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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2023

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	**46-1073877**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
9920 Pacific Heights Blvd, Suite 350 San Diego, California	**92121**
(Address of principal executive offices)	**(Zip Code)**

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

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

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

None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

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 definition 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on the Nasdaq Capital Market on June 30, 2023 (the last trading day of the registrant's second fiscal quarter of 2023), was $93,700,028. Shares of voting stock held by directors, officers and stockholders or stockholder groups whose beneficial ownership exceeds 5% of the registrant's common stock outstanding have been excluded in that such persons may be deemed to be affiliates. The number of shares owned by stockholders whose beneficial ownership exceeds 5% was determined based upon information supplied by such persons and upon Schedules 13D and 13G, if any, filed with the Securities and Exchange Commission. This assumption regarding affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of the Registrant's Common Stock outstanding as of January 31, 2024 was 100,488,339.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement for its 2024 Annual Meeting of Stockholders or an amendment to this Annual Report on Form 10-K to be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2023 are incorporated by reference into Part III of this Annual Report on Form 10-K.

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This Annual Report on Form 10-K 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 Annual Report on Form 10-K and in our other Securities and Exchange Commission filings. Furthermore, such forward-looking statements speak only as of the date of this report. We undertake no obligation to update any forward-looking statements to reflect events or circumstances occurring after the date of such statement.

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

PART I

Item 1. Business.

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.

Our lead clinical program's drug candidate, VK2809, is an orally available, tissue and receptor-subtype selective agonist of the thyroid hormone receptor beta, or TRß. In November 2019, we initiated the VOYAGE study, a Phase 2b clinical trial of VK2809 in patients with biopsy-confirmed non-alcoholic steatohepatitis, or 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 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. Results from the biopsy after 52 weeks of dosing are expected to be available in 2024.

VK2809 has been evaluated in eight completed clinical studies, which enrolled more than 300 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.

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 insulinotropic 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 >= 30 kg/m2) or adults who are overweight (BMI >= 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 we expect to report data from the study in the first half of 2024.

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.

We are also developing VK0214, which is also an orally available, tissue and receptor-subtype selective agonist of TRß 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 TRß 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 is a multi-center, randomized, double-blind, placebo-controlled study in adult male patients with the adrenomyeloneuropathy, or AMN, form of X-ALD. The study is initially targeting enrollment across three cohorts: placebo, VK0214 20 mg daily, and VK0214 40 mg daily. Pending a blinded review of preliminary safety, tolerability, and pharmacokinetic data, additional dosing cohorts may be pursued.

The primary objective of the study is to evaluate the safety and tolerability of VK0214 administered once-daily over a 28-day dosing period. Secondary and exploratory objectives include an evaluation of the pharmacokinetics and pharmacodynamics of VK0214 following 28 days of dosing in this population.

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.

Our Development Pipeline

The following table highlights our current development pipeline:

Development Programs	Indication	Stage of Development				Status
		Preclin	Phase 1	Phase 2	Phase 3	
VK2809 (TRβ agonist)	*NASH*					Phase 2b VOYAGE trial ongoing
VK2735 (Dual GLP-1/GIP agonist)	*Obesity*					Phase 2 VENTURE study ongoing
VK2735 Oral (Dual GLP-1/GIP agonist)	*Obesity*					Phase 1 ongoing
VK0214 (TRβ agonist)	*X-ALD*					Phase 1b ongoing

Key: TRß, thyroid receptor beta; NASH, nonalcoholic steatohepatitis; GLP-1, glucagon-like peptide 1, GIP, glucose-dependent insulinotropic polypeptide; X-ALD, X-linked adrenoleukodystrophy.

We also have three additional programs targeting metabolic diseases and anemia. The most advanced is VK0612, a first-in-class, orally available Phase 2b-ready drug candidate for type 2 diabetes. Preliminary clinical data suggest VK0612 has the potential to provide substantial glucose-lowering effects, with an attractive safety and convenience profile compared with existing type 2 diabetes therapies. Our preclinical programs are focused on developing inhibitors of diacylglycerol acyltransferase-1, or DGAT-1, for the potential treatment of obesity and dyslipidemia and on identifying orally available erythropoietin, or EPO, receptor, or EPOR, agonists for the potential treatment of anemia.

Novel Selective TRß Agonists for Metabolic Disorders and Adrenoleukodystrophy

Summary Overview

VK2809 and VK0214 are novel, orally available, selective TRß agonists in development for metabolic disorders and X-ALD. Thyroid hormone receptors are found in various tissues throughout the body. TRß is the major receptor isoform expressed in the liver and thyroid hormone receptor alpha, or TRα, is the major isoform expressed in the heart. The unique properties of our TRß agonists are designed to reduce or eliminate the deleterious effects of extra-hepatic thyroid receptor activation. In particular, high tissue and TRß selectivity may lead to reduced activity at the TRα receptor, which can be associated with increased respiration and cardiac tissue hypertrophy. Selective activation of the TRß receptor in liver tissue is believed to favorably affect cholesterol and lipoprotein levels via multiple mechanisms, including increasing the expression of low-density lipoprotein receptors and increasing mitochondrial fatty acid oxidation. These characteristics in turn lead to reductions of LDL-C, plasma and liver triglycerides. In addition, our chemical structures are not substrates for certain transporters involved in the uptake of thyroid hormone. Various animal models have shown that our molecules, as a result of their unique profiles, may have reduced cardiovascular effects versus thyroid hormone and other thyromimetics. As a result of these characteristics, we believe our selective TRß agonists are capable of eliciting a unique lipid lowering profile without eliciting unwanted effects on the heart and thyroid hormone axis.

VK2809 in NASH

In November 2019, we initiated the VOYAGE study, a Phase 2b clinical trial of VK2809 in patients with biopsy-confirmed 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 NASH and fibrosis ranging from stages F1 to F3. The study is targeting enrollment of approximately 340 patients across five treatment arms. The primary endpoint of the study will evaluate the relative change in liver fat content, as assessed by 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. Results from the biopsy after 52 weeks of dosing are expected to be available in 2024.

VK2809 in NAFLD

In September 2018, we announced top-line results from our 12-week, Phase 2 clinical trial of our lead clinical program's drug candidate, VK2809, in patients with NAFLD and elevated LDL-C. The study successfully achieved its primary endpoint, with patients receiving VK2809 demonstrating statistically significant reductions in LDL-C compared with placebo. In addition, the trial's secondary endpoint was achieved, with VK2809-treated patients experiencing statistically significant reductions in liver fat content compared with placebo. VK2809 demonstrated encouraging safety and tolerability in this study, with no SAEs reported.

Top-line study results from the Phase 2 clinical trial include:

Reduction in LDL-C

Patients receiving VK2809 demonstrated statistically significant reductions in LDL-C of 20% or more, compared with placebo-treated patients. In addition, VK2809-treated patients demonstrated statistically significant improvements in other lipids, including atherogenic proteins apolipoprotein B and lipoprotein (a).

Reduction in Liver Fat Content

Patients receiving VK2809 experienced statistically significant reductions in liver fat content, as assessed by MRI-PDFF, relative to placebo after 12 weeks of treatment.

	Placebo	**VK2809 5 mg QD**	**VK2809 10 mg QOD**	**VK2809 10 mg QD**	**VK2809 combined**
Median relative change in liver fat by MRI-PDFF	-9.4%	-53.8% ($p<0.001$)	-56.5% ($p<0.01$)	-59.7% ($p<0.001$)	-58.1% ($p<0.001$)
Percentage of patients experiencing ≥ 30% reduction in liver fat	16.7%	100% ($p<0.001$)	76.9% ($p<0.01$)	90.9% ($p<0.001$)	83.3% ($p<0.001$)

Safety and Tolerability

No SAEs were reported among patients receiving VK2809 or placebo. Mean alanine aminotransferase, or ALT, levels among patients receiving VK2809 were reduced relative to those of patients receiving placebo. Among patients with elevated baseline ALT levels, those receiving VK2809 also demonstrated reduction relative to placebo. There were no clinically or numerically meaningful differences in direct bilirubin, indirect bilirubin, alkaline phosphatase or international normalized ratio between patients treated with VK2809 or placebo. In addition, no meaningful changes to the thyroid hormone axis were observed among VK2809-treated patients compared with placebo-treated patients.

VK2809 Summary Characteristics

VK2809 has been evaluated in one Phase 2 clinical trial and seven Phase 1 clinical trials. Based on these clinical and additional preclinical data, we believe VK2809 has the following important characteristics that may benefit patients with metabolic or lipid disorders:

- *Broader efficacy:* Current Phase 2 and Phase 1 data suggest VK2809 could reduce liver fat, plasma LDL-C, triglyceride and atherogenic protein levels by greater amounts than existing oral therapies. Such broad and potent lipid lowering-activity may be particularly desirable for NASH patients with hypercholesterolemia or dyslipidemia, or among patients with risk factors such as chronic kidney disease.
- *Encouraging safety profile:* VK2809 has demonstrated encouraging safety to date in over 300 subjects from completed studies. No drug related serious adverse events were observed. In addition, no cardiovascular abnormalities were reported, in-line with the expected high tissue and receptor selectivity for VK2809.
- *Encouraging tolerability:* VK2809 has been well-tolerated at and above doses that we are currently administrating and plan to administer in future clinical trials.

- *Novel mechanism of action:* Based on its selective thyroid receptor targeting mechanism of action, we believe VK2809 has the potential to lower plasma and liver lipid levels in a manner complementary to existing agents such as statins. In particular, based upon the Phase 2 trial results, we believe the unique liver-targeting properties of VK2809 impart a robust lipid lowering effect within hepatic tissue, with potential therapeutic applications in fatty liver diseases such as NASH.
- *Combinability:* VK2809's novel mechanism of action is expected to allow combinability with many existing therapies, leading to enhanced efficacy and potentially delaying transition to subsequent therapies.
- *Once-daily oral dosing:* Clinical data suggest that VK2809 has the potential to lower plasma lipid levels in NASH or hypercholesterolemia patients as a once-daily oral therapy.

Phase 1 Clinical Data for VK2809

VK2809 has also been evaluated in seven Phase 1 clinical trials. The initial Phase 1 safety, tolerability and pharmacokinetic study of VK2809 was conducted in 2006. This was followed by a 14-day Phase 1b clinical trial in 56 patients with mild hypercholesterolemia, defined as baseline plasma LDL-C of at least 100 mg/dL. This study was initiated in 2007 and completed in 2008. VK2809 was shown to be safe and well-tolerated across doses ranging from 0.25 mg to 40 mg per day. There were no serious adverse events, and the frequency of adverse events in VK2809-treated patients was similar to placebo-treated patients. The clinical trial results also showed dose-related reductions in fasting LDL-C and fasting triglyceride, or TG, levels at day 14. Significant placebo-adjusted LDL-C reductions from baseline were observed at doses of 5 mg and above and ranged from approximately 15%-41%, while placebo-adjusted TG levels were reduced by more than 30% at doses of 2.5 mg and above. In addition, statistically significant reductions of lipoprotein a, or Lp(a), and apolipoprotein, or Apo(B), which are believed to be positively associated with a patient's risk of developing cardiovascular disease, were observed in certain cohorts. In addition, VK2809 was evaluated in five additional Phase 1 trials, evaluating the pharmacokinetics, pharmacodynamics, potential drug-drug interaction of VK2809 when co-administered with a statin, alternative dosing regimens and hepatic impairment, respectively.

VK2735

Activation of the glucagon-like peptide 1 (GLP-1) receptor has been shown to decrease glucose, reduce appetite, lower body weight and improve insulin sensitivity in patients with type 2 diabetes, obesity, or both. More recently, research efforts have explored the potential co-activation of the glucose-dependent insulinotropic peptide (GIP) receptor as a means of enhancing the therapeutic benefits of GLP-1 receptor activation. VK2735 is a dual agonist of the GLP-1 and GIP receptors that the Company is developing for the potential treatment for various metabolic disorders.

In January 2022, we announced the initiation of a Phase 1 SAD and MAD clinical trial of VK2735, a novel dual agonist of the GLP-1 and GIP receptors. VK2735 is in development for the potential treatment of various metabolic disorders, including obesity.

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 >= 30 kg/m2), or adults who are overweight (BMI >= 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 we expect to report data from the study in the first half of 2024.

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.

VK0214 in X-ALD

We are developing VK0214 for X-ALD, a rare X-linked, inherited neurological disorder characterized by a breakdown in the protective barriers surrounding brain and nerve cells. X-ALD is caused by mutations in a peroxisomal transporter of VLCFA known as ABCD1. As a result, transporter function is impaired and patients are unable to efficiently metabolize VLCFA. TRß 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 September 2020, we initiated a randomized, double-blind, placebo controlled Phase 1 SAD and MAD clinical trial of VK0214 in healthy patients. The primary objective of the study was to evaluate the safety and tolerability of VK0214 administered orally for up to 14 days. The secondary objective was to evaluate the pharmacokinetics of VK0214 following single and multiple oral doses. The first portion of the study evaluated single doses of VK0214; in the second portion of the study, subjects received VK0214 once daily for 14 days. Subsequent cohorts in both portions of the study received successively higher VK0214 doses.

In June 2021, we announced the results of the study. VK0214 was shown to be safe and well-tolerated at all doses evaluated in this study. No serious adverse events were reported, and no treatment or dose-related trends were observed for vital signs, gastrointestinal effects, cardiovascular measures or physical examinations. VK0214 demonstrated dose-dependent exposures, no evidence of accumulation following multiple doses, and a half-life consistent with anticipated once-daily dosing regimens. While the study's primary objective was to evaluate safety and tolerability, laboratory assessments included a lipid panel to determine potential pharmacodynamic effects following exposure to VK0214. The results showed that subjects who received VK0214 experienced reductions in low-density lipoprotein cholesterol, or LDL-C, triglycerides and apolipoprotein B following 14 days of treatment at all VK0214 doses. Many of the observed lipid reductions achieved statistical significance, though the study was not powered to demonstrate statistical significance on laboratory assessments.

% Change in Lipid Markers Following 14 Days of Treatment of VK0214

	Placebo[1] (n=11)	**5 mg (n=6)**	**10 mg (n=6)**	**25 mg (n=6)**	**50 mg (n=6)**	**75 mg (n=6)**	**100 mg (n=6)**
LDL-C	3.8%	-0.7%	-12.5%*	-21.4%**	-19.5%**	-19.1%***	-18.9%**
Triglycerides	4.9%	-6.7%	-19.5%*	-1.7%	-36.8%**	-45.0%***	-39.1%**
ApoB	4.4%	-5.7%	-12.5%**	-23.3%***	-24.0%***	-28.3%***	-28.2%***

(1) Excludes one placebo subject due to an anomalous triglyceride value (>7x higher than SD). **p < 0.05; **p < 0.01; ***p < 0.001*.

In June 2021, we initiated a Phase 1b clinical trial of VK0214 in patients with X-ALD. The Phase 1b trial is a multi-center, randomized, double-blind, placebo-controlled study in adult male patients with the AMN form of X-ALD. The study is initially targeting enrollment across three cohorts: placebo, VK0214 20 mg daily, and VK0214 40 mg daily. Pending a blinded review of preliminary safety, tolerability, and pharmacokinetic data, additional dosing cohorts may be pursued.

The primary objective of the study is to evaluate the safety and tolerability of VK0214 administered once-daily over a 28-day dosing period. Secondary and exploratory objectives include an evaluation of the pharmacokinetics and pharmacodynamics of VK0214 following 28 days of dosing in this population.

