respect to our in-licensed patents or patent applications we may file in the future, our competitors might be able to use our technologies, which would have a material adverse effect on our business, financial condition and results of operations.

The patent positions of pharmaceutical products are often complex and uncertain. The breadth of claims allowed in pharmaceutical patents in the U.S. and many jurisdictions outside of the U.S. is not consistent. For example, in many jurisdictions, the support standards for pharmaceutical patents are becoming increasingly strict. Some countries prohibit method of treatment claims in patents. Changes in either the patent laws or interpretations of patent laws in the U.S. and other countries may diminish the value of our licensed or owned intellectual property or create uncertainty. In addition, publication of information related to our current drug candidates and potential products may prevent us from obtaining or enforcing patents relating to these drug candidates and potential products, including without limitation composition-of-matter patents, which are generally believed to offer the strongest patent protection.

Our intellectual property includes licenses covering issued patents and pending patent applications for composition of matter, method of use and method of manufacture. As of September 30, 2024, for each of VK2809 and VK0214, we in-licensed three patents in the U.S. and additional patents in certain foreign jurisdictions, and owned or co-owned and in-licensed three U.S. patents, four U.S. patent applications, and additional patents and patent applications in certain foreign jurisdictions. We also in-licensed one additional U.S. patent and one Japanese patent directed to VK0214, and owned two additional U.S. patents, one PCT application, and several patent applications in the U.S. and certain foreign jurisdictions directed to VK2809 as of September 30, 2024. For VK5211, as of September 30, 2024, we in-licensed ten patents and one patent application in the U.S. and several other patents and patent applications in certain foreign jurisdictions. As of September 30, 2024, for our GLP-1 program, we own one U.S. patent, additional patents in certain foreign jurisdictions, two PCT applications, and several patent applications in the U.S. and certain foreign jurisdictions. With respect to our other current drug candidates, we have a license covering several issued patents both in the U.S. and in certain foreign jurisdictions.

Patents that we currently license and patents that we may own or license in the future do not necessarily ensure the protection of our licensed or owned intellectual property for a number of reasons, including, without limitation, the following:

- the patents may not be broad or strong enough to prevent competition from other products that are identical or similar to our drug candidates;
- there can be no assurance that the term of a patent can be extended under the provisions of patent term extension afforded by U.S. law or similar provisions in foreign countries, where available;
- the issued patents and patents that we may obtain or license in the future may not prevent generic entry into the U.S. market for our drug candidates;
- we do not at this time license or own a granted European patent or national phase patents in any European jurisdictions that would prevent generic entry into the European market for one of our primary drug candidates, VK2809;
- we, or third parties from who we in-license or may license patents, may be required to disclaim part of the term of one or more patents;
- there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim;
- there may be prior art of which we are aware, which we do not believe affects the validity or enforceability of a patent claim, but which, nonetheless, ultimately may be found to affect the validity or enforceability of a patent claim;
- there may be other patents issued to others that will affect our freedom to operate;
- if the patents are challenged, a court could determine that they are invalid or unenforceable;
- there might be a significant change in the law that governs patentability, validity and infringement of our licensed patents or any future patents we may own that adversely affects the scope of our patent rights;
- a court could determine that a competitor's technology or product does not infringe our licensed patents or any future patents we may own; and

- the patents could irretrievably lapse due to failure to pay fees or otherwise comply with regulations or could be subject to compulsory licensing.

If we encounter delays in our development or clinical trials, the period of time during which we could market our potential products under patent protection would be reduced.

Our competitors may be able to circumvent our licensed patents or future patents we may own by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may seek to market generic versions of any approved products by submitting abbreviated new drug applications to the FDA in which our competitors claim that our licensed patents or any future patents we may own are invalid, unenforceable or not infringed. Alternatively, our competitors may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend or assert our licensed patents or any future patents we may own, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our licensed patents or any future patents we may own invalid or unenforceable. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Even if we own or in-license valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

The issuance of a patent is not conclusive as to its inventorship, scope, ownership, priority, validity or enforceability. In this regard, third parties may challenge our licensed patents or any future patents we may own in the courts or patent offices in the U.S. and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and potential products. In addition, given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized.

We may infringe the intellectual property rights of others, which may prevent or delay our drug development efforts and prevent us from commercializing or increase the costs of commercializing our products.

Our commercial success depends significantly on our ability to operate without infringing the patents and other intellectual property rights of third parties. For example, there could be issued patents of which we are not aware that our current or potential future drug candidates infringe. There also could be patents that we believe we do not infringe, but that we may ultimately be found to infringe.

Moreover, patent applications are in some cases maintained in secrecy until patents are issued. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and patent applications were filed. Because patents can take many years to issue, there may be currently pending applications of which we are unaware that may later result in issued patents that our drug candidates or potential products infringe. For example, pending applications may exist that claim or can be amended to claim subject matter that our drug candidates or potential products infringe. Competitors may file continuing patent applications claiming priority to already issued patents in the form of continuation, divisional, or continuation-in-part applications, in order to maintain the pendency of a patent family and attempt to cover our drug candidates.

Third parties may assert that we are employing their proprietary technology without authorization and may sue us for patent or other intellectual property infringement. These lawsuits are costly and could adversely affect our business, financial condition and results of operations and divert the attention of managerial and scientific personnel. If we are sued for patent infringement, we would need to demonstrate that our drug candidates, potential products or methods either do not infringe the claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the U.S., proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. If a court holds that any third-party patents are valid, enforceable and cover our products or their use, the holders of any of these patents may be able to block our ability to commercialize our products unless we acquire or obtain a license under the applicable patents or until the patents expire.

We may not be able to enter into licensing arrangements or make other arrangements at a reasonable cost or on reasonable terms. Any inability to secure licenses or alternative technology could result in delays in the introduction of our products or lead to prohibition of the manufacture or sale of products by us. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our drug candidates or force us to cease some of our business operations, which could materially and adversely affect our business, financial condition and results of operations. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar material and adverse effect on our business, financial condition and

results of operations. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

***Any claims or lawsuits relating to infringement of intellectual property rights brought by or against us will be costly and time consuming and may adversely affect our business, financial condition and results of operations.**

We may be required to initiate litigation to enforce or defend our licensed and owned intellectual property. For example, we were previously aware of at least two third-party companies that were selling products in the U.S. bearing the name "LGD-4033," which is the name previously used by Ligand to refer to VK5211, without authority from either us or Ligand, and we may experience other potential intellectual property infringement in the future. In addition, in December 2022, we filed suit against Ascleitis Bioscience Co., Ltd., Gannex Pharma Co., Ltd., Ascleitis Pharmaceuticals Co., Ltd., Ascleitis Pharma Inc., and Jinzi Jason Wu, or the Ascleitis Defendants, in the Southern District of California, San Diego division, alleging, among other things: (1) violation of the Defend Trade Secrets Act; (2) violation of the California Uniform Trade Secrets Act; (3) breach of contract; (4) breach of the implied covenant of good faith and fair dealing; and (5) tortious interference with contract. In a related action, we also filed suit against the same Ascleitis Defendants in the International Trade Commission, or the ITC, for unlawful and unfair methods of competition. On October 3, 2024, the ITC's Chief Administrative Law Judge issued a Notice of his determination that the Ascleitis Defendants misappropriated our trade secrets and engaged in discovery misconduct, warranting monetary and non-monetary sanctions. Lawsuits to protect our intellectual property rights can be time consuming and costly. There is a substantial amount of litigation involving patent and other intellectual property rights in the biopharmaceutical industry generally. Such litigation or proceedings could increase our operating expenses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

In any infringement litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are resolved. Further, any claims we assert against a perceived infringer could provoke these parties to assert counterclaims against us alleging that we have infringed their patents. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

In addition, our licensed patents and patent applications, and patents and patent applications that we may apply for, own or license in the future, could face other challenges, such as interference proceedings, opposition proceedings, re-examination proceedings and other forms of post-grant review. Any of these challenges, if successful, could result in the invalidation of, or in a narrowing of the scope of, any of our licensed patents and patent applications and patents and patent applications that we may apply for, own or license in the future. Any of these challenges, regardless of their success, would likely be time-consuming and expensive to defend and resolve and would divert our management and scientific personnel's time and attention.