X-ALD is a rare, often fatal condition believed to occur with an incidence of approximately one in 17,000 births. X-ALD is caused by mutations in the gene encoding for ABCD1, which is located on the X chromosome. Men have one X chromosome, while women have two. Because of this, an inherited mutation in the ABCD1 gene is more likely to manifest in males relative to females. The ABCD1 protein plays a critical role in the transport of VLCFA into a cellular organelle called the peroxisome, where VLCFA metabolism and disposal occur. Without functional ABCD1, VLCFA accumulate in cells, including neural cells, where they can lead to membrane disruption and damage to the myelin sheath, a protective and insulating membrane that surrounds nerve cells in the brain. This damage can result in decreased motor coordination and function, visual and hearing disturbances, the loss of cognitive function, dementia, seizures, adrenal dysfunction and other complications, including death. X-ALD is divided into various sub-segments, which are broadly characterized by the presence or absence of brain inflammation:

- **Cerebral adrenoleukodystrophy, or CALD:** The most severe form of X-ALD is CALD. CALD is characterized by a progressive inflammatory destruction of myelin, leading to severe loss of neurological function and eventual death. Approximately 35% to 40% of male X-ALD patients present with cerebral involvement at a younger age, between

the ages of 5 and 12 years. However, up to 20% of male X-ALD patients develop cerebral involvement later in life, between the ages of 20 and 35 years. In male children affected by CALD, learning and behavioral problems are often the first clinical manifestations of disease. In the absence of intervention, patients affected by CALD typically experience rapid degeneration into vegetative state within 3 to 5 years, often resulting in death within 10 years of diagnosis.

- **Adrenomyeloneuropathy, or AMN:** AMN is the more common form of X-ALD and is considered the default form of the disease in patients surviving beyond childhood. AMN is expected to affect all adult males with ABCD1 mutations, and approximately 65% of females. In males, the diagnosis is usually made between the ages of 20 and 50 and in females after the age of 65. AMN accounts for approximately half of all patients diagnosed with X-ALD. Patients with AMN generally present with slowly progressive symptoms resulting from (non-inflammatory) disruption of the axons, which are a fundamental component of the central nervous system (which allows nerve signals to be transmitted), in the spinal cord. Patients experience a variety of symptoms, including weakness in the legs, impaired vibration sense, incontinence and impotence. Severe motor disability, requiring the use of a wheelchair or cane, develops over a three to 15-year period. Many patients experience lower limb paralysis. While AMN is generally considered to develop more gradually relative to CALD, approximately 35% of AMN patients experience a rapid progression of myelopathy over a three to five-year period. In addition, approximately 40% of AMN patients have or will develop CALD, with varying degrees of associated inflammation.

There is a clear unmet medical need for patients suffering from X-ALD. CALD has been more commonly targeted for treatment due to its devastating effects, which are often manifested at a young age. For these patients, an effective treatment option is allogeneic hematopoietic stem cell, or HSC, transplant. In this procedure, the patient is treated with HSCs containing the properly functioning copy of the ABCD1 gene, contributed by a donor other than the patient. Additionally, a method of ex vivo insertion of a functional copy of the ABCD1 gene via a lentiviral vector into the patient's own HSCs to correct the aberrant expression of ABCD1 in patients with CALD has recently been approved. Over time with either method, as the transplanted cells grow and repopulate, a partial restoration of ABCD1 function can be achieved, leading many patients to resolution of progression in the cerebral form of the disease. However, recent data suggest that, even among successfully transplanted patients, AMN can develop. We believe our thyroid receptor agonists, which have the potential to normalize metabolism of VLCFAs peripherally, and potentially centrally, may positively impact all forms of X-ALD, including the currently untreatable AMN form.

VK5211: A SARM for Hip Fracture

VK5211 is an orally available, non-steroidal SARM in development for the treatment of patients recovering from non-elective hip fracture surgery. VK5211 is designed to selectively produce the therapeutic benefits of testosterone in muscle and bone tissue with improved safety and tolerability. Tissue selectivity is critical in treating patients recovering from hip fracture. These patients experience elevated rates of metabolic breakdown of muscle tissue and loss of bone mineral density. This results in a loss of muscle strength, an increased risk of additional fractures and increased mortality.

Clinical Data for VK5211

In November 2017, we announced positive top-line results from our 12-week, Phase 2 clinical trial of VK5211 in patients who recently suffered a hip fracture. 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.

The Phase 2 clinical trial was a randomized, double-blind, placebo-controlled, parallel group, international study designed to evaluate the efficacy, safety and tolerability of VK5211 in patients recovering from hip fracture surgery. A total of 108 patients were randomized to receive once-daily VK5211 doses of 0.5 mg, 1.0 mg, 2.0 mg, or placebo for 12 weeks. Top-line results include:

- All doses of VK5211 demonstrated statistically significant increases in total lean body mass, less head, the study's primary endpoint. Placebo-adjusted increases in lean body mass were 4.8% at 0.5 mg ($p < 0.005$), 7.2% at 1.0 mg ($p < 0.001$), and 9.1% at 2.0 mg ($p < 0.001$). These corresponded to placebo-adjusted increases of 1.6 kg at 0.5 mg ($p < 0.005$), 2.5 kg at 1.0 mg ($p < 0.001$), and 3.1 kg at 2.0 mg ($p < 0.001$).
- The proportion of patients experiencing at least a 5% increase in total lean body mass, less head, were 19% with placebo, 61% at 0.5 mg, 65% at 1.0 mg, and 75% at 2.0 mg ($p < 0.01$ for each). The proportion of patients demonstrating at least a 2.0 kg gain in total lean body mass, less head, were 14% with placebo, 57% at 0.5 mg, 65% at 1.0 mg, and 81% at 2.0 mg ($p < 0.01$ for each).

- All doses of VK5211 produced statistically significant increases in appendicular lean body mass, a secondary efficacy endpoint. Placebo-adjusted increases in appendicular lean body mass were 6.1% at 0.5 mg ($p < 0.01$), 9.0% at 1.0 mg ($p < 0.001$), and 10.2% at 2.0 mg ($p < 0.001$). These corresponded to placebo-adjusted increases of 0.8 kg at 0.5 mg ($p < 0.05$), 1.3 kg at 1.0 mg ($p < 0.001$), and 1.4 kg at 2.0 mg ($p < 0.001$).
- All doses of VK5211 produced statistically significant increases in total lean body mass, including head, a secondary efficacy endpoint. Increases in total lean body mass were 6.3% ($p < 0.005$), 8.2% ($p < 0.001$), and 9.9% ($p < 0.001$) from baseline, corresponding to placebo-adjusted increases of 4.7% at 0.5 mg ($p < 0.005$), 6.8% at 1.0 mg ($p < 0.001$), and 8.3% at 2.0 mg ($p < 0.001$). These corresponded to placebo-adjusted increases of 1.7 kg at 0.5 mg ($p < 0.005$), 2.6 kg at 1.0 mg ($p < 0.001$), and 3.1 kg at 2.0 mg ($p < 0.001$).
- Patients receiving VK5211 demonstrated numerical improvements in certain exploratory assessments of functional performance, including the 6-minute walk test and short physical performance battery, compared with placebo. These endpoints were not powered for significance. Further evaluation of exploratory functional endpoints is underway.
- There were no significant differences in the rates of adverse events reported among patients receiving VK5211 compared with placebo. There were no dose-related differences in reported adverse events among various VK5211 treatment groups. No drug-related SAEs were observed in patients receiving VK5211.

Our intent is to continue to pursue partnering or licensing opportunities for VK5211 prior to conducting additional clinical studies.

Three Pipeline Programs Target Metabolic Disease with Large Unmet Medical Need

We have a pipeline with three additional programs targeting metabolic diseases and anemia. Our pipeline programs include VK0612, a first-in-class, orally available Phase 2b-ready drug candidate for type 2 diabetes. Preliminary clinical data suggest VK0612 has the potential to provide substantial glucose-lowering effects, with an attractive safety and convenience profile compared with existing type 2 diabetes therapies. Our preclinical programs are focused on developing inhibitors of DGAT-1 for the potential treatment of obesity and dyslipidemia and on identifying orally available EPOR agonists for the potential treatment of anemia.

Fructose-1,6-bisphosphatase, or FBPase, Inhibitor Program

VK0612 is a first-in-class, orally available drug candidate for type 2 diabetes, one of the largest global healthcare challenges today. Preliminary clinical data suggest VK0612 has the potential to provide substantial glucose-lowering effects, with an attractive safety and convenience profile compared with existing type 2 diabetes therapies. VK0612 is a potent, selective inhibitor of FBPase an enzyme that plays an important role in endogenous glucose production, or the synthesis of glucose by the body. We believe the inhibition of FBPase provides an attractive approach to controlling blood glucose levels in patients with diabetes. VK0612 has demonstrated potent glucose lowering effects in diabetic animal models. Clinical trials have shown that VK0612 is safe, well-tolerated and leads to significant glucose-lowering effects in patients with type 2 diabetes.

DGAT-1 Inhibitor Program

We are developing small molecule inhibitors of the enzyme DGAT-1 for the potential treatment of metabolic disorders such as obesity and dyslipidemia. According to the CDC, approximately 42% of the adult U.S. population is obese, with the prevalence expected to exceed 50% by 2030. The World Health Organization estimates at least 650 million adults are currently obese worldwide. DGAT-1 is a potential therapeutic target for reduction of triglyceride levels in the circulation and fat accumulation in adipose tissues. DGAT-1 null mice exhibit both reduced post-meal plasma triglyceride levels and increased energy expenditure, but have normal levels of circulating free fatty acids. Conversely, transgenic mice that overexpress DGAT-1 in adipose tissue are predisposed to obesity when fed a high-fat diet and have elevated levels of circulating free fatty acids. We have developed a series of novel compounds with tissue- targeting properties intended to mitigate potential side effects by selectively targeting the enterocyte, or intestinal absorptive cells, in the intestine, to inhibit dietary triglyceride uptake, or the liver, to inhibit *de novo* triglyceride synthesis. We plan to conduct further preclinical studies and file an investigation new drug application, or IND, with the FDA at a future date.

Competition

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.

VK2809

While no therapies are currently approved for the treatment of non-alcoholic steatohepatitis, we are aware of numerous development-stage programs targeting this disease, including resmetirom from Madrigal Pharmaceuticals, Inc., arachidyl amido cholanoic acid from Galmed Pharmaceuticals Ltd., belapectin from Galectin Therapeutics Inc., lanifibranor from Inventiva S.A., semaglutide from Novo Nordisk A/S, 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., efruxifermin (AKR-001) from Akero Therapeutics, 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 Altimmune, Inc. In addition, we are aware of active programs at Aligos Therapeutics, Inc., Arrowhead Pharmaceuticals, Inc., Ascletis Biopharmaceutical, AstraZeneca PLC, Boston Pharmaceuticals Inc., Can-Fite BioPharma Ltd., 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., Gelesis Holdings Inc., Hepagene Therapeutics, Inc., Kowa Company, Ltd., MediciNova Inc., NGM Biopharmaceuticals, Inc., NorthSea Therapeutics BV, Pliant Therapeutics, Inc., Poxel SA, Seal Rock Therapeutics, Inc., Theratechnologies Inc., Yuhan Corporation, and Cadila Healthcare Limited (a.k.a. Zydus Cadila).

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 Altimmune, Inc., Amgen Inc., AstraZeneca, D&D Pharmatech, Inc., ERX Pharmaceuticals Inc., F. Hoffmann-La Roche Ltd, Hanmi Pharmaceutical Co., Ltd., Kallyope Inc., Pfizer Inc., Rivus Pharmaceuticals Inc., Structure Therapeutics Inc., Terns Pharmaceuticals, Inc., and Zealand Pharma A/S.

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 SwanBio 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, Helsinn Group, and Pluri Inc. (formerly Pluristem Therapeutics Inc.). In addition, nutritional and growth hormone-based therapies are sometimes used in patients experiencing muscle wasting.

Manufacturing and Supply

We do not have any manufacturing facilities and do not intend to develop any manufacturing capabilities. We believe that we have sufficient supplies of drug substance to allow for completion of our planned clinical studies. Bulk active pharmaceutical ingredient, or API, and certain dosage forms are currently in storage in compliance with good manufacturing practices, or cGMP, requirements. We believe that a majority of the existing API will be suitable for formulation into clinical trial material. We also have identified multiple contract manufacturers to provide commercial supplies of the formulated drug candidates if they are approved for marketing. We intend to secure contract manufacturers with established track records of quality product supply and significant experience with the regulatory requirements of the FDA and the European Medicines Agency, or EMA.

Our History

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 VK2809, VK2735, VK0214 and VK5211 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.

Agreements with Ligand

Master License Agreement

On May 21, 2014, we entered into a Master License Agreement, as amended on each of September 6, 2014, April 8, 2015 and March 21, 2016, or the Master License Agreement, with Ligand pursuant to which, among other things, Ligand granted to us and our affiliates an exclusive, perpetual, irrevocable, worldwide, royalty-bearing right and license under (1) patents related to (a) our VK2809 and VK0214 programs and any other compounds comprised by specified TRß patents and any derivatives of such compounds, or TRß Compounds, (b) our VK5211 program and any other compounds comprised by specified SARM patents and derivatives of such compounds, or SARM Compounds, (c) our VK0612 program and any other compounds comprised by specified FBPase patents and derivatives of such compounds, or FBPase Compounds, (d) our DGAT-1 program and any other compounds comprised by specified DGAT-1 patents and derivatives of such compounds, or DGAT-1 Compounds, and (e) our EPOR program and any other compounds comprised by specified EPOR patents and derivatives of such compounds, or EPOR Compounds, and; (2) related know-how controlled by Ligand; and (3) physical quantities of TRß Compounds, SARM Compounds, FBPase Compounds, DGAT-1 Compounds and EPOR Compounds or, collectively, the Licensed Technology, to research, develop, manufacture, have manufactured, use and commercialize the Licensed Technology in and for all therapeutic and diagnostic uses in humans or animals. We have the right to sublicense these rights in certain circumstances. Pursuant to the terms of the Master License Agreement, we have the exclusive right and sole responsibility and decision-making authority for researching and developing any pharmaceutical products that contain or comprise one or any combination of a TRß Compound, SARM Compound, FBPase Compound, DGAT-1 Compound or EPOR Compound, or, collectively, the Licensed Products. We also have the exclusive right and sole responsibility and decision-making authority to conduct all clinical trials and preclinical studies that we believe are appropriate to obtain the regulatory approvals necessary for commercialization of the Licensed Products, and we will own and maintain all regulatory filings and all regulatory approvals for the Licensed Products. Additionally, pursuant to the terms of the Master License Agreement, we have the sole decision-making authority and responsibility and the exclusive right to commercialize any of the Licensed Products, either by ourselves or, in certain circumstances, through sublicensees selected by us. We also have the exclusive right to manufacture or have manufactured any Licensed Product ourselves or, in certain circumstances, through sublicensees or third parties selected by us. We will own any intellectual property that we develop in connection with the license granted under the Master License Agreement.

As partial consideration for the grant of the rights and licenses to us under the Master License Agreement, we issued to Ligand at the closing of our initial public offering of our common stock, or the IPO, 3,655,964 shares of our common stock having an estimated aggregate value of $29.2 million.

As further partial consideration for the grant of the rights and licenses to us by Ligand under the Master License Agreement, we have agreed to pay to Ligand certain one-time, non-refundable milestone payments in connection with Licensed Products containing (1) VK2809, VK0214 or any other TRß Compound, in an aggregate amount of up to $75.0 million per indication (for up to a total of three indications) upon the achievement of certain development and regulatory milestones and up to $150.0 million upon the achievement of

certain sales milestones; (2) VK5211 or any other SARM Compound, in an aggregate amount of up to $85.0 million per indication (for up to a total of two indications) upon the achievement of certain development and regulatory milestones and up to $100.0 million upon the achievement of certain sales milestones; (3) VK0612 or any other FBPase Compound, in an aggregate amount of up to $60.0 million per indication (for up to a total of four indications) upon the achievement of certain development and regulatory milestones and up to $150.0 million upon the achievement of certain sales milestones; (4) any EPOR Compound, in an aggregate amount of up to $48.0 million per indication (for up to a total of three indications) upon the achievement of certain development and regulatory milestones and up to $50.0 million upon the achievement of certain sales milestones; and (5) any DGAT-1 Compound, in an aggregate amount of up to $78.0 million per indication (for up to a total of two indications) upon the achievement of certain development and regulatory milestones and up to $150.0 million upon the achievement of certain sales milestones. Additionally, we will pay to Ligand a one-time, non-refundable milestone payment of $2.5 million upon the occurrence of the first commercial sale of VK0612 or any other FBPase Compound by one of our sublicensees. We will also pay to Ligand royalties on aggregate annual worldwide net sales of Licensed Products by us, our affiliates and our sublicensees at tiered percentage rates in the following ranges based upon net sales: (a) low-to-middle single digit royalties upon sales of VK2809, VK0214 or any other TRß Compound, (b) upper single digit royalties upon sales of VK5211 or any other SARM Compound, (c) upper single digit royalties upon sales of VK0612 or any other FBPase Compound, (d) low-to-middle single digit royalties upon sales of any DGAT-1 Compound, and (e) middle-to-upper single digit royalties upon sales of any EPOR Compound; in each case subject to reduction in certain circumstances.