In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the market price of our common stock.

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 products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is costly, time-consuming and inherently uncertain. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act included a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and that may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first to file" system in which the first inventor to file a patent application is typically entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO, and may become involved in post-grant proceedings, including opposition, derivation, reexamination, inter partes review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations

governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we might obtain 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 weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, in June 2023, a new unitary patent system was introduced, which will significantly impact European patents, including those granted before the introduction of the system. Under the unitary patent system, after a European patent is granted, the patent proprietor can request unitary effect, thereby getting a European patent with unitary Effect, or a Unitary Patent. Each Unitary Patent is subject to the jurisdiction of the Unitary Patent Court, or the 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 may 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 the new unitary patent system.

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

Filing, prosecuting and defending patents on drug candidates throughout the world would be prohibitively expensive. Competitors may use our licensed and owned technologies in jurisdictions where we have not licensed or obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain or license patent protection, but where patent enforcement is not as strong as that in the U.S. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our licensed patents and future patents we may own, or marketing of competing products in violation of our proprietary rights generally. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the U.S. As a result, we may encounter significant problems in protecting and defending our licensed and owned intellectual property both in the U.S. and abroad. For example, China, where we currently have a number of licensed patents and licensed and owned patent applications, currently affords less protection to a company's intellectual property than some other jurisdictions. As such, the lack of strong patent and other intellectual property protection in China may significantly increase our vulnerability regarding unauthorized disclosure or use of our intellectual property and undermine our competitive position. Proceedings to enforce our future patent rights, if any, in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Many countries, including European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under certain circumstances to grant licenses to third parties. In those countries, as of September 30, 2024, we had several licensed and owned patents and several licensed and owned patent applications and may have limited remedies if such patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of such patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

We may be unable to adequately prevent unauthorized disclosure of trade secrets and other proprietary information.

In order to protect our proprietary and licensed technology and processes, we rely in part on confidentiality agreements with our corporate partners, employees, consultants, manufacturers, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent unauthorized disclosure of our confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. For example, in our suit against the Ascleitis Defendants that we filed in the Southern District of California, San Diego division, in December 2022, we brought claims related to breach of confidential disclosure agreements. There can be no assurance that we will be successful in this suit. In addition, others may independently discover our trade secrets and proprietary information. Failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other biopharmaceutical companies. Although we have no knowledge of any such claims against us, we may be subject to claims that we or our employees, consultants or independent contractors have

inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. To date, none of our employees have been subject to such claims.

We may be subject to claims challenging the inventorship of our licensed patents, any future patents we may own and other intellectual property.

Although we are not currently experiencing any claims challenging the inventorship of our licensed patents or our licensed or owned intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our licensed patents or other licensed or owned intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our drug candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business, financial condition and results of operations. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

If we do not obtain additional protection under the Hatch-Waxman Amendments and similar foreign legislation extending the terms of our licensed patents and any future patents we may own, our business, financial condition and results of operations may be materially and adversely affected.

Depending upon the timing, duration and specifics of FDA regulatory approval for our drug candidates, one or more of our licensed U.S. patents or future U.S. patents that we may license or own may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during drug development and the FDA regulatory review process. This period is generally one-half the time between the effective date of an investigational new drug application (falling after issuance of the patent), and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Patent term restorations, however, cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval by the FDA.

The application for patent term extension is subject to approval by the USPTO, in conjunction with the FDA. It takes at least six months to obtain approval of the application for patent term extension. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain earlier approval of competing products, and our ability to generate revenues could be materially adversely affected.

Risks Relating to Ownership of Our Common Stock

The market price of our common stock may be highly volatile.