The term of the Master License Agreement will continue unless the agreement is terminated by us or Ligand. 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 and substantial obligations and fail to cure the default within a specified period of time. We have the right to terminate the Master License Agreement under certain circumstances, including, but not limited to: (i) if Ligand does not pay an undisputed amount owing under the Master License Agreement when due and fails to cure such default within a specified period of time, or (ii) if Ligand defaults on certain of its material and substantial obligations and fails to cure the default within a specified period of time. In addition, provisions of the Master License Agreement can be terminated on a licensed program-by-program basis under certain circumstances. In the event that the Master License Agreement is terminated in its entirety or with respect to a specific licensed program for any reason: (A) all licenses granted to us under the Master License Agreement (or with respect to the specific licensed program) will terminate and we will, upon Ligand's request (subject to Ligand assuming legal responsibility for any clinical trials of the Licensed Products then ongoing), assign and transfer to Ligand (or to such transferee as Ligand may direct), at no cost to Ligand, all regulatory documentation and all regulatory approvals prepared or obtained by us or on our behalf related to the Licensed Products (or those related to the specific licensed program), or, if Ligand does not make such a request, we will wind down any ongoing clinical trials with respect to the Licensed Products (or those related to the specific licensed program) at no cost to Ligand; (B) we will, upon Ligand's request, sell and transfer to Ligand (or to such transferee as Ligand may direct), at a price equal to 125% of our costs of goods, any and all chemical, biological or physical materials relating to or comprising the Licensed Products (or those related to the specific licensed program); (C) we will have, for a period of six months following termination, the right to sell on the normal business terms in existence before such termination any finished commercial inventory of Licensed Products (or those related to the specific licensed program) which remains on hand, so long as we pay to Ligand the applicable royalties and sales milestones; (D) Ligand has the right to require us to assign to Ligand the trademarks owned by us relating to the Licensed Products (or those related to the specific licensed program); and (E) we will grant to Ligand a non-exclusive, worldwide, royalty-bearing sublicensable 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 Products (or those related to the specific licensed program) anywhere in the world at a royalty rate in the low single digits.

Under the Master License Agreement, we have agreed to indemnify Ligand for claims relating to the performance of our obligations under the Master License Agreement, any breach of the representations and warranties made by us under the Master License Agreement, clinical trials conducted by us and the research, development and commercialization of the Licensed Products by us and our affiliates, sublicensees, distributors and agents. In addition, Ligand has agreed to indemnify us for claims relating to the performance of its obligations under the Master License Agreement, its breach of representations and warranties under the agreement and its research and development of the licensed compounds before the effective date of the Master License Agreement. Each party's indemnification obligations will not apply to the extent the claims result from the negligence or willful misconduct of the indemnified party or any of its employees, agents, officers or directors or from the indemnified party's breach of its representations or warranties set forth in the Master License Agreement.

Government Regulation

FDA Regulation and Marketing Approval

In the U.S., the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act of 1938, as amended, or FDCA, and related regulations. Drugs are also subject to other federal, state and local statutes and regulations. Failure to comply with the applicable U.S.

regulatory requirements at any time during the drug development process, approval process or after approval may subject an applicant to administrative or judicial sanctions and non-approval of drug candidates. These sanctions could include the imposition by the FDA or an Institutional Review Board, or IRB, of a clinical hold on clinical trials, the FDA's refusal to approve pending applications or related supplements, withdrawal of an approval, untitled or warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, restitution, disgorgement, civil penalties or criminal prosecution. Such actions by government agencies could also require us to expend a large amount of resources to respond to the actions. Any agency or judicial enforcement action could have a material adverse effect on us.

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products.

These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, packaging, storage, distribution, record-keeping, approval, post-approval monitoring, advertising, promotion, sampling and import and export of our products. Our drugs must be approved by the FDA through the new drug application, or NDA, process before they may be legally marketed in the U.S. See "The NDA Approval Process" under Part I, "Item 1. Business" of this Annual Report on Form 10-K.

The process required by the FDA before drugs may be marketed in the U.S. generally involves the following:

- completion of non-clinical laboratory tests, animal studies and formulation studies conducted according to good laboratory practice or other applicable regulations;

- submission of an IND, which allows clinical trials to begin unless the FDA objects within 30 days;

- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use or uses conducted in accordance with FDA regulations, good clinical practices, or GCP, which are international ethical and scientific quality standards meant to assure that the rights, safety and well-being of trial participants are protected, and to define the roles of clinical trial sponsors, administrators and monitors and to assure clinical trial data integrity;

- pre-approval inspection of manufacturing facilities and clinical trial sites; and

- FDA approval of an NDA, which must occur before a drug can be marketed or sold.

IND and Clinical Trials

Prior to commencing the first clinical trial, an IND, which contains the results of preclinical studies along with other information, such as information about product chemistry, manufacturing and controls and a proposed protocol, must be submitted to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA unless the FDA within the 30-day time period raises concerns or questions about the conduct of the clinical trial. In such a case, the IND sponsor must resolve any outstanding concerns with the FDA before the clinical trial may begin. A separate submission to the existing IND must be made for each successive clinical trial to be conducted during drug development. Further, an independent IRB for each site proposing to conduct the clinical trial must review and approve the investigational plan for any clinical trial before it commences at that site. Informed written consent must also be obtained from each trial subject. Regulatory authorities, including the FDA, an IRB, a data safety monitoring board or the sponsor, may suspend or terminate a clinical trial at any time on various grounds, including a finding that the participants are being exposed to an unacceptable health risk or that the clinical trial is not being conducted in accordance with FDA requirements.

For purposes of NDA approval, human clinical trials are typically conducted in sequential phases that may overlap:

- *Phase 1* – the drug is initially given to healthy human subjects or patients in order to determine metabolism and pharmacologic actions of the drug in humans, side effects and, if possible, to gain early evidence on effectiveness. During Phase 1 clinical trials, sufficient information about the investigational drug's pharmacokinetics and pharmacologic effects may be obtained to permit the design of well-controlled and scientifically valid Phase 2 clinical trials.

- *Phase 2* – clinical trials are conducted to evaluate the effectiveness of the drug for a particular indication or in a limited number of patients in the target population to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase

3 clinical trials. Throughout this Annual Report on Form 10-K, we refer to our initial Phase 2 clinical trials as "Phase 2a clinical trials" and our subsequent Phase 2 clinical trials as "Phase 2b clinical trials."

- *Phase 3* – when Phase 2 clinical trials demonstrate that a dosage range of the product appears effective and has an acceptable safety profile, and provide sufficient information for the design of Phase 3 clinical trials, Phase 3 clinical trials in an expanded patient population at multiple clinical sites may be undertaken. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to further evaluate dosage, effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug and to provide an adequate basis for product labeling and approval by the FDA. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug in an expanded patient population at multiple clinical trial sites.

All clinical trials must be conducted in accordance with FDA regulations, GCP requirements and their protocols in order for the data to be considered reliable for regulatory purposes.

An investigational drug product that is a combination of two different drugs in the same dosage form must comply with an additional rule that requires that each component make a contribution to the claimed effects of the drug product. This typically requires larger studies that test the drug against each of its components. In addition, typically, if a drug product is intended to treat a chronic disease, as is the case with some of our products, safety and efficacy data must be gathered over an extended period of time, which can range from six months to three years or more. Government regulation may delay or prevent marketing of drug candidates or new drugs for a considerable period of time and impose costly procedures upon our activities.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial, is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

The NDA Approval Process

In order to obtain approval to market a drug in the U.S., a marketing application must be submitted to the FDA that provides data establishing to the FDA's satisfaction the safety and effectiveness of the investigational drug for the proposed indication. Each NDA submission requires a substantial user fee payment (currently exceeding $3.2 million for fiscal year 2023) unless a waiver or exemption applies. The application includes all relevant data available from pertinent non-clinical studies, or preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators that meet GCP requirements.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2 clinical trials, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the end-of-Phase 2 clinical trials meetings to discuss their Phase 2 clinical trials results and present their plans for the pivotal Phase 3 registration trial that they believe will support approval of the new drug.

Concurrent with clinical trials, companies usually complete additional preclinical safety studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for the NDA sponsor's manufacturing the product in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drugs. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf-life.

The results of drug development, non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. It may request additional information rather than accept an NDA for filing. In this

event, the NDA must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. The FDA has 60 days from its receipt of an NDA to conduct an initial review to determine whether the application will be accepted for filing based on the FDA's threshold determination that the application is sufficiently complete to permit substantive review. If the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA has agreed to specific performance goals on the review of NDAs and seeks to review standard NDAs within 12 months from submission of the NDA. The review process may be extended by the FDA for three additional months to consider certain late submitted information or information intended to clarify information already provided in the submission. After the FDA completes its initial review of an NDA, it will communicate to the sponsor that the drug will either be approved, or it will issue a complete response letter to communicate that the NDA will not be approved in its current form and inform the sponsor of changes that must be made or additional clinical, non-clinical or manufacturing data that must be received before the application can be approved, with no implication regarding the ultimate approvability of the application or the timing of any such approval, if ever. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two to six months depending on the type of information included. The FDA may refer applications for novel drug products or drug products that present difficult questions of safety or effectiveness to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical sites to assure compliance with GCP regulations. If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable, it typically will outline the deficiencies and often will request additional testing or information. This may significantly delay further review of the application. If the FDA finds that a clinical site did not conduct the clinical trial in accordance with GCP regulations, the FDA may determine the data generated by the clinical site should be excluded from the primary efficacy analyses provided in the NDA. Additionally, notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase 4 or post-approval clinical trials may be made a condition to be satisfied for continuing drug approval. The results of Phase 4 clinical trials can confirm the effectiveness of a drug candidate and can provide important safety information. In addition, the FDA now has express statutory authority to require sponsors to conduct post-marketing trials to specifically address safety issues identified by the agency. See "Post-Marketing Requirements" under Part I, "Item 1. Business" of this Annual Report on Form 10-K.

The FDA also has authority to require a Risk Evaluation and Mitigation Strategy, or a REMS, from manufacturers to ensure that the benefits of a drug outweigh its risks. A sponsor may also voluntarily propose a REMS as part of the NDA submission. The need for a REMS is determined as part of the review of the NDA. Based on statutory standards, elements of a REMS may include "dear doctor letters," a medication guide, more elaborate targeted educational programs, and in some cases elements to assure safe use, or ETASU, which is the most restrictive REMS. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. These elements are negotiated as part of the NDA approval, and in some cases if consensus is not obtained until after the Prescription Drug User Fee Act of 1992, as amended, review cycle, the approval date may be delayed. Once adopted, REMS are subject to periodic assessment and modification.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Even if a drug candidate receives regulatory approval, the approval may be limited to specific disease states, patient populations and dosages, or might contain significant limitations on use in the form of warnings, precautions or contraindications, or in the form of onerous risk management plans, restrictions on distribution or post-marketing trial requirements. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delay in obtaining, or failure to obtain, regulatory approval for our products, or obtaining approval but for significantly limited use, would harm our business. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

Orphan Designation and Exclusivity

The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States and there is no reasonable expectation that the cost of developing and making the drug for this type of disease or condition will be recovered from sales in the United States.

Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical study costs, tax advantages, and user-fee waivers. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. In addition, the first NDA or Biologics License Application, or BLA, applicant to receive orphan drug designation for a particular drug is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years in the United States, except in limited circumstances. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition.

The Hatch-Waxman Amendments

Under the Drug Price Competition and Patent Term Restoration Act of 1984, as amended, commonly known as the Hatch-Waxman Amendments, a portion of a product's U.S. patent term that was lost during clinical development and regulatory review by the FDA may be restored. The Hatch-Waxman Amendments also provide a process for listing patents pertaining to approved products in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book) and for a competitor seeking approval of an application that references a product with listed patents to make certifications pertaining to such patents. In addition, the Hatch-Waxman Amendments provide for a statutory protection, known as non-patent exclusivity, against the FDA's acceptance or approval of certain competitor applications.

Patent Term Restoration

Patent term restoration can compensate for time lost during drug development and the regulatory review process by returning up to five years of patent life for a patent that covers a new product or its use. This period is generally one-half the time between the effective date of an IND (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, provided the sponsor acted with diligence. Patent term restorations, however, cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended and the extension must be applied for prior to expiration of the patent. The United States Patent and Trademark Office, or the USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed by the NDA holder listed in the drug's application or otherwise is then published in the FDA's Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical studies or clinical trials to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a Section VIII statement certifying that its proposed ANDA label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

An applicant submitting an NDA under Section 505(b)(2) of the FDCA, which permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference, is required to certify to the FDA regarding any patents listed in the Orange Book for the approved product it references to the same extent that an ANDA applicant would.

Market Exclusivity

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a Paragraph IV certification. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the non-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Post-Marketing Requirements

Following approval of a new product, a pharmaceutical company and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting to the applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet, including social media. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses. Modifications or enhancements to the product or its labeling or changes of the site of manufacture are often subject to the approval of the FDA and other regulators, who may or may not grant approval, or may include in a lengthy review process.

Prescription drug advertising is subject to federal, state and foreign regulations. In the U.S., the FDA regulates prescription drug promotion, including direct-to-consumer advertising. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Any distribution of prescription drug products and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act of 1987, as amended, or the PDMA, a part of the FDCA.

In the U.S., once a product is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that products be manufactured in specific, approved facilities and in accordance with cGMP. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. cGMP regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. NDA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms and, in certain circumstances, qualified

suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such product or may result in restrictions on a product, manufacturer, or holder of an approved NDA, including, among other things, recall or withdrawal of the product from the market.

The FDA also may require post-marketing testing, also known as Phase 4 testing, REMS to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, untitled or warning letters from the FDA, mandated corrective advertising or communications with doctors, withdrawal of approval, and civil or criminal penalties, among others. Newly-discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products in development.

Reimbursement, Anti-Kickback and False Claims Laws and Other Regulatory Matters

In the U.S., the research, manufacturing, distribution, sale and promotion of drug products and medical devices are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services (*e.g.*, the Office of Inspector General), the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, state Attorneys General and other state and local government agencies. For example, sales, marketing and scientific/educational grant programs must comply with the federal Anti-Kickback Statute, the federal False Claims Act of 1986, as amended, or the federal False Claims Act, the privacy regulations promulgated under the Health Insurance Portability and Accountability Act of 1996, as amended, or HIPAA, and similar state laws. Pricing and rebate programs must comply with the Medicaid Drug Rebate Program requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veterans Health Care Act of 1992, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive regulatory approval. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-government payors.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of our drug candidate, if any such product or the condition that it is intended to treat is the subject of a clinical trial. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our drug candidate. If third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the U.S. and generally tend to be priced significantly lower than in the U.S.

As noted above, in the U.S., we are subject to complex laws and regulations pertaining to healthcare "fraud and abuse," including, but not limited to, the federal Anti-Kickback Statute, the federal False Claims Act, and other state and federal laws and regulations. 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. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. In addition, many states have adopted laws similar to the federal Anti-Kickback Statute. Some of these state prohibitions apply to the referral of patients for healthcare services reimbursed by any insurer, not just federal healthcare programs such as Medicare and Medicaid. Due to the breadth of these federal and state anti-kickback laws, the absence of guidance in the form of regulations or court decisions and the potential for additional legal or regulatory change in this area, it is possible that our future sales and marketing practices or our future relationships with medical professionals might be challenged under anti-kickback laws, which could harm us. Because we intend to commercialize products that could be reimbursed under a federal healthcare program and other governmental healthcare programs, we plan to develop a comprehensive compliance program that establishes internal controls to facilitate adherence to the rules and program requirements to which we will or may become subject.

The federal False Claims Act prohibits anyone from knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed or claims for medically unnecessary items or services. Although we would not submit claims directly to payors, manufacturers can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. For example, pharmaceutical companies have been found liable under the federal False Claims Act in connection with their off-label promotion of drugs. Penalties for a federal False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties effective as of May 9, 2022 of between $12,537 and $25,076 for each separate false claim (each of which is subject to adjustment for inflation), the potential for exclusion from participation in federal healthcare programs and, although the federal False Claims Act is a civil statute, conduct that results in a federal False Claims Act violation may also implicate various federal criminal statutes. If the government were to allege that we were, or convict us of, violating these false claims laws, we could be subject to a substantial fine and may suffer a decline in our stock price. In addition, private individuals have the ability to bring actions under the federal False Claims Act and certain states have enacted laws modeled after the federal False Claims Act.

There are also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. In addition, as discussed below, beginning in 2013, a similar federal requirement requires manufacturers to track and report to the federal government certain payments made to physicians and teaching hospitals in the previous calendar year. These laws may affect our sales, marketing and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state, and soon federal, authorities.

The failure to comply with regulatory requirements subjects companies to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a company to enter into supply contracts, including government contracts.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (1) changes to our manufacturing arrangements; (2) additions or modifications to product labeling; (3) the recall or discontinuation of our products; or (4) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Patient Protection and Affordable Care Act

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, which includes measures that have or will significantly change the way healthcare is financed by both governmental and private insurers. Among the provisions of the PPACA of greatest importance to the pharmaceutical industry are the following:

- The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services as a condition for states to receive federal matching funds for the manufacturer's covered outpatient drugs furnished to Medicaid patients. Effective in 2010, the PPACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs and biologic agents to 23.1% of the average manufacturer price, or AMP, and adding a new rebate calculation for "line extensions" (*i.e.*, new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The PPACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization as of 2010 and by expanding the population potentially eligible for Medicaid drug benefits, phased-in by 2014. The CMS have proposed to expand Medicaid rebate liability to the territories of the U.S. as well. In addition, the PPACA provides for the public availability of retail survey prices and certain weighted average AMPs under the Medicaid program. The implementation of this requirement by the CMS may also provide for the public availability of pharmacy acquisition of cost data, which could negatively impact our sales.

- In order for a pharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. Effective in 2010, the PPACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly-eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs when used for the orphan indication. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase.

- Effective in 2011, the PPACA imposed a requirement on manufacturers of branded drugs and biologic agents to provide a 50% discount off the negotiated price of branded drugs dispensed to Medicare Part D patients in the coverage gap (*i.e.*, "donut hole").

- Effective in 2011, the PPACA imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications.

- Effective in 2012, the PPACA required pharmaceutical manufacturers to track certain financial arrangements with physicians and teaching hospitals, including any "transfer of value" made or distributed to such entities, as well as any investment interests held by physicians and their immediate family members. Manufacturers are required to track this information and were required to make their first reports in March 2014. The information reported is publicly available on a searchable website.

- As of 2010, a new Patient-Centered Outcomes Research Institute was established pursuant to the PPACA to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research. The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products.

- The PPACA created the Independent Payment Advisory Board, which has the authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription drugs. Under certain circumstances, these recommendations will become law unless Congress enacts legislation that will achieve the same or greater Medicare cost savings.

- The PPACA established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

There have been continued public announcements by members of the U.S. Congress regarding plans to repeal and replace the PPACA. For example, on December 22, 2017, the Tax Cuts and Jobs Act of 2017 was signed into law, which, among other things, eliminated

the individual mandate requiring most Americans (other than those who qualify for a hardship exemption) to carry a minimum level of health coverage, effective January 1, 2019. President Biden and his administration have announced plans to amend the PPACA to, among other things, expand the scope of the law. We cannot predict the ultimate form or timing of any repeal, replacement, amendment, expansion or other modification of the PPACA or the effect such a repeal, replacement, amendment, expansion or other modification would have on our business.

Pediatric Exclusivity and Pediatric Use

Under the Best Pharmaceuticals for Children Act, or the BPCA, certain drugs may obtain an additional six months of exclusivity if the sponsor submits information requested in writing by the FDA, or a Written Request, relating to the use of the active moiety of the drug in children. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. The FDA may not issue a Written Request for studies on unapproved or approved indications or where it determines that information relating to the use of a drug in a pediatric population, or part of the pediatric population, may not produce health benefits in that population. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

We have not received a Written Request for such pediatric studies, although we may ask the FDA to issue a Written Request for such studies in the future. To receive the six-month pediatric market exclusivity, we would need to receive a Written Request from the FDA, conduct the requested studies in accordance with a written agreement with the FDA or, if there is no written agreement, in accordance with commonly accepted scientific principles, and submit reports of the studies. A Written Request may include studies for indications that are not currently in the labeling if the FDA determines that such information will benefit the public health. The FDA will accept the reports upon its determination that the studies were conducted in accordance with, and are responsive to, the original Written Request or commonly accepted scientific principles, as appropriate, and that the reports comply with the FDA's filing requirements.

Under the Pediatric Research Equity Act of 2003, or the PREA, an NDA or supplement thereto must contain data that is adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The PREA also authorizes the FDA to require holders of approved NDAs for marketed drugs to conduct pediatric studies under certain circumstances. With the enactment of the Food and Drug Administration Safety and Innovation Act, or the FDASIA, in 2012, sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA and the FDA's internal review committee must then review the information submitted, consult with each other and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in the FDASIA. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Intellectual Property

We have in-licensed from Ligand patents and patent applications that contain claims that recite our compounds, as set forth below. We have filed additional patent applications in the U.S., E.U. and other foreign jurisdictions on our clinical and preclinical programs. Information regarding the issued patents and pending patent applications, as of December 31, 2023, is as follows:

Subject Matter/Compounds	# Pending Applications	# Issued Patents	Geographical Scope	Nominal Patent Term
TRß agonists	59	30	U.S., Australia, Canada, China, Japan, Korea, Hong Kong, Mexico, Brazil, Russia, New Zealand, South Africa, Europe and PCT	2025-2043
VK5211 (SARM)	13	21	U.S., Australia, Europe, Chile, Brazil, Canada, China, India, Japan, Korea, Mexico, New Zealand, South Africa, Taiwan and Venezuela	2025-2040
Other SARM	1	4	U.S., Japan, Korea, Argentina and Israel	2026
DGAT-1 Inhibitors	0	5	U.S. and Hong Kong	2030
EPOR Inhibitors	0	11	U.S., Australia, Canada, China, Europe, India, Japan, and Korea	2030
GLP-1 agonists	33	1	U.S., Argentina, Australia, Brazil, Canada, China, Europe, Indonesia, Israel, India, Japan, Korea, Mexico, New Zealand, Philippines, Russia, Saudi Arabia, South Africa, Taiwan and PCT	2042-2043

Corporate Information

We were incorporated under the laws of the State of Delaware on September 24, 2012. Our principal executive offices are located at 9920 Pacific Heights Blvd, Suite 350, San Diego, CA 92121, and our telephone number is (858) 704-4660. Our website address is *www.vikingtherapeutics.com.* We do not incorporate the information on, or accessible through, our website into this Annual Report on Form 10-K, and you should not consider any information on, or accessible through, our website as part of this Annual Report on Form 10-K. We have included our website address in this Annual Report on Form 10-K solely as an inactive textual reference.

Employees & Human Capital

As of December 31, 2023, we had twenty-seven full-time employees, seven of whom hold a Ph.D. or M.D. degree. All employees are engaged in research and development, business development and finance. None of our employees are subject to a collective bargaining agreement. We have never experienced a material work stoppage or disruption to our business relating to employee matters. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards.

Item 1A. Risk Factors.

You should consider carefully the following information about the risks described below, together with the other information contained in this Annual Report on Form 10-K and in our other public filings in evaluating our business. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline.

Risk Factor Summary

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 Annual Report on Form 10-K and our other filings with the Securities and Exchange Commission, or the SEC, before making an investment decision regarding our common stock.

- We are a clinical-stage company, have a very 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 very 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 VK2809, VK2735 subcutaneous, VK5211 and VK0612, which are currently in Phase 2 clinical development, VK2735, currently in an oral Phase 1 SAD/MAD clinical trial, and VK0214, currently in a Phase 1b clinical trial, as well as the diacylglycerol acyltransferase-1, or DGAT-1 and erythropoietin receptor, or EPOR, 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 December 31, 2023, we had an accumulated deficit of $377.9 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, VK2809, VK2735, VK0214, VK5211, VK0612 and our earlier-stage assets, our DGAT-1 and EPOR 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, VK2809, VK2735, VK0214, VK5211, VK0612 and our earlier-stage assets, our DGAT-1 and EPOR 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.

We licensed most of the intellectual property related to our current drug candidates from Ligand pursuant to the Master License Agreement. In May 2023, we reported positive top-line results from the VOYAGE Phase 2b clinical trial for VK2809. In late 2017, we reported positive top-line results from a Phase 2 clinical trial for VK5211. However, there is no guarantee that the results of our Phase 2 clinical trials for VK2809 or VK5211 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 December 31, 2023, we had cash, cash equivalents and investments totaling $362.1 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.

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 be reluctant or unable to visit clinical sites, or may delay 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 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.

VK2809

While no therapies are currently approved for the treatment of non-alcoholic steatohepatitis, we are aware of numerous development-stage programs targeting this disease, including resmetirom from Madrigal Pharmaceuticals, Inc., arachidyl amido cholanoic acid from Galmed Pharmaceuticals Ltd., belapectin from Galectin Therapeutics Inc., lanifibranor from Inventiva S.A., semaglutide from Novo Nordisk A/S, 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., efruxifermin (AKR-001) from Akero Therapeutics, 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 Altimmune, Inc. In addition, we are aware of active programs at Aligos Therapeutics, Inc., Arrowhead Pharmaceuticals, Inc., Ascletis Biopharmaceutical, AstraZeneca PLC, Boston Pharmaceuticals Inc., Can-Fite BioPharma Ltd., 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., Gelesis Holdings Inc., Hepagene Therapeutics, Inc., Kowa Company, Ltd., MediciNova Inc., NGM Biopharmaceuticals, Inc., NorthSea Therapeutics BV,

Pliant Therapeutics, Inc., Poxel SA, Seal Rock Therapeutics, Inc., Theratechnologies Inc., Yuhan Corporation, and Cadila Healthcare Limited (a.k.a. Zydus Cadila).

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 Altimmune, Inc., Amgen Inc., AstraZeneca, D&D Pharmatech, Inc., ERX Pharmaceuticals Inc., F. Hoffmann-La Roche Ltd, Hanmi Pharmaceutical Co., Ltd., Kallyope Inc., Pfizer Inc., Rivus Pharmaceuticals Inc., Structure Therapeutics Inc., Terns Pharmaceuticals, Inc., and Zealand Pharma A/S.

VK0214

In the U.S., there are currently no marketed therapies for the treatment of X-linked adrenoleukodystrophy, or 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 SwanBio 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, Helsinn Group, 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 shall take 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.

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, Indiana, Iowa, Montana, Oregon, Tennessee and Texas have

adopted privacy laws, which take effect from July 1, 2024 through 2026. Further, Washington's My Health My Data Act, taking effect July 1, 2024, imposes similar requirements specific to consumer health data. 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 December 31, 2023, we had twenty-seven full-time employees 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. 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, the SEC has announced proposed rules that, among other matters, will establish a framework for reporting of climate-related risks. To the extent the proposed rules impose additional reporting obligations, we could face increased costs. 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.

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 December 31, 2023, we owned or co-owned 92 patent applications and 23 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 December 31, 2023, 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 two U.S. patents, six 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 December 31, 2023. For VK5211, as of December 31, 2023, 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 December 31, 2023, for our GLP-1 program, we own one U.S. patent, four 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 Ascletis Bioscience Co., Ltd., Gannex Pharma Co., Ltd., Ascletis Pharmaceuticals Co., Ltd., Ascletis Pharma Inc., and Jinzi Jason Wu, or the Ascletics 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 Ascletis Defendants in the International Trade Commission for unlawful and unfair methods of competition. 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 December 31, 2023, 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 Ascletis 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 December 31, 2023, our executive officers, directors and 5% or greater stockholders beneficially owned 19.9% 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 are not required to reflect the change in our smaller reporting company status and comply with the increased disclosure obligations until our quarterly report for the quarter ending March 31, 2024, the first quarter in our fiscal year ending December 31, 2024.

We will need to reassess, as of June 30, 2024, whether we will continue to qualify as a large accelerated filer for filings beyond the fiscal year ending December 31, 2024.

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 ending 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.

The timing and amount of any repurchases under our stock repurchase program are subject to a number of uncertainties.

On March 10, 2022, our board of directors authorized a stock repurchase program effective March 18, 2022, whereby we may purchase up to $50.0 million in shares of our common stock over a period of up to two years, or the Repurchase Program. The Repurchase Program may be 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. The Repurchase Program may be suspended, modified or discontinued at any time, and we have no obligation to repurchase any amount of our common stock under the Repurchase Program.

The Inflation Reduction Act of 2022, enacted on August 16, 2022, imposes a 1% excise tax on net repurchases of shares by U.S. corporations whose stock is traded on an established securities market. The excise tax will be imposed on repurchases that occur after December 31, 2022. The imposition of the excise tax on repurchases of our shares will increase the cost to us of making repurchases and may cause us to reduce the number of shares repurchased pursuant to the Repurchase Program.

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 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity

Our board of directors is responsible for overseeing our risk management program and cybersecurity is a critical element of this program. Management is responsible for the day-to-day administration of our risk management program and our cybersecurity policies, processes, and practices. Our cybersecurity policies, standards, processes, and practices are based on recognized frameworks established by the National Institute of Standards and Technology, the International Organization for Standardization and other applicable industry standards and are fully integrated into our overall risk management system and processes as part of our IT security incident response plan.

Cybersecurity Risk Management and Strategy

Our cybersecurity risk management strategy focuses on several areas:

- Identification and Reporting: We have implemented a cross-functional approach to assessing, identifying and managing material cybersecurity threats and incidents. Our program includes controls and procedures to identify, classify and escalate certain cybersecurity incidents to provide management visibility and obtain direction from management as to the public disclosure and reporting of material incidents in a timely manner.

- Technical Safeguards: We implement technical safeguards that are designed to protect our information systems from cybersecurity threats, including firewalls, intrusion prevention and detection systems, anti-malware functionality, and access controls, which are evaluated and improved through vulnerability assessments and cybersecurity threat intelligence, as well as outside audits and certifications.

- Incident Response and Recovery Planning: We have established and maintain comprehensive incident response, business continuity, and disaster recovery plans designed to address our response to a cybersecurity incident. We conduct regular tabletop exercises to test these plans and ensure personnel are familiar with their roles in a response scenario.

- Third-Party Risk Management: We maintain a risk-based approach to identifying and overseeing material cybersecurity threats presented by third parties, including vendors, service providers, and other external users of our systems, as well as the systems of third parties that could adversely impact our business in the event of a material cybersecurity incident affecting those third-party systems, including any outside auditors or consultants who advise on our cybersecurity systems.

- Education and Awareness: We provide regular, mandatory training for all employees regarding cybersecurity threats as a means to equip our employees with tools to make employees aware of and to address cybersecurity threats, and to communicate our evolving information security policies, standards, processes, and practices.

We conduct periodic assessments and testing of our policies, standards, processes, and practices in a manner intended to address cybersecurity threats and events. The results of such assessments, audits, and reviews are evaluated by management and reported to our Audit Committee and our board of directors, and we adjust our cybersecurity policies, standards, processes, and practices as necessary based on the information provided by these assessments, audits, and reviews. Risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, have not materially affected and are not reasonably likely to materially affect our company, including our business strategy, results of operations, or financial condition.

Governance

Our board of directors, in coordination with our Audit Committee, oversees our risk management program, including the management of cybersecurity threats. Our board of directors and our Audit Committee each receive regular presentations and reports on developments in the cybersecurity space, including risk management practices, recent developments, evolving standards, vulnerability assessments, third-party and independent reviews, the threat environment, technological trends, and information security issues encountered by our peers and third parties. Our board of directors and our Audit Committee also receive prompt and timely information regarding any cybersecurity risk that meets pre-established reporting thresholds, as well as ongoing updates regarding any such risk. On an annual basis, our board of directors and the Audit Committee discuss our approach to overseeing cybersecurity threats with our Information Systems Representative and other members of senior management.