The trading price of our common stock is likely to be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- any delay in filing an NDA for any of our drug candidates and any adverse development or perceived adverse development with respect to the FDA's review of that NDA;
- adverse results or delays in clinical trials, if any;
- significant lawsuits, including patent or stockholder litigation;
- inability to obtain additional funding;
- failure to successfully develop and commercialize our drug candidates;
- changes in laws or regulations applicable to our drug candidates;
- inability to obtain adequate product supply for our drug candidates, or the inability to do so at acceptable prices;
- unanticipated serious safety concerns related to any of our drug candidates;

- adverse regulatory decisions;
- introduction of new products or technologies by our competitors;
- failure to meet or exceed drug development or financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- the perception of the biopharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our licensed and owned technologies;
- additions or departures of key scientific or management personnel;
- changes in the market valuations of similar companies;
- general economic and market conditions and overall fluctuations in the U.S. equity market;
- public health emergencies such as the COVID-19 pandemic;
- sales of our common stock by us or our stockholders in the future; and
- trading volume of our common stock.

In addition, the stock market, in general, and small biopharmaceutical companies, in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. Further, a decline in the financial markets and related factors beyond our control may cause our stock price to decline rapidly and unexpectedly.

An active trading market for our common stock may not be sustained, and you may not be able to resell your common stock at a desired market price.

If no active trading market for our common stock is sustained, you may be unable to sell your shares when you wish to sell them or at a price that you consider attractive or satisfactory. The lack of an active market may also adversely affect our ability to raise capital by selling securities in the future, or impair our ability to acquire or in-license other drug candidates, businesses or technologies using our shares as consideration.

***Our management owns a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.**

As of September 30, 2024, our executive officers, directors and 5% or greater stockholders beneficially owned 32.7% of our common stock. Therefore, our executive officers, directors and 5% or greater stockholders have the ability to influence us through this ownership position.

This concentration of stock ownership may adversely affect the trading price for our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. As a result, these stockholders, if they acted together, could materially influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. These stockholders may be able to determine all matters requiring stockholder approval. The interests of these stockholders may not always coincide with our interests or the interests of other stockholders. This may also prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

We are no longer a “smaller reporting company” within the meaning of the Securities Act of 1933, as amended, and as a result we are subject to certain enhanced disclosure requirements which will require us to incur significant expenses and expend time and resources.

We are no longer a “smaller reporting company,” as of January 1, 2024 and, as a result, we are or will be required to comply with various disclosure and compliance requirements that did not previously apply, such as the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, the requirement that we hold a nonbinding advisory vote on executive compensation and obtain shareholder approval of any golden parachute payments not previously approved, the requirement to provide full and more detailed executive compensation disclosure and the reduction in the amount of time for filing our periodic and annual reports. Compliance with these additional requirements increases our legal and financial compliance costs and causes management and other personnel to divert attention from operational and other business matters to these additional public company reporting requirements. In addition, if we are not able to comply with changing requirements in a timely manner, the market price of our stock could decline and we could be subject to delisting proceedings by the stock exchange on which our common shares are listed, or sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

We became a large-accelerated filer effective January 1, 2024. We reassessed, as of June 30, 2024, and determined that we continue to qualify as a large accelerated filer for filings beyond the fiscal year ending December 31, 2024. We will need to reassess, as of June 30, 2025, whether we will continue to qualify as a large accelerated filer for filings beyond the fiscal year ending December 31, 2025.

Our internal control over financial reporting may not meet the standards required by Section 404 of the Sarbanes-Oxley Act, and failure to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act, could have a material adverse effect on our business and share price.

During the fiscal year 2023, our management was required to report, on a quarterly basis, on the effectiveness of our internal control over financial reporting. Commencing with the fiscal year ended December 31, 2023, in addition to our management's report on the effectiveness of our internal controls over financial reporting, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. The rules governing the standards that must be met for our management and our independent registered public accounting firm to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation.

In connection with the implementation of the necessary procedures and practices related to internal control over financial reporting, we may identify deficiencies or material weaknesses that we may not be able to remediate in time to meet the deadline imposed by the Sarbanes-Oxley Act for compliance with the requirements of Section 404. In addition, we may encounter problems or delays in completing the implementation of any requested improvements and receiving a favorable attestation in connection with the attestation provided by our independent registered public accounting firm. Failure to achieve and maintain an effective internal control environment could have a material adverse effect on our business, financial condition and results of operations and could limit our ability to report our financial results accurately and in a timely manner.