The Information Systems Representative, in coordination with senior management including our Chief Executive Officer and Chief Financial Officer, works collaboratively across our company to implement a program designed to protect our information systems from cybersecurity threats and to promptly respond to any material cybersecurity incidents in accordance with our incident response and recovery plans. To facilitate the success of our cybersecurity program, a cross-functional team throughout our company addresses cybersecurity threats and responds to cybersecurity incidents. Through ongoing communications with this team, the Information Systems Representative and senior management are informed about and monitor the prevention, detection, mitigation and remediation of cybersecurity threats and incidents in real time and report such threats and incidents to the Audit Committee when appropriate. The Information Systems Representative has served in various roles in information technology and information security for over 25 years, including serving as the Director of Information Technology of another public company.

Item 2. Properties.

Our facilities consist of office space in San Diego, California. We lease approximately 7,940 square feet of space for our headquarters in San Diego, California under an agreement that expires on July 31, 2027. We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

Item 3. 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 Ascletis Bioscience Co., Ltd., Gannex Pharma Co., Ltd., Ascletis Pharmaceuticals Co., Ltd., Ascletis Pharma Inc., and Jinzi Jason Wu, or the Ascletis 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 Ascletis Defendants in the International Trade Commission for unlawful and unfair methods of competition. These legal proceedings arise at least in part from the misappropriation of our trade secrets. We intend to vigorously pursue all of our legal remedies in these litigations, but there is no guarantee that we will be successful in these efforts.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock began trading on the Nasdaq Capital Market on April 28, 2015 and trades under the symbol "VKTX". Prior to April 28, 2015, there was no public market for our common stock.

Holders of Record

As of December 31, 2023, there were approximately eight stockholders of record of our common stock. Certain shares are held in "street" name and, accordingly, the number of beneficial owners of such shares is not known or included in the foregoing number.

Performance Graph

We were a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, as of December 31, 2023, and are not required to provide a performance graph.

Unregistered Sales of Equity Securities

None.

Issuer Purchases of Equity Securities

None.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis in conjunction with Part II, "Item 8. Financial Statements and Supplementary Data" included below in this Annual Report on Form 10-K. Operating results are not necessarily indicative of results that may occur in future periods.

The following discussion and analysis of our financial condition and results of operations contains forward-looking statements that involve a number of risks, uncertainties and assumptions. Actual events or results may differ materially from our expectations. Important factors that could cause actual results to differ materially from those stated or implied by our forward-looking statements include, but are not limited to, those set forth in Part I, "Item 1A. Risk Factors" in this Annual Report on Form 10-K. All forward-looking statements included in this Annual Report on Form 10-K are based on information available to us as of the time we file this Annual Report on Form 10-K and, except as required by law, we undertake no obligation to update publicly or revise any forward-looking statements.

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.

Our lead clinical program's drug candidate, VK2809, is an orally available, tissue and receptor-subtype selective agonist of the thyroid hormone receptor beta, or TRß. In November 2019, we initiated the VOYAGE study, a Phase 2b clinical trial of VK2809 in patients with biopsy-confirmed non-alcoholic steatohepatitis, or 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 NASH and fibrosis ranging from stages F1 to F3. The study is targeting enrollment of approximately 340 patients across five treatment arms. 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, 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. Results from the biopsy after 52 weeks of dosing are expected to be available in 2024.

VK2809 has been evaluated in eight completed clinical studies, which enrolled more than 300 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.

VK2809 has been evaluated in eight completed clinical studies, which enrolled more than 300 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.

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 insulinotropic 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 >= 30 kg/m2) or adults who are overweight (BMI >= 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 we expect to report data from the study in the first half of 2024.

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.

We are also developing VK0214, which is also an orally available, tissue and receptor-subtype selective agonist of TRß 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 TRß 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 is a multi-center, randomized, double-blind, placebo-controlled study in adult male patients with the adrenomyeloneuropathy, or AMN, form of X-ALD. The study is initially targeting enrollment across three cohorts: placebo, VK0214 20 mg daily, and VK0214 40 mg daily. Pending a blinded review of preliminary safety, tolerability, and pharmacokinetic data, additional dosing cohorts may be pursued.

The primary objective of the study is to evaluate the safety and tolerability of VK0214 administered once-daily over a 28-day dosing period. Secondary and exploratory objectives include an evaluation of the pharmacokinetics and pharmacodynamics of VK0214 following 28 days of dosing in this population.

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 VK2809, VK2735, VK0214 and VK5211 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" under Part I, "Item 1. Business" of this Annual Report on Form 10-K.

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 VK2809 Phase 2b VOYAGE clinical trial, the VK2735 Phase 2 VENTURE clinical trial, the VK2735 Phase 1 clinical trial and the VK0214 Phase 1b clinical trial. During the year ended December 31, 2022, we incurred $54.2 million in research and development expense primarily related to our efforts in conducting the VK2809 Phase 2b VOYAGE clinical trial, the VK2735 Phase 1 clinical trial and the VK0214 Phase 1b clinical trial. 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 NASH, on our behalf;

- payments to third-party manufacturers, which will produce our active pharmaceutical ingredients and finished 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 VK2809, VK2735 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 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 financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these 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 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. 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.

While our significant accounting policies are more fully described in Note 1 to our financial statements included elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies will be critical to understanding our historical and future performance, as these policies relate to the significant areas involving management's judgments and estimates in the preparation of our financial statements.

Research and Development

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, or 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.

We estimate our preclinical study and clinical trial expenses based on the services we received pursuant to contracts with research institutions and CROs that conduct and manage preclinical studies and clinical trials on our 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 for a combination of these elements. We accrue 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 our service providers invoice us in arrears, and to the extent that amounts invoiced differ from our estimates of expenses incurred, we accrue 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, we have not experienced any events requiring us to make material adjustments to our accruals for service fees. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates, which could materially affect our results of operations. Adjustments to our accruals are recorded as changes in estimates become evident. Furthermore, based on amounts invoiced to us by our service providers, we may also record payments made to those providers as prepaid expenses that will be recognized as expense in future periods as services are rendered.

In May 2014, we entered into the Master License Agreement, pursuant to which we acquired certain rights to a number of research and development programs from Ligand. In doing so, we updated our policy on research and development to include the purchase of rights to intangible assets. In accordance with Accounting Standards Codification, or ASC, Topic 730, *Research and Development,* intangible assets that are acquired and have an alternative future use, as defined, should be capitalized and reported as an intangible asset; however, the cost of acquired intangible assets that do not have alternative future uses should be reported as research and development expense as incurred. We note that intangible assets acquired that are in the preclinical or clinical stages of development when acquired, and not approved by the U.S. Food and Drug Administration, are deemed to have not satisfied the definition of having an alternative future use, as defined. Accordingly, assets acquired in the preclinical and clinical stages of development are expensed as incurred in our statement of operations.

Stock-Based Compensation

We generally use 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 estimate 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, we generally use 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 use the fair value at grant date to value the awards. For restricted stock that vests upon the satisfaction of certain performance conditions, we recognize stock-based compensation expense when it becomes probable that the performance conditions will be met. At the grant date, we determine the grant date fair value, as a publicly traded company, using the intrinsic value, or the closing price of our stock on the date of grant. At the point where the criteria are deemed probable of being met, we record 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 our Employee Stock Purchase Plan, or ESPP, we generally recognize compensation expense for the fair value of the purchase options, as measured on the grant date, and use the graded vesting method to allocate this compensation cost to each purchase period

within the related two-year offering period. As our ESPP also allows for up to one increase in contributions during each purchase period, if an employee elects to increase their contributions, we treat 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.

Income Taxes

We account for our 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 we will not realize those tax assets through future operations.

ASC Topic 740-10, *Income Taxes*, clarifies the accounting for uncertainty in income taxes recognized in our financial statements in accordance with accounting principles generally accepted in the United States of America, or 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.

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

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2023 and 2022 (in thousands, except % change).

	Year Ended December 31,		$ Change	% Change
	2023	2022		
Research and development expenses	$ 63,806	$ 54,234	$ 9,572	17.6%

The increase in research and development expenses during the year ended December 31, 2023 as compared to the year ended December 31, 2022 was primarily due to increased expenses related to pre-clinical studies, stock-based compensation, manufacturing for our drug candidates, salaries and benefits and services provided by third-party consultants, partially offset by a decrease in expenses related to clinical studies.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the years ended December 31, 2023 and 2022 (in thousands, except % change).

	Year Ended December 31,		$ Change	% Change
	2023	2022		
General and administrative expenses	$ 37,021	$ 16,121	$ 20,900	129.6%

The increase in general and administrative expenses during the year ended December 31, 2023 as compared to the year ended December 31, 2022 was primarily due to increased expenses related to legal and patent services, stock-based compensation, third-party consultants and salaries and benefits.

Other Income, net

The following table summarizes our other income, net for the years ended December 31, 2023 and 2022 (in thousands, except % change).

	Year Ended December 31,		$ Change	% Change
	2023	2022		
Other income, net	$ 14,932	$ 1,488	$ 13,444	903.5%

Other income, net recognized during the year ended December 31, 2023 consisted primarily of interest income, partially offset by expense relating to the amortization of certain financing costs.

Other income, net recognized during the year ended December 31, 2022 consisted primarily of interest income, offset by expense relating to the amortization of certain financing costs and realized loss on investment.

Comparison of the Years Ended December 31, 2022 and 2021

For a discussion regarding our financial condition and results of operations for the year ended December 31, 2022 as compared to the year ended December 31, 2021, please refer to the discussion under the heading "Results of Operations—Comparison of the Years Ended December 31, 2022 and 2021" in Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the SEC on February 10, 2023.

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 December 31, 2023, we had cash, cash equivalents and short-term investments of $362.1 million. As such, we believe our cash, cash equivalents and short-term investments will be sufficient to fund our operations through at least the first quarter of 2025, which is more than one year after the date our December 31, 2023 financial statements were issued.

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 VK2809, VK2735, 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 filed with the SEC a universal Shelf Registration Statement on Form S-3 (File No. 333-258231), or the Shelf Registration Statement. The Shelf Registration Statement initially provides us with the ability to offer up to $600.0 million of securities, including equity, debt and other securities as described in the Shelf Registration Statement. The Shelf Registration Statement was declared effective by the SEC on August 11, 2021 and the offering of all remaining unsold securities under the 2021 Shelf Registration Statement terminated on July 26, 2023.

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 may 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 are to be issued pursuant to the Shelf Registration Statement and the 424(b) prospectus supplement relating to the ATM Offering dated August 11, 2021. The 2021 Shelf Registration Statement terminated on July 26, 2023. From its inception through the termination of the 2021 Shelf Registration Statement, 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 March 17, 2020, our board of directors authorized a stock repurchase program, or the Prior Repurchase Program, whereby we could purchase up to $50.0 million in shares of our common stock and outstanding warrants to purchase our common stock, over a period of up to two years. The Prior 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 or privately negotiated transactions. Through March 17, 2022, the termination date of the Prior Repurchase Program, we repurchased an aggregate of 1,464,217 shares of our common stock under the Prior Repurchase Program. These shares repurchased by us under the Prior Repurchase Program are being held in treasury until such time as we reissue or retire them.

On March 10, 2022, our board of directors authorized a new stock repurchase program, or the New Repurchase Program, effective March 18, 2022, whereby we may purchase up to $50.0 million in shares of our common stock over a period of up to two years. The New Repurchase Program may be 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 December 31, 2023, we repurchased an aggregate of 729,034 shares of our common stock under the New Repurchase Program. These shares repurchased by us under the New Repurchase Program are being held in treasury until such time as we reissue or retire them.

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 December 31, 2023, no shares of our common stock were sold pursuant to the ATM Offering and, as of December 31, 2023, we may sell shares of our common stock for remaining gross proceeds of up to $200.0 million from time to time pursuant to the ATM Prospectus.

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

	2023	2022	2021
Net cash used in operating activities	$ (73,376)	$ (48,397)	$ (47,586)
Net cash (used in) provided by investing activities	$ (179,086)	$ 54,753	$ 37,960
Net cash provided by financing activities	$ 271,376	$ 4,163	$ 6,880

Net Cash Used in Operating Activities

During the year ended December 31, 2023, net cash used in operating activities of $73.4 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.

During the year ended December 31, 2022, net cash used in operating activities of $48.4 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 liability as well as changes in our working capital accounts, primarily consisting of an increase in accounts payable, accrued expenses and accrued interest, net of interest received on maturity of investments, partially offset by a decrease in lease liability and an increase in prepaids and other current assets.

Net Cash Provided by Investing Activities

During the year ended December 31, 2023, net cash used in investing activities of $179.1 million resulted from the purchase of investments of $478.3 million, offset by the proceeds of maturities of investments of $299.2 million.

During the year ended December 31, 2022, net cash provided by investing activities of $54.8 million resulted from the proceeds of maturities of investments of $176.2 million, offset by the purchase of investments of $121.4 million.

Net Cash Provided by Financing Activities

During the year ended December 31, 2023, net cash provided by financing activities was $271.4 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 of $6.8 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.

During the year ended December 31, 2022, net cash provided by financing activities was $4.2 million, which consisted primarily of proceeds from the ATM Offering, net of fees of $11.7 million, proceeds from certain warrant exercises of $633,000 and proceeds from ESPP purchases of $215,000, partially offset by $6.8 million in repurchases of our common stock under the Repurchase Program and the New Repurchase Program and the value of shares withheld to cover taxes of $1.5 million.

Future Funding Requirements

As of December 31, 2023, and based upon our current operating plan, we believe that we will have sufficient cash to meet our projected operating requirements for at least the next 12 months following the issuance of the financial statements. 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. Although we expect to finance future cash needs through public or private equity or debt offerings, 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 7A. Quantitative and Qualitative Disclosures About Market Risk.

We were a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, as of December 31, 2023, and are not required to provide the information required under this item.

Item 8. Financial Statements and Supplementary Data.

The information required by this Item 8 is contained on the pages indicated in Part IV, Item 15(a)(1) of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures.

We maintain disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Disclosure controls and procedures are controls and other procedures designed to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and our 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 and not absolute assurance of achieving the desired control objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on our management's evaluation (with the participation of the individuals serving as our principal executive officer and principal financial officer) of our disclosure controls and procedures as required by Rules 13a-15 and 15d-15 under the Exchange Act, each of the individuals serving as our principal executive officer and principal financial officer has concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2023, the end of the period covered by this report.

Management's Report on Internal Control over Financial Reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including the individuals serving as our principal executive officer and principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. Management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013 Framework). Based on this assessment, our management concluded that, as of December 31, 2023, our internal control over financial reporting was effective based on those criteria.

Changes in Internal Control over Financial Reporting.

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Attestation Report on Internal Control over Financial Reporting.

Our independent registered public accounting firm, Marcum, LLP, issued an attestation report on our internal control over financial reporting, as noted below.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON INTERNAL CONTROL OVER FINANCIAL REPORTING

To the Shareholders and Board of Directors of Viking Therapeutics, Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Viking Therapeutics, Inc. 's (the "Company") internal control over financial reporting as of December 31, 2023, based on criteria established in *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheet as of December 31, 2023 and the related consolidated statements of operations and comprehensive loss,

shareholders' equity, and cash flows and the related notes for the one year in the period ended December 31, 2023 of the Company, and our report dated February 7, 2024 expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying "Management Annual Report on Internal Control over Financial Reporting". Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that degree of compliance with the policies or procedures may deteriorate.

/s/ Marcum LLP

Marcum LLP
Costa Mesa, California
February 7, 2024

Item 9B. Other Information.

During the fiscal quarter ended December 31, 2023, 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.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item will be contained in our definitive proxy statement on Schedule 14A to be filed with the SEC in connection with our 2024 annual meeting of stockholders, or the Proxy Statement, which we expect to file not later than 120 days after the end of our year ended December 31, 2023, and is incorporated in this report by reference.

Item 11. Executive Compensation.

The information required by this item will be contained in the Proxy Statement, which we expect to file not later than 120 days after the end of our year ended December 31, 2023, and is incorporated in this report by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item will be contained in the Proxy Statement, which we expect to file not later than 120 days after the end of our year ended December 31, 2023, and is incorporated in this report by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item will be contained in the Proxy Statement, which we expect to file not later than 120 days after the end of our year ended December 31, 2023, and is incorporated in this report by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this item will be contained in the Proxy Statement, which we expect to file not later than 120 days after the end of our year ended December 31, 2023, and is incorporated in this report by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a)(1) The Financial Statements required to be filed by Items 8 and 15(c) of this Annual Report on Form 10-K, and filed herewith, are as follows:

(a)(2) Financial Statement Schedules have been omitted because they are either not applicable or the required information is included in the financial statements or notes thereto listed in (a)(1) above.

(a)(3) Exhibits.

The following exhibits are filed herewith or incorporated herein by reference:

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
4.2	Description of Registrant's Securities.	10-K	2/1/2023	4.2
10.1#	Form of Indemnification Agreement between Viking Therapeutics, Inc. and its directors and executive officers.	S-1	7/1/2014	10.1
10.2#	2014 Equity Incentive Plan.	S-1/A	3/2/2015	10.2
10.3#	Form of Stock Option Award Agreement (2014 Equity Incentive Plan).	S-1	7/1/2014	10.3
10.4#	Form of Restricted Stock Unit Award Agreement (2014 Equity Incentive Plan).	S-1	7/1/2014	10.4
10.5#	Form of Restricted Stock Award Agreement (2014 Equity Incentive Plan).	S-1/A	9/2/2014	10.23
10.6#	Form of Stock Appreciation Rights Award Agreement (2014 Equity Incentive Plan).	S-1	7/1/2014	10.5
10.7#	2014 Employee Stock Purchase Plan.	S-1/A	3/2/2015	10.22
10.8#	Amendment No. 1 to 2014 Employee Stock Purchase Plan.	S-1	11/24/2015	10.8
10.9#	Employment Agreement, effective as of June 2, 2014, by and between Viking Therapeutics, Inc. and Brian Lian, Ph.D.	S-1/A	9/2/2014	10.6
10.10#	First Amendment to Employment Agreement, effective as of March 14, 2016, by and between Viking Therapeutics, Inc. and Brian Lian, Ph.D.	8-K	3/15/2016	10.1

Exhibit Number	Description	Registrant's Form	Date Filed with the SEC	Exhibit Number
10.11#*	Non-Employee Director Compensation Policy.			
10.12†	Master License Agreement, dated May 21, 2014, by and among Viking Therapeutics, Inc., Ligand Pharmaceuticals Incorporated and Metabasis Therapeutics, Inc.	S-1	7/1/2014	10.12
10.13†	First Amendment to Master License Agreement, dated September 6, 2014, by and among Viking Therapeutics, Inc., Ligand Pharmaceuticals Incorporated and Metabasis Therapeutics, Inc.	S-1/A	9/8/2014	10.24
10.14†	Second Amendment to Master License Agreement, dated April 8, 2015, by and among Viking Therapeutics, Inc., Ligand Pharmaceuticals Incorporated and Metabasis Therapeutics, Inc.	S-1/A	4/10/2015	10.30
10.15#†	Common Stock Purchase Agreement, dated February 20, 2014, by and between Viking Therapeutics, Inc. and Brian Lian, Ph.D.	S-1	7/1/2014	10.21
10.16#	Amendment No. 1 to Common Stock Purchase Agreement, dated May 4, 2015, by and between Viking Therapeutics, Inc. and Brian Lian, Ph.D.	10-Q	6/12/2015	10.5
10.17	At-The-Market Equity Offering Sales Agreement, dated as of July 28, 2021, by and among Viking Therapeutics, Inc., Stifel, Nicolaus & Company, Incorporated Truist Securities, Inc. and H.C. Wainwright & Co., LLC.	S-3	7/28/2021	1.2
10.18	Amendment No. 1 to At-the-Market Equity Offering Sales Agreement, dated as of July 26, 2023, by and among Viking Therapeutics, Inc., Stifel, Nicolaus & Company, Incorporated, Truist Securities, Inc., H.C. Wainwright & Co., LLC and BTIG, LLC.	10-Q	7/26/2023	10.1
21.1	List of Subsidiaries of Viking Therapeutics, Inc.	10-K	2/9/2022	21.1
23.1	Consent of Marcum LLP, Independent Registered Public Accounting Firm.			
24.1	Power of Attorney (included on the signature page to this Annual Report on Form 10-K).			
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.			
97*	Viking Therapeutics, Inc. Clawback Policy			
101.INS	Inline XBRL Instance Document.			
101.SCH	Inline XBRL Taxonomy Extension Schema Document.			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.			
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)			

Attached as Exhibit 101 to this report are the following formatted in XBRL (Extensible Business Reporting Language): (i) Consolidated Balance Sheets as of December 31, 2023 and December 31, 2022, (ii) Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2023 and 2022, (iii) Consolidated Statements of Stockholders' Equity for the period from December 31, 2021 to December 31, 2023, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2023 and 2022, and (v) Notes to Consolidated Financial Statements.

* Filed herewith.
# Indicates compensatory plan or arrangement.
† Confidential treatment has been granted with respect to certain portions of this exhibit, which portions have been omitted and filed separately with the Securities and Exchange Commission.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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: February 7, 2024

By: /s/ Brian Lian, Ph.D.
Brian Lian, Ph. D.
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints, jointly and severally, Brian Lian, Ph.D. and Greg Zante, and each of them acting individually, as his attorney-in-fact, each with full power of substitution and resubstitution, for him in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact, or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ Brian Lian, Ph.D. Brian Lian, Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	February 7, 2024
/s/ Greg Zante Greg Zante	Chief Financial Officer (Principal Accounting and Financial Officer)	February 7, 2024
/s/ Lawson Macartney, DVM, Ph.D. Lawson Macartney, DVM, Ph.D.	Director	February 7, 2024
/s/ Matthew W. Foehr Matthew W. Foehr	Director	February 7, 2024
/s/ Sarah Kathryn Rouan Sarah Kathryn Rouan	Director	February 7, 2024
/s/ Charles A. Rowland Jr. Charles A. Rowland Jr.	Director	February 7, 2024
/s/ J. Matthew Singleton J. Matthew Singleton	Director	February 7, 2024

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Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors of
Viking Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Viking Therapeutics, Inc. (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2023, based on the criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in 2013 and our report dated February 7, 2024, expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Accrual for preclinical study and clinical trial costs

As described in Note 1 to the financial statements, the Company estimates its preclinical study and clinical trial expenses based on the services it received pursuant to contracts with research institutions and contract research organizations ("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.

The principal consideration for our determination that performing procedures related to the preclinical study and clinical trial expenses, specifically related to the year-end accrual for preclinical study and clinical trial costs, is a critical audit matter is that there was judgment by management in determining the achievement of milestones, patient enrollments and occurrence of other events that creates a present obligation for the Company to pay the research institutions and CROs for their services.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others, (i) obtaining an understanding of the Company's estimation process relating to accrual for preclinical study and clinical trial costs; (ii) testing management's identification of milestones, patient enrollment requirements and other events in its contracts with the research institutions and CROs; (iii) testing management's determination of the accrual for preclinical study and clinical trial costs for a sample of such milestones, patient enrollments and other events; and (iv) testing the mathematical accuracy of the schedule of accrual for preclinical study and clinical trial costs prepared by management.

/s/ Marcum LLP

We have served as the Company's auditor since 2014.

Marcum LLP
Costa Mesa, California
February 7, 2024

Viking Therapeutics, Inc.
Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 55,516	$ 36,632
Short-term investments – available-for-sale	306,563	118,853
Prepaid clinical trial and preclinical study costs	2,624	8,144
Prepaid expenses and other current assets	2,522	3,411
Total current assets	367,225	167,040
Right-of-use assets	1,126	1,418
Deferred financing costs	106	38
Deposits	33	33
Total assets	$ 368,490	$ 168,529
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 7,512	$ 8,529
Other accrued liabilities	11,299	13,114
Lease liability, current	324	304
Total current liabilities	19,135	21,947
Lease liability, net of current portion	936	1,260
Total long-term liabilities	936	1,260
Total liabilities	20,071	23,207
Commitments and contingencies (*Note 11*)		
Stockholders' equity:		
Preferred stock, $0.00001 par value: 10,000,000 shares authorized at December 31, 2023 and 2022; no shares issued and outstanding at December 31, 2023 and 2022	—	—
Common stock, $0.00001 par value: 300,000,000 shares authorized at December 31, 2023 and 2022; 100,113,770 shares issued and outstanding at December 31, 2023 and 78,257,258 shares issued and outstanding at December 31, 2022	1	1
Treasury stock at cost, 2,193,251 shares at December 31, 2023 and 2022	(6,795)	(6,795)
Additional paid-in capital	733,546	445,267
Accumulated deficit	(377,944)	(292,049)
Accumulated other comprehensive loss	(389)	(1,102)
Total stockholders' equity	348,419	145,322
Total liabilities and stockholders' equity	$ 368,490	$ 168,529

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

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

(In thousands, except per share amounts)

	Year Ended December 31,		
	2023	2022	2021
Revenues	$ —	$ —	$ —
Operating expenses:			
Research and development	63,806	54,234	44,981
General and administrative	37,021	16,121	10,701
Total operating expenses	100,827	70,355	55,682
Loss from operations	(100,827)	(70,355)	(55,682)
Other income (expense):			
Amortization of financing costs	(88)	(59)	(18)
Interest income, net	15,020	1,589	703
Realized loss on investments, net	—	(42)	—
Foreign exchange gain	—	—	7
Total other income, net	14,932	1,488	692
Net loss	(85,895)	(68,867)	(54,990)
Other comprehensive loss, net of tax:			
Unrealized gain (loss) on securities	742	(295)	(495)
Foreign currency translation loss	(29)	(258)	—
Comprehensive loss	$ (85,182)	$ (69,420)	$ (55,485)
Basic and diluted net loss per share	$ (0.91)	$ (0.90)	$ (0.71)
Weighted-average shares used to compute basic and diluted net loss per share	94,347	76,834	77,198

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

Viking Therapeutics, Inc.
Consolidated Statements of Stockholders' Equity

(In thousands, except share amounts)

	Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Treasury Stock	
	Shares	Amount	Capital	Deficit	Loss	Amount	Total
Balance at December 31, 2020	**73,215,940**	**$ 1**	**$ 412,589**	**$ (168,192)**	**$ (54)**	**$ —**	**$244,344**
Employee stock-based compensation, net	—	—	6,100	—	—	—	6,100
Shares withheld related to employee tax withholding	(117,025)	—	(707)	—	—	—	(707)
Issuance of common stock under employee stock plans	421,174	—	570	—	—	—	570
Issuance of common stock from warrant exercises	4,728,312	—	7,062	—	—	—	7,062
Unrealized loss on investments	—	—	—	—	(495)	—	(495)
Net loss	—	—	—	(54,990)	—	—	(54,990)
Balance at December 31, 2021	**78,248,401**	**$ 1**	**$ 425,614**	**$ (223,182)**	**$ (549)**	**$ —**	**$201,884**
Employee stock-based compensation, net	—	—	8,673	—	—	—	8,673
Shares withheld related to employee tax withholding	(215,498)	—	(1,533)	—	—	—	(1,533)
Issuance of common stock under employee stock plans	521,319	—	215	—	—	—	215
Issuance of common stock from warrant exercises	487,087	—	633	—	—	—	633
Repurchase of common stock	(2,193,251)	—	—	—	—	(6,795)	(6,795)
Sale of common stock, net of issuance costs	1,409,200	—	11,665	—	—	—	11,665
Unrealized loss on investments	—	—	—	—	(295)	—	(295)
Unrealized currency translation loss	—	—	—	—	(258)	—	(258)
Net loss	—	—	—	(68,867)	—	—	(68,867)
Balance at December 31, 2022	**78,257,258**	**$ 1**	**$ 445,267**	**$ (292,049)**	**$ (1,102)**	**$ (6,795)**	**$145,322**
Employee stock-based compensation, net	—	—	16,750	—	—	—	16,750
Shares withheld related to employee tax withholding	(509,686)	—	(7,121)	—	—	—	(7,121)
Issuance of common stock under employee stock plans	2,359,694	—	6,768	—	—	—	6,768
Sale of common stock, net of issuance costs	20,006,504	—	271,882	—	—	—	271,882
Unrealized gain on investments	—	—	—	—	742	—	742
Unrealized currency translation loss	—	—	—	—	(29)	—	(29)
Net Loss	—	—	—	(85,895)	—	—	(85,895)
Balance at December 31, 2023	**100,113,770**	**$ 1**	**$ 733,546**	**$ (377,944)**	**$ (389)**	**$ (6,795)**	**$348,419**

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

Viking Therapeutics, Inc.
Consolidated Statements of Cash Flows

(In thousands)

	Year Ended December 31,		
	2023	**2022**	**2021**
Cash flows from operating activities			
Net loss	$ (85,895)	$ (68,867)	$ (54,990)
Adjustments to reconcile net loss to net cash used in operating activities			
(Accretion) amortization of investment premiums	(8,202)	1,217	3,906
Amortization of financing costs	88	59	18
Stock-based compensation	16,750	8,673	6,100
Amortization of right-of-use assets	292	291	296
Interest expense related to operating lease liability	43	41	11
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	6,408	(3,130)	(711)
Accrued interest, net of interest receivable on maturity of investments	321	614	1,176
Accounts payable	(1,018)	7,085	(2,544)
Accrued expenses	(1,816)	5,809	(506)
Lease liability	(347)	(189)	(342)
Net cash used in operating activities	(73,376)	(48,397)	(47,586)
Cash flows from investing activities			
Purchases of investments	(478,303)	(121,431)	(168,015)
Proceeds from sales and maturities of investments	299,217	176,184	205,975
Net cash (used in) provided by investing activities	(179,086)	54,753	37,960
Cash flows from financing activities			
Public offering, net of offering costs	269,760	(22)	(46)
Value of shares withheld related to employee tax withholding	(7,121)	(1,533)	(707)
Repurchase of common stock	—	(6,795)	—
Proceeds from warrant and option exercises and stock issuances under employee stock purchase plan	6,768	848	7,633
ATM offering, net of fees	1,969	11,665	—
Net cash provided by financing activities	271,376	4,163	6,880
Net increase (decrease) in cash and cash equivalents	18,914	10,519	(2,746)
Cash and cash equivalents beginning of period	36,632	26,371	29,117
Effect of exchange rate changes on cash	(30)	(258)	-
Cash and cash equivalents end of period	$ 55,516	$ 36,632	$ 26,371
Supplemental disclosure of non-cash investing and financing transactions			
Unpaid deferred public offering and other financing costs	$ 50	$ 31	$ 50
Right-of-use asset obtained in exchange for lease obligation	$ —	$ 1,664	$ —

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

Viking Therapeutics, Inc.

Notes to Consolidated Financial Statements

1. Organization, Liquidity and Management's Plan, 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, CA, with a subsidiary located in Adelaide, Australia.

Basis of Presentation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP").

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 financial statements. Significant estimates made in preparing these financial statements relate to accounting for accruals for our clinical and preclinical efforts and stock-based compensation. Actual results could differ from those estimates.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its subsidiary, Viking Therapeutics, PTY LTD, incorporated in Australia. To date, the aggregate operations of this subsidiary have not been significant and all intercompany transactions and balances have been eliminated in consolidation.

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 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 5 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 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 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.

In May 2014, the Company entered into a master license agreement, pursuant to which it acquired certain rights to a number of research and development programs from Ligand Pharmaceuticals Incorporated ("Ligand"). In doing so, the Company updated its policy on research and development to include the purchase of rights to intangible assets. In accordance with Accounting Standards Codification ("ASC") Topic 730, *Research and Development,* intangible assets that are acquired and have an alternative future use, as defined, should be capitalized and reported as an intangible asset; however, the cost of acquired intangible assets that do not have alternative future uses should be reported as research and development expense as incurred. The Company notes that intangible assets acquired that are in the preclinical or clinical stages of development when acquired, and not approved by the U.S. Food and Drug Administration, are deemed to have not satisfied the definition of having an alternative future use, as defined. Accordingly, assets acquired in the preclinical and clinical stages of development are expensed as incurred in the Company's statement of operations.