As a result of operating as a public company, we may incur significantly increased costs and our management and other personnel will be required to devote substantial time to new compliance initiatives.

As a public company and particularly after December 31, 2023, when we ceased to be a “smaller reporting company” and “non-accelerated filer,” and became a “large accelerated filer”, we expect to incur additional significant legal, accounting and other expenses. In addition, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, or the Dodd-Frank Act, as well as rules subsequently implemented by the SEC and The Nasdaq Stock Market LLC have imposed various requirements on public companies. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact (in ways we cannot currently anticipate) the manner in which we operate our business. We have a small management team that, along with other personnel, will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such insurance coverage.

As a publicly traded company, we have incurred and will incur legal, accounting and other expenses associated with the SEC reporting requirements applicable to a company whose securities are registered under the Exchange Act, as well as corporate governance requirements, including those under the Sarbanes-Oxley Act, the Dodd-Frank Act and other rules implemented by the SEC and The Nasdaq Stock Market LLC. In addition, we expect that we will need to hire additional personnel in our finance department to help us comply with the various requirements applicable to public companies. The expenses incurred by public companies generally to meet

SEC reporting, Sarbanes-Oxley Act compliance, finance and accounting and corporate governance requirements have been increasing in recent years as a result of changes in, and the adoption of, new rules and regulations applicable to public companies.

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

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecast of 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, demand for our common stock could decrease, which might cause our stock price and trading volume to decline.

Sales of a substantial number of shares of our common stock in the public market by our existing stockholders or future issuances of our common stock or rights to purchase our common stock, could cause our stock price to fall.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock.

Our management will continue to have broad discretion over the use of the proceeds we received from our prior financings and available cash, and might not apply the proceeds in ways that increase the value of your investment.

Our management will continue to have broad discretion to use the net proceeds from our prior financings and available cash and you will be relying on the judgment of our management regarding the application of these proceeds. Our management might not apply the proceeds in ways that ultimately increase the value of your investment and the failure by our management to apply these proceeds effectively could harm our business. Because of the number and variability of factors that will determine our use of these remaining net proceeds, their ultimate use may vary substantially from their currently intended use. If we do not invest or apply these net proceeds in ways that enhance stockholder value, we may fail to achieve the expected financial results, which could cause our stock price to decline.

We are at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business, financial condition and results of operations.

Our ability to use our net operating loss carryforwards may be subject to certain limitations.

As of December 31, 2023, we had approximately \$98.7 million of federal net operating loss carryforwards, of which \$17.8 million will begin to expire in 2032 and the remaining \$80.9 million of which can be carried forward indefinitely. We have \$79.9 million of state net operating loss carryforwards that will begin to expire in 2034.

Our ability to utilize our federal net operating loss carryforwards may be limited under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code. In the event of an "ownership change," Section 382 imposes an annual limitation on the amount of post-ownership change taxable income that may be offset with pre-ownership change net operating losses of the loss corporation experiencing the ownership change. An "ownership change" is defined by Section 382 as a cumulative change in ownership of our company of more than 50% within a three-year period. Additionally, we have determined that our underwritten public offering of common stock completed in February 2018 resulted in an "ownership change" of us. However, as of December 31, 2023, there is no limitation on the federal and state net operating losses. In addition, current or future changes in our stock ownership may trigger an "ownership change," some of which may be outside our control. Accordingly, our ability to utilize our net operating loss carryforwards to offset federal taxable income, if any, will likely be limited by Section 382, which could potentially result in increased future tax liability to us.

We may never pay dividends on our common stock so any returns would be limited to the appreciation of our stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult or expensive for a third party to acquire us or change our board of directors or current management.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. These provisions include:

- authorizing the issuance of “blank check” preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a classified board of directors;
- providing that no stockholder is permitted to cumulate votes at any election of directors;
- allowing the authorized number of our directors to be changed only by resolution of our board of directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- requiring the approval of the holders of at least 66 2/3% of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our charter documents;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at stockholder meetings.