Related to the Company's Australian subsidiary, Viking Therapeutics, PTY LTD, the Company is eligible, and has received, under the AusIndustry Research and Tax Development Tax Incentive Program, an amount of cash from the Australian Taxation Office (ATO). The annual 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 "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 ESPP also allows for up to one increase in contributions during each purchase period, as an employee elects to increase his or her 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.

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.

ASC Topic 740-10, *Income Taxes*, clarifies the accounting for uncertainty in income taxes recognized in the Company's 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 is 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.

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):

	Year Ended December 31,		
	2023	2022	2021
Historical net loss per share			
Numerator			
Net loss	$ (85,895)	$ (68,867)	$ (54,990)
Denominator			
Weighted-average common shares outstanding	94,530,086	77,016,725	77,380,775
Less: Weighted-average shares subject to repurchase	(183,095)	(183,095)	(183,095)
Denominator for basic and diluted net loss per share	94,346,991	76,833,630	77,197,680
Basic and diluted net loss per share	$ (0.91)	$ (0.90)	$ (0.71)

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):

	Year Ended December 31,		
	2023	2022	2021
Common stock warrants	—	—	487,087
Restricted stock units	2,855,656	1,868,518	962,299
Common stock subject to repurchase	183,095	183,095	183,095
Common stock options	5,248,682	5,157,857	4,088,084
	8,287,433	7,209,470	5,720,565

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 December 31, 2023 and 2022, the Company's investments were in money market funds, commercial paper and corporate debt securities. There were no sales of available-for-sale securities during the years ended December 31, 2023 and 2022.

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
	$ 306,661	$ 156	$ (254)	$ 306,563

(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 balance sheet and none 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, 2022 consisted of the following (in thousands):

As of December 31, 2022	Amortized Cost	Gross Unrealized Gains [1]	Gross Unrealized Losses [1]	Aggregate Estimated Fair Value
Commercial paper [2]	$ 43,780	$ —	$ —	$ 43,780
Corporate debt securities [2]	72,183	—	(824)	71,359
Government debt securities [2]	3,732	—	(18)	3,714
	$ 119,695	$ —	$ (842)	$ 118,853

(1) Unrealized gains and losses on available-for-sale securities are included as a component of comprehensive loss. At December 31, 2022, there were no securities in an unrealized gain position and 39 securities in an unrealized loss position. The unrealized losses were less than $124,000 individually and $842,000 in the aggregate. Twenty-two 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, 2022, none of these securities were classified as cash and cash equivalents on the Company's 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 December 31, 2023 and 2022, 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 and certificates of deposit. The Company's financial assets valued based on Level 2 inputs consist of corporate 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 December 31, 2023, the Company's investments were in government money market funds, commercial paper and corporate debt securities.

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

	Total	Fair Value Measurements at December 31, 2023 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	$ 347,042	$ 16,411	$ 330,631	$ —

	Total	Fair Value Measurements at December 31, 2022 Level 1	Level 2	Level 3
Financial assets carried at fair value:				
Cash equivalents:	$ 16,243	$ 5,617	$ 10,626	$ —
Short-term investments				
Commercial paper, available for sale	43,780	—	43,780	—
Corporate debt securities, available-for-sale	71,359	—	71,359	—
Government debt securities, available-for-sale	3,714	—	3,714	—
Total financial assets	$ 135,096	$ 5,617	$ 129,479	$ —

4. Agreements with Ligand Pharmaceuticals Incorporated

In May 2014, the Company entered into a master license agreement with Ligand, as amended (the "Master License Agreement"), pursuant to which, among other things, the Company acquired the rights to a number of research and development programs under patents related to the Company's VK2809, VK0214, VK5211, VK0612, erythropoietin receptor ("EPOR") and diacylglycerol acyltransferase-1 ("DGAT-1") programs, related know-how controlled by Ligand and physical quantities of VK2809, VK0214, VK5211, VK0612, EPOR and DGAT-1 compounds.

Pursuant to the terms of the Master License Agreement, the Company has the exclusive right and sole responsibility and decision-making authority for researching and developing any pharmaceutical products that contain or comprise one or any combination of the technology and compounds licensed from Ligand pursuant to the Master License Agreement (the "Licensed Products"). The Company also has the exclusive right and sole responsibility and decision-making authority to conduct all clinical trials and preclinical studies that the Company believes are appropriate to obtain the regulatory approvals necessary for commercialization of the Licensed Products, and the Company will own and maintain all regulatory filings and all regulatory approvals for the Licensed Products. Additionally, pursuant to the terms of the Master License Agreement, the Company has the sole decision-making authority and responsibility and the exclusive right to commercialize any of the Licensed Products, either by itself or, in certain circumstances, through sublicensees selected by the Company. The Company also has the exclusive right to manufacture or have manufactured any Licensed Product itself or, in certain circumstances, through sublicensees or third parties selected by the Company. The Company will own any intellectual property that it develops in connection with the license granted under the Master License Agreement.

As partial consideration for the grant of the rights and licenses to the Company under the Master License Agreement, the Company issued to Ligand at the closing of the Company's initial public offering ("IPO") 3,655,964 shares of its common stock having an estimated aggregate value of $29.2 million.

As further partial consideration for the grant of the rights and licenses to the Company by Ligand under the Master License Agreement, the Company has agreed to pay to Ligand certain one-time, non-refundable milestone payments in connection with the Licensed Products of up to $1.54 billion in the aggregate upon the achievement of certain development, regulatory and sales milestones. The Company will also pay to Ligand royalties on aggregate annual worldwide net sales of Licensed Products by the Company, its affiliates and its sublicensees at tiered percentage rates from the low-to-upper single digits based upon net sales.

The term of the Master License Agreement will continue unless the agreement is terminated by the Company or Ligand, and each of the Company and Ligand have the right to terminate the Master License Agreement in certain circumstances, including, without limitation, if the other party defaults on certain of its obligations under the Master License Agreement.

Ligand has the right to terminate the Master License Agreement under certain circumstances, including, but not limited to: (1) in the event of the Company's insolvency or bankruptcy, (2) if the Company does not pay an undisputed amount owing under the Master License Agreement when due and fails to cure such default within a specified period of time, or (3) if the Company defaults on certain of its material and substantial obligations and fails to cure the default within a specified period of time. The Company has the right to terminate the Master License Agreement under certain circumstances, including, but not limited to: (i) if Ligand does not pay an undisputed amount owing under the Master License Agreement when due and fails to cure such default within a specified period of time, or (ii) if Ligand defaults on certain of its material and substantial obligations and fails to cure the default within a specified period of time. In addition, provisions of the Master License Agreement can be terminated on a licensed program-by-program basis under certain circumstances. In the event that the Master License Agreement is terminated in its entirety or with respect to a specific licensed program for any reason: (A) all licenses granted to the Company under the Master License Agreement (or with respect to the specific licensed program) will terminate and the Company will, upon Ligand's request (subject to Ligand assuming legal responsibility for any clinical trials of the Licensed Products then ongoing), assign and transfer to Ligand (or to such transferee as Ligand may direct), at no cost to Ligand, all regulatory documentation and all regulatory approvals prepared or obtained by the Company or on its behalf related to the Licensed Products (or those related to the specific licensed program), or, if Ligand does not make such a request, the Company will wind down any ongoing clinical trials with respect to the Licensed Products (or those related to the specific licensed program) at no cost to Ligand; (B) the Company will, upon Ligand's request, sell and transfer to Ligand (or to such transferee as Ligand may direct), at a price equal to 125% of the Company's costs of goods, any and all chemical, biological or physical materials relating to or comprising the Licensed Products (or those related to the specific licensed program); (C) the Company will have, for a period of six months following termination, the right to sell on the normal business terms in existence before such termination any finished commercial inventory of Licensed Products (or those related to the specific licensed program) which remains on hand, so long as the Company pays to Ligand the applicable royalties and sales milestones; (D) Ligand has the right to require the Company to assign to Ligand the trademarks owned by the Company relating to the Licensed Products (or those related to the specific licensed program); and (E) the Company will grant to Ligand a non-exclusive, worldwide, royalty-bearing sublicensable license under any patent rights and know-how controlled by the Company to the extent necessary to make, have made, import, use, offer to sell and sell the Licensed Products (or those related to the specific licensed program) anywhere in the world at a royalty rate in the low single digits.

Under the Master License Agreement, the Company has agreed to indemnify Ligand for claims relating to the performance of the Company's obligations under the Master License Agreement, any breach of the representations and warranties made by the Company under the Master License Agreement, clinical trials conducted by the Company and the research, development and commercialization of the Licensed Products by the Company and its affiliates, sublicensees, distributors and agents. In addition, Ligand has agreed to indemnify the Company for claims relating to the performance of its obligations under the Master License Agreement, its breach of representations and warranties under the agreement and its research and development of the licensed compounds before the effective date of the Master License Agreement. Each party's indemnification obligations will not apply to the extent the claims result from the negligence or willful misconduct of the indemnified party or any of its employees, agents, officers or directors or from the indemnified party's breach of its representations or warranties set forth in the Master License Agreement.

In May 2014, the Company also entered into a Management Rights Letter (the "Management Rights Letter") with Ligand that required the Company to expand the size of the Company's Board of Directors to create an additional directorship on the Company's Board of Directors and to allow Ligand to appoint an individual to fill the new directorship. On March 28, 2023, the Management Rights Letter terminated upon the date that Ligand ceased to beneficially own at least 7.5% of the Company's outstanding voting stock.

5. Operating Leases – Right-of-Use Assets and Lease Liability Obligations

As of December 31, 2023, the Company has only one operating lease (the "Office Lease"), which is for office space under a lease that commenced on March 1, 2022 and expires in July 2027 (the "Term"). Below is a summary of the Company's right-of-use assets and lease liabilities as of December 31, 2023 and 2022 (in thousands, except for years and %):

	December 31, 2023	December 31, 2022
Right of use assets	$ 1,126	$ 1,418
Lease liability obligations, current	$ 324	$ 304
Lease liability obligations, less current portion	936	1,260
Total lease liability obligations	$ 1,260	$ 1,564
Weighted-average remaining lease term	3.58 years	4.58 years
Weighted-average discount rate	3.00 %	3.00 %

During the years ended December 31, 2023, 2022 and 2021, the Company recognized $339,000, $340,000 and $320,000, respectively, in operating lease expenses, which are included in operating expenses in the Company's statement of operations.

Approximate future minimum lease payments for the Company's right-of-use assets over the remaining lease period as of December 31, 2023 are as follows (in thousands):

2024	$	357
2025		368
2026		379
2027		227
Total minimum lease payments	$	1,331
Less: amount representing interest	$	(71)
Total lease liability obligations	$	1,260

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 Office Lease, 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 of the Office Lease was recognized as part of the Company's lease liability and right-of-use assets.

6. Stockholders' Equity

Preferred Stock

The Company is authorized to issue up to 10,000,000 shares of $0.00001 par value preferred stock, with no shares of preferred stock outstanding as of December 31, 2023 and 2022. The Company's Board of Directors is authorized to designate the terms and conditions of any preferred stock the Company issues without further action by the common stockholders.

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 will 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; therefore, the Company recorded $31,000 of stock-based compensation expense through December 31, 2016. No similar expense was recognized during the years ended December 31, 2023 and 2022. 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 September 28, 2017, the Company entered into a purchase agreement (the "Commitment Purchase Agreement") with Lincoln Park Capital Fund, LLC ("LPC"), pursuant to which the Company has the right to sell to LPC up to $15,000,000 in shares of common stock, subject to certain limitations and conditions set forth in the Commitment Purchase Agreement. The Company has the right, from time to time at its sole discretion until May 1, 2023, to direct LPC to purchase up to 75,000 shares of common stock on any business day (subject to certain limitations contained in the Commitment Purchase Agreement), with such amounts increasing based on certain threshold prices set forth in the Commitment Purchase Agreement; however, not to exceed $1.0 million in total purchase proceeds per purchase date. The purchase price of shares of common stock that the Company elects to sell to LPC pursuant to the Commitment Purchase Agreement will be based on the market prices of the common stock at the time of such purchases as set forth in the Commitment Purchase Agreement. In addition to regular purchases, as described above, the Company may also direct LPC to purchase additional amounts as accelerated purchases or as additional purchases if the closing sale price of the common stock is not below certain threshold prices, as set forth in the Commitment Purchase Agreement. In all instances, the Company may not sell shares of its common stock to LPC under the Commitment Purchase Agreement if it would result in LPC beneficially owning more than 4.99% of the Company's common stock. As consideration for LPC's commitment to purchase shares of common stock pursuant to the Commitment Purchase Agreement, the Company issued to LPC 100,000 shares of common stock. From inception of the Commitment Purchase Agreement through December 31, 2017, 343,051 shares were issued pursuant to the Commitment Purchase Agreement resulting in aggregate gross proceeds of $802,000 in addition to the Initial Shares and the Commitment Shares. In May 2020, the Company extended the termination date of the Commitment Purchase Agreement to May 1, 2023, and the Commitment Purchase Agreement terminated on that date. No additional shares were issued during the years ended December 31, 2018 through 2022 or during 2023 until the termination date.

On July 28, 2021, the Company filed with the SEC a universal Shelf Registration Statement on Form S-3 (File No. 333-258231) (the "2021 Shelf Registration Statement"). The 2021 Shelf Registration Statement provided the Company with the ability to offer up to $600.0 million of securities, including equity, debt and other securities as described in the 2021 Shelf Registration Statement. The 2021 Shelf Registration Statement was declared effective by the SEC on August 11, 2021 and the offering of all remaining unsold securities under the 2021 Shelf Registration Statement terminated on July 26, 2023.

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 may 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 the 2021 Shelf Registration Statement and the 424(b) prospectus supplement relating to the ATM Offering dated August 11, 2021. The 2021 Shelf Registration Statement terminated on July 26, 2023. From its inception through the termination of the 2021 Shelf Registration Statement, 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 17, 2020, the Company's Board of Directors authorized a stock repurchase program, whereby the Company may purchase up to $50.0 million in shares of its common stock and outstanding warrants to purchase its common stock, over a period of up to two years (the "Repurchase Program"). The Repurchase Program could 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 17, 2022, the termination date of the Repurchase Program, an aggregate of 1,464,217 shares of the Company's common stock were repurchased by the Company under the Repurchase Program. These shares repurchased by the Company under the Repurchase Program are being held in treasury until such time as they are reissued or retired by the Company.

On March 10, 2022, the Company's Board of Directors authorized a new stock repurchase program effective March 18, 2022, whereby the Company may purchase up to $50.0 million in shares of its common stock over a period of up to two years (the "New Repurchase Program"). The New Repurchase Program may 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 December 31, 2023, 729,034 shares of the Company's common stock were repurchased by the Company under the New Repurchase Program. Shares repurchased by the Company under the New Repurchase Program are being held in treasury until such time as they are reissued or retired by the Company.

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 December 31, 2023, no shares of the Company's common stock were sold pursuant to the ATM Offering and, as of December 31, 2023, the Company may sell shares of its common stock for remaining gross proceeds of up to $200.0 million from time to time pursuant to the ATM Prospectus.

During the years ended December 31, 2023, 2022 and 2021, and in accordance with the ESPP, the Company issued an aggregate of 180,174, 111,750 and 43,408 shares of its common stock to certain employees, respectively.

7. Stock-Based Compensation

In connection with the IPO, the Company's 2014 Equity Incentive Plan (the "2014 Plan") and the ESPP became effective on April 28, 2015, the date of the execution and delivery of the underwriting agreement for the IPO. A total of 1,527,770 shares of the Company's common stock were initially reserved for issuance under the 2014 Plan, and 458,331 shares of the Company's common stock were initially reserved for issuance under the ESPP. From January 1, 2016 and through December 31, 2023, in accordance with the terms of the 2014 Plan, an additional 15,407,065 shares of the Company's common stock were added to the number of shares reserved for issuance under the 2014 Plan, and, in accordance with the terms of the ESPP, an additional 4,402,017 shares of the Company's common stock were added to the number of shares reserved for issuance under the ESPP.