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, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the General Corporation Law of the State of Delaware, or the DGCL, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved in advance by our board of directors or ratified by our board of directors and certain of our stockholders. This provision could have the effect of delaying or preventing a change in control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

Our amended and restated bylaws designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our amended and restated bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee to us or our stockholders, (3) any action asserting a claim against us or our directors, officers or employees arising pursuant to any provision of our amended and restated bylaws, our amended and restated certificate of incorporation or the DGCL, (4) any action asserting a claim against us or our directors, officers or employees that is governed by the internal affairs doctrine, or (5) any action to interpret, apply, enforce or determine the validity of our amended and restated bylaws or our amended and restated certificate of incorporation. Any person purchasing or otherwise acquiring any interest in any shares of our capital stock shall be deemed to have notice of and to have consented to this provision of our amended and restated bylaws. This choice-of-forum provision may limit our stockholders' ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits. In addition, a stockholder that is unable to bring a claim in the judicial forum of its choosing may be required to incur additional costs in the pursuit of actions that are subject to these exclusive forum provisions, particularly if the stockholder does not reside in or near Delaware. Alternatively, if a court were to find this provision of our amended and restated bylaws inapplicable or unenforceable with respect to one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could materially and adversely affect our business, financial condition and results of operations.

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

Not applicable.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information**Insider Adoption or Termination of Trading Arrangements:**

During the fiscal quarter ended September 30, 2024, none of our directors or officers (as defined in Section 16 of the Securities Exchange Act of 1934, as amended) adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any "non-Rule 10b5-1 trading arrangement," as defined in Item 408(a) of Regulation S-K, except as described in the table below:

Name & Title	Date Adopted	Type of Plan	Aggregate Number of Shares of Common Stock to be Sold Pursuant to Trading Arrangement	Duration
Greg Zante, Chief Financial Officer	July 29, 2024	Rule 10b5-1 trading arrangement	131,687	March 31, 2025 ⁽¹⁾

1. The trading arrangement permits transactions through and including the earlier to occur of (a) the date that all shares subject to the trading arrangement have been sold and (b) the date listed in the table.

Item 6. Exhibits

Exhibit Number	Description	Registrant's Form	Date Filed with the SEC	Exhibit Number
3.1	Amended and Restated Certificate of Incorporation.	S-1	7/1/2014	3.3
3.2	Amended and Restated Bylaws of Viking Therapeutics, Inc., effective as of May 9, 2023.	8-K	5/11/2023	3.1
4.1	Form of Common Stock Certificate.	S-1	7/1/2014	4.1
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.			
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.			
32.1	Certification of the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.			
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.			
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents.			
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)			

Attached as Exhibit 101 to this report are the following formatted in iXBRL (Inline Extensible Business Reporting Language): (i) Consolidated Balance Sheets as of September 30, 2024 and December 31, 2023, (ii) Consolidated Statements of Operations and Comprehensive Loss for the three and nine months ended September 30, 2024 and 2023, (iii) Consolidated Statements of Stockholders' Equity (Deficit) for the three and nine months ended September 30, 2024 and 2023, (iv) Consolidated Statements of Cash Flows for the nine months ended September 30, 2024 and 2023, and (v) Notes to Consolidated Financial Statements.

* Filed herewith.

SIGNATURES

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

Viking Therapeutics, Inc.

Date: October 23, 2024

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

Date: October 23, 2024

By: /s/ Greg Zante
Greg Zante
Chief Financial Officer
(Principal Accounting and Financial Officer)

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

I, Brian Lian, Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Viking 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 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 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: October 23, 2024

By:

/s/ Brian Lian, Ph.D.

Brian Lian, Ph.D.
Chief Executive Officer

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

I, Greg Zante, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Viking 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 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 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: October 23, 2024

By:

/s/ Greg Zante
Greg Zante
Chief Financial Officer

**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**

In connection with the Quarterly Report on Form 10-Q of Viking Therapeutics, Inc. (the "Company") for the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to their knowledge that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Brian Lian, Ph.D.
 Brian Lian, Ph.D.
 Chief Executive Officer
 October 23, 2024

By: /s/ Greg Zante
 Greg Zante
 Chief Financial Officer
 October 23, 2024

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Report, is not deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.