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 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 ESPP also 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 2014 Plan provides that the compensation committee of the Company's Board of Directors (the "Compensation Committee") may 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 number of shares available for issuance under the 2014 Plan will, unless otherwise determined by the Company's Board of Directors or the Compensation Committee, be automatically increased on January 1st of each year commencing on January 1, 2016 and ending 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 31st 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. 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 will 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, will again be available for issuance under the 2014 Plan.

ESPP. Initially, a total of 458,331 shares of the Company's common stock were reserved for issuance pursuant to the ESPP. The number of shares available for issuance under the ESPP will, unless otherwise determined by the Company's Board of Directors or the Compensation Committee, be automatically increased on January 1st of each year commencing on January 1, 2016 and ending 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 31st of the preceding calendar year. The shares of common stock available for purchase pursuant to the ESPP are authorized but unissued shares of the Company's common stock, shares of the Company's common stock that the Company otherwise holds 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 will be offered for purchase under the ESPP as determined by the Compensation Committee through a series of successive offerings that each have a term of 24 months and consist of four consecutive purchase periods of six months each. Prior to the commencement of any future offering under the 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 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 (the "Code")), is eligible to participate in the ESPP for each purchase period within such offering. The purchase price per share of the Company's common stock under the 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 years ended December 31, 2023, 2022 and 2021, the Company recognized the following stock-based compensation expense (in thousands):

	Year Ended December 31,		
	2023	2022	2021
Stock-based compensation expense by type of award:			
Stock options	5,768	3,842	3,276
Restricted stock and restricted stock units	9,420	4,598	2,597
Employee stock purchase plan	1,562	233	227
Total stock-based compensation expense included in expenses	$ 16,750	$ 8,673	$ 6,100
Stock-based compensation expense by line item:			
Research and development expenses	4,732	2,313	1,623
General and administrative expenses	12,018	6,360	4,477
Total stock-based compensation expense included in expenses	$ 16,750	$ 8,673	$ 6,100

The following table sets forth the Company's unrecognized stock-based compensation expense, net of estimated forfeitures, 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 December 31, 2023	
	Unrecognized Expense	Weighted-average Recognition Period (in years)
Type of award:		
Stock options	$ 9,216	2.68
Restricted stock and restricted stock units	$ 9,723	1.81

The following table is a summary of restricted shares granted during the years ended December 31, 2023, 2022 and 2021:

	Shares	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2020	183,095	$ 0.17
Granted	—	$ —
Vested	—	$ —
Forfeited	—	$ —
Repurchased	—	$ —
Unvested at December 31, 2021	183,095	$ 0.17
Granted	—	$ —
Vested	—	$ —
Forfeited	—	$ —
Repurchased	—	$ —
Unvested at December 31, 2022	183,095	$ 0.17
Granted	—	$ —
Vested	—	$ —
Forfeited	—	$ —
Repurchased	—	$ —
Unvested at December 31, 2023	183,095	$ 0.17

The following table summarizes restricted stock unit activity during the years ended December 31, 2023, 2022 and 2021:

	Shares	Weighted-Average Grant Date Value
Unvested at December 31, 2020	679,363	$ 7.65
Granted	654,820	$ 5.80
Vested	(270,063)	$ 7.47
Forfeited	(35,821)	$ 6.14
Unvested at December 31, 2021	1,028,299	$ 6.57
Granted	1,249,788	$ 4.88
Vested	(409,569)	$ 6.88
Forfeited	—	$ —
Unvested at December 31, 2022	1,868,518	$ 5.37
Granted	1,772,243	$ 8.52
Vested	(785,105)	$ 5.40
Forfeited	—	$ —
Unvested December 31, 2023	2,855,656	$ 7.32

In January 2019, the Company issued 221,600 performance-based restricted stock units ("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, with any then-unvested portion of the PRSU awards to be cancelled on the four-year anniversary of the grant dates. As of December 31, 2022, 40,000 PRSU awards were forfeited and three of the milestones had been met, resulting in the Company recording stock-based compensation expense of $1.4 million through December 31, 2022.

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 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, with any then-unvested portion of the PRSU awards to be cancelled on the four-year anniversary of the grant dates. As of December 31, 2023, 10,500 PRSU awards were forfeited, two of the three milestones had been met and the remaining one was deemed improbable of achievement, resulting in the Company recording cumulative stock-based compensation expense of $1.2 million through December 31, 2023 and stock-based compensation expense of $(454,000) during the year ended December 31, 2023.

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 dates. As of December 31, 2023, 10,000 PRSU awards were forfeited, one of the four milestones had been met and two of the four milestones were deemed probable of achievement, resulting in the Company recording cumulative stock-based compensation expense of $1.0 million through December 31, 2023 and stock-based compensation expense of $64,000 during the year ended December 31, 2023.

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 dates. As of December 31, 2023, no PRSU awards were forfeited, three of the four milestones had been met and the remaining one was deemed probable of achievement, resulting in the Company recording cumulative stock-based compensation expense of $3.9 million through December 31, 2023 and stock-based compensation expense of $2.0 million during the year ended December 31, 2023.

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 dates. As of December 31, 2023, no PRSU awards were forfeited and all four of the milestones were deemed probable of achievement, resulting in the Company recording stock-based compensation expense of $5.0 million during the year ended December 31, 2023.

The following table summarizes stock option activity during the years ended December 31, 2023, 2022 and 2021:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Options outstanding at December 31, 2020	3,371,323	$ 5.57	7.32	$ 389,000
Granted	1,081,520	$ 5.87		
Exercised	(107,703)	$ 3.26		
Forfeited	(132,745)	$ 6.25		
Cancelled	(124,311)	$ 7.48		
Options outstanding at December 31, 2021	4,088,084	$ 5.63	7.02	$ 2,885,000
Granted	1,109,773	$ 4.79		
Exercised	—	$ —		
Forfeited	(30,000)	$ 5.16		
Cancelled	(10,000)	$ 5.16		
Options outstanding at December 31, 2022	5,157,857	$ 5.45	6.66	$20,515,000
Granted	1,488,990	$ 9.34		
Exercised	(1,394,415)	$ 4.59		
Forfeited	—	$ —		
Cancelled	(3,750)	$ 4.05		
Options outstanding at December 31, 2023	5,248,682	$ 6.79	7.10	$62,210,000
Options exercisable at December 31, 2023	2,471,741	$ 6.05	5.71	$31,097,000

The Company received $6.4 million, $0 and $351,000 in cash proceeds from exercises of stock options during the years ended December 31, 2023, 2022 and 2021, respectively.

The total fair value of stock options that vested during the years ended December 31, 2023, 2022 and 2021 was $4.0 million, $3.2 million and $2.9 million, respectively.

Compensation expense 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 years ended December 31, 2023, 2022 and 2021 was $6.76, $3.50 and $4.16, respectively.

As stock-based compensation expense recognized is based on options ultimately expected to vest, the fair value of each employee option grant during the years ended December 31, 2023, 2022 and 2021 was estimated on the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions:

	Year ended December 31,		
	2023	2022	2021
Expected volatility	81.3%	86.6%	84.7%
Expected term (in years)	6.17	6.13	6.10
Risk-free interest rate	3.88%	1.67%	0.67%
Expected dividend yield	0%	0%	0%

Expected Volatility. Historically through December 31, 2021, the expected volatility rate used to value stock option grants was based on volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies in the pharmaceutical and biotechnology industry in a similar stage of development to the Company. Given the length of time the Company's common stock has been publicly traded, starting January 1, 2022, 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 December 31, 2023, no excess tax benefits for the tax deductions related to stock-based awards were recognized in the Consolidated Statements of Operations.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance as of December 31, 2023 is as follows:

Restricted stock units	2,855,656
Common stock options	5,248,682
Available for grant under the 2014 Plan	6,526,433
Available for issuance under Employee Stock Purchase Plan	4,251,444
	18,882,215

8. Warrants

On April 13, 2016, pursuant to an underwritten public offering (the "April 2016 Offering"), the Company sold 7,500,000 shares of its common stock and warrants to purchase up to 7,500,000 shares of its common stock at a public offering price of $1.25 per share of common stock and related warrant. The warrants had an exercise price of $1.50 per share of common stock and were immediately exercisable upon issuance and expired on April 13, 2021. Additionally, on April 13, 2016, the underwriters for the April 2016 Offering partially exercised the over-allotment option for warrants to purchase an additional 1,125,000 shares of the Company's common stock at a public offering price of $0.01 per warrant to purchase a share of common stock. During the year ended December 31, 2021, 3,618,312 warrants were exercised, and 29,101 warrants expired unexercised on April 13, 2021.

On April 13, 2016, pursuant to the terms of the loan and security agreement with Ligand, the Company issued to Ligand a warrant to purchase up to 960,000 shares of the Company's common stock (the "Ligand Warrant"). The Ligand Warrant had an exercise price of $1.50 per share of the Company's common stock, was immediately exercisable upon issuance (subject to a limitation on exercise to the extent that any exercise thereof would increase Ligand's beneficial ownership of the Company's common stock to greater than 49.9%) and was set to expire on April 13, 2021. The Ligand Warrant was issued to Ligand as part of the repayment of $1.2 million of the Company's obligation under the secured convertible promissory note issued by the Company to Ligand pursuant to that certain loan and security agreement with Ligand. The Ligand Warrant was exercised in full during the year ended December 31, 2021.

On June 14, 2017, the Company entered into a securities purchase agreement, with certain accredited investors (the "Purchasers"), pursuant to which the Company sold an aggregate of 3,749,783 shares (the "Shares") of its common stock, and the warrants to purchase up to an aggregate 2,812,337 shares of its common stock to the Purchasers (the "Warrants"). The combined purchase price for one Share and one Warrant to purchase 0.75 shares of common stock was $1.15. The closing of the issuance of the Shares and the Warrants occurred on June 19, 2017. The Warrants had an exercise price of $1.30 per share, subject to adjustment as provided therein, and became exercisable beginning on December 19, 2017 through December 19, 2022. The Warrants were exercised in full as of December 31, 2022.

9. Income Taxes

Income tax expense from continuing operations consists of the following for the years ended December 31, 2023, 2022 and 2021 (in thousands):

	December 31,		
	2023	2022	2021
Current:			
Federal	$ —	$ —	$ —
State	1	1	2
	$ 1	$ 1	$ 2
Deferred:			
Federal	$ (22,303)	$ (16,075)	$ (13,281)
State	(6,785)	(6,016)	(4,182)
	$ (29,088)	$ (22,091)	$ (17,463)
Change in valuation allowance	29,088	22,091	17,463
Total income tax expense	$ 1	$ 1	$ 2

The reconciliations of the U.S. federal statutory tax rate to the effective income tax rate for the years ended December 31, 2023, 2022 and 2021 are as follows:

	December 31,		
	2023	2022	2021
Tax provision at U.S. Federal statutory rates	21%	21%	21%
State income taxes net of federal benefit	7%	7%	7%
Non-deductible permanent items	(1)%	(1)%	(1)%
Stock options	3%	—	1%
Research and development credits	4%	6%	4%
Change in valuation allowance	(34)%	(33)%	(32)%
Effective income tax rate	—	—	—

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred taxes as of December 31, 2023, 2022 and 2021 are as follows (in thousands):

	December 31,		
	2023	2022	2021
Deferred tax assets:			
Accrued liabilities	$ 437	$ 508	$ 80
Intangible assets	68,792	56,180	43,829
Net operating loss carryforwards	26,303	15,292	11,049
Share-based compensation	6,595	4,691	3,747
Credit Carryforwards	17,101	13,353	8,919
Other	44	242	161
Total deferred tax assets	119,272	90,266	67,785
Valuation Allowance	(118,957)	(89,869)	(67,778)
Total deferred tax assets, net of allowance	$ 315	$ 397	$ 7
Deferred tax liabilities:			
Right of use assets	$ (315)	$ (397)	$ (7)
Other	—	—	—
Total deferred tax liabilities:	$ (315)	$ (397)	$ (7)
Net deferred tax assets (liabilities):	$ —	$ —	$ —

A valuation allowance of $119.0 million and $89.9 million at December 31, 2023 and December 31, 2022, respectively, has been recorded to offset net deferred tax assets, as the Company is unable to conclude that it is more likely than not that such deferred tax assets will be realized.

At December 31, 2023, the Company 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. The Company has $79.9 million of state net operating loss carryforwards that will begin to expire in 2034.

The Company's ability to utilize its federal net operating loss carryforwards may be limited under Section 382 of the Code. Specifically, this limitation may arise in the event of an "ownership change," which is defined by Section 382 of the Code as a cumulative change in ownership of the Company of more than 50% within a three-year period. If the Company undergoes one or more ownership changes in connection with any future transactions in its stock, the Company's ability to utilize net operating loss carryforwards to offset federal taxable income, if any, could potentially result in increased future tax liability to the Company. An ownership change under Section 382 of the Code occurred during the year ended December 31, 2018. However, as of December 31, 2023, there is no limitation on the federal and state net operating losses.

The Company is subject to U.S. federal income tax as well as income tax in various state jurisdictions. The Company is currently open to audit under the statute of limitations by the Internal Revenue Service and various state agencies for the years ended December 31, 2019 through December 31, 2023.

At December 31, 2023, the Company has federal and state research and development tax credit carry-forwards of approximately $12.2 million and $4.9 million, respectively. The federal credits begin to expire in 2036. The state credits do not expire.

The differences between the Company's effective income tax rate and the statutory federal rate for the year ended December 31, 2023 and the year ended December 31, 2022 relate primarily to losses incurred for which no tax benefit was recognized, due to uncertainty of realization. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the

period in which those temporary differences become deductible. The Company considers projected future taxable income and tax planning strategies in making this assessment. At each of December 31, 2023 and December 31, 2022, the Company provided a full valuation allowance against its deferred tax assets due to uncertainty surrounding the realization of those assets as a result of historical taxable net losses.

The Coronavirus Aid, Relief, and Economic Security (CARES) Act was enacted on March 27, 2020. Among the business provisions, the CARES Act provided for various payroll tax incentives, changes to net operating loss carryback and carryforward rules, business interest expense limitation increases, and bonus depreciation on qualified improvement property. Additionally, the Consolidated Appropriations Act of 2021 was signed on December 27, 2020 which provided additional COVID relief provisions for businesses. The Company has evaluated the impact of both Acts and has determined that any impact is not material to its financial statements.

The Company has reviewed its operations and has not identified any material uncertain tax positions. As a result, there is no liability for uncertain tax positions in the income tax provision as of December 31, 2023 or December 31, 2022.

10. Related-Party Transactions

In May 2014, the Company entered into the Master License Agreement with Ligand, pursuant to which, among other things, Ligand granted the Company an exclusive worldwide license to certain clinical and preclinical programs. See Note 4 for more information related to this agreement. In connection with the Master License Agreement, the Company considered Ligand to be a related party.

11. Commitments and Contingencies

On May 25, 2018, the Company entered into an Office Lease (the "Lease") with Kilroy Realty, L.P. The Lease was for approximately 7,149 rentable square feet of space located at 12340 El Camino Real, Suite 250, San Diego, California 92130 (the "2018 Premises"). The 2018 Premises was the Company's corporate headquarters.

The Lease commenced on November 1, 2018 and expired on January 31, 2022. Monthly base rent payments due under the Lease for the 2018 Premises were $27,000, subject to annual increases of 3.0% during the Lease term. Under the Lease, the Company was responsible for certain charges for common area maintenance and other costs, including electricity and utility expenses and the Lease provided for abatement of rent during certain periods and escalating rent payments throughout the Lease term. Rent expense was recorded on a straight-line basis over the life of the Lease and the difference between the rent expense and rent paid was recorded as deferred rent.

On November 15, 2021, the Company entered into an Office Lease (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.

12. Subsequent Events

The Company evaluated subsequent events through the date of the filing of this Annual Report on Form 10-K with the SEC, to ensure that this filing includes appropriate disclosure of events both recognized in the financial statements as of December 31, 2023, and events which occurred subsequent to December 31, 2023 but were not recognized in the financial statements. The Company has determined that there were no subsequent events which required recognition, adjustment to or disclosure in the financial statements.