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, 2024
or

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

For the transition period from to
Commission file number 001-36483



VIRIDIAN THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**47-1187261**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

221 Crescent Street, Suite 103A, Waltham, MA 02453
(Address of principal executive offices)

Registrant's telephone number, including area code: **(617) 272-4600**

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value per share	VRDN	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 Section 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 definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

Indicate by check mark whether the registrant 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 Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant, based upon the closing sale price of the registrant's common stock on June 28, 2024, as reported on The Nasdaq Capital Market, was $731.8 million. Shares of common stock held by each executive officer and director and by each person who owns 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 20, 2025, there were 81,484,950 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the 2025 annual meeting of stockholders (the "2025 Proxy Statement") are incorporated herein by reference in Part III of this Annual Report on Form 10-K where indicated. The 2025 Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2024.

VIRIDIAN THERAPEUTICS, INC.
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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K ("Annual Report") contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. The words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "will," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Forward-looking statements contained in this Annual Report include, but are not limited to, statements about:

- the ability of our clinical trials to demonstrate safety and efficacy of our product candidates and other results;
- the potential utility, efficacy, potency, safety, clinical benefits, half-life, clinical response, convenience and number of indications of our product candidates, including our expectation that VRDN-003 will demonstrate a similar clinical response as veligrotug;
- the timing and focus of our ongoing and future nonclinical studies and clinical trials and the timing of reporting data from those studies and trials, including that we expect to receive VRDN-006 proof of concept immunoglobulin G ("IgG") reduction data in the third quarter of 2025 and that we anticipate submitting an Investigational New Drug Application ("IND") for VRDN-008 by the end of 2025;
- supply chain disruptions, enrollment in clinical trials involving our product candidates or other delays in such trials;
- our plans relating to commercializing our product candidates, including our plans to commercialize products candidates as combination products, if approved, including the geographic areas of focus and sales strategy;
- potential market sizes and market opportunities, including the rate and degree of market acceptance and clinical utility for our product candidates;
- expectations regarding the initiation of clinical trials and interactions and alignment with regulatory authorities;
- the timing or likelihood of regulatory filings and approvals, including the anticipated biologics license application ("BLA") submission for veligrotug in the second half of 2025 and a Marketing Authorization Application ("MAA") to the European Medicines Agency ("EMA") in the first half of 2026, as well as our expectation to seek an accelerated approval pathway and special designations, for our product candidates for various diseases;
- our plans relating to the further development of our product candidates, including additional indications we may pursue;
- our plans to obtain or protect intellectual property rights;
- our continued reliance on third parties to conduct additional clinical trials of our product candidates and for the manufacture of our product candidates for nonclinical studies, clinical trials and commercialization;
- our plans regarding any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- our estimates regarding expenses, future revenue, capital requirements and our ability to obtain additional financing to fund our operations and complete further development and commercialization of our product candidates; and
- the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements.

Any forward-looking statements in this Annual Report reflect our current views with respect to future events and with respect to our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those described under Part I, Item 1A, "Risk Factors" and elsewhere in this Annual Report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

All of our forward-looking statements are as of the date of this Annual Report only. In each case, actual results may differ materially from such forward-looking information. We can give no assurance that such expectations or forward-looking statements will prove to be correct. An occurrence of or any material adverse change in one or more of the risk factors or risks and uncertainties referred to in this Annual Report or included in our other public disclosures or our other periodic reports or other documents or filings filed with or furnished to the U.S. Securities and Exchange Commission ("SEC") could materially and adversely affect our business, prospects, financial condition and results of operations. Except as required by law, we do not undertake or plan to update or revise any such forward-looking statements to reflect actual results, changes in plans, assumptions, estimates or projections or other circumstances affecting such forward-looking statements occurring after the date of this Annual Report, even if such results, changes or circumstances make it clear that any forward-looking information will not be realized. Any public statements or disclosures by us following this Annual Report that modify or impact any of the forward-looking statements contained in this Annual Report will be deemed to modify or supersede such statements in this Annual Report.

We may from time to time provide estimates, projections and other information concerning our industry, the general business environment, and the markets for certain diseases, including estimates regarding the potential size of those markets and the estimated incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events, circumstances or numbers, including actual disease prevalence rates and market size, may differ materially from the information reflected in this Annual Report. Unless otherwise expressly stated, we obtained this industry, business information, market data, prevalence information and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources, in some cases applying our own assumptions and analysis that may, in the future, prove not to have been accurate.

Unless otherwise mentioned or unless the context requires otherwise, all references in this Annual Report, to "Viridian," "Viridian Therapeutics," the "Company," "we," "us," and "our" or similar references refer to Viridian Therapeutics, Inc. and our consolidated subsidiaries.

SUMMARY OF THE MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

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 "Item 1A. Risk Factors" and should be carefully considered, together with other information in this Annual Report and our other filings with the SEC, before making an investment decision regarding our common stock.

- If we are unable to raise additional capital when needed, we would be forced to delay, reduce, or eliminate our research and product development programs or future commercialization efforts.
- We have historically incurred losses, have a limited operating history on which to assess our business, and anticipate that we will continue to incur significant losses for the foreseeable future.
- Clinical trials are costly, time consuming, and inherently risky, and we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.
- Regulatory approval processes are lengthy, time-consuming and inherently unpredictable. Failure to obtain regulatory approval for our product candidates would have a material adverse effect upon our business and business prospects.
- Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial viability of approved labeling, or result in significant negative consequences following marketing approval, if any.
- We are heavily dependent on the success of our product candidates, which are in clinical development. Some of our product candidates have produced results only in nonclinical settings, or for other indications than those for which we contemplate conducting development and seeking U.S. Food and Drug Administration ("FDA") or other regulatory approval, and we cannot give any assurance that we will generate data for any of our product candidates sufficiently supportive to receive regulatory approval in our planned indications, which will be required before they can be commercialized.
- Product development involves a lengthy and expensive process with an uncertain outcome, and results of earlier nonclinical studies and clinical trials may not be predictive of future clinical trial results.
- We rely on third parties to conduct our nonclinical development activities and clinical trials, manufacture our product candidates, and perform other services. If these third parties do not successfully perform and/or comply with regulatory requirements, we may not be able to successfully complete clinical development, obtain regulatory approval, or commercialize our product candidates and our business could be substantially harmed.
- We rely on patent rights, trade secret protections, and confidentiality agreements to protect intellectual property, including intellectual property related to our product candidates and any future product candidates. If we are unable to obtain or maintain exclusivity from the combination of these approaches, we may not be able to compete effectively in our markets.
- If we are unable to establish commercial manufacturing, sales and marketing capabilities or enter into agreements with third parties to commercially manufacture, market and sell our product candidates, we may be unable to generate any revenue.
- We face substantial competition and our competitors may discover, develop, or commercialize products faster or more successfully than us.
- Our future success depends in part on our ability to attract, retain, and motivate qualified personnel. If we lose key personnel, or if we fail to recruit additional highly skilled personnel, our ability to develop our product candidates will be impaired and our business may be harmed.

PART I

ITEM 1. BUSINESS

Company Overview

We are a biopharmaceutical company focused on discovering, developing, and commercializing potential best-in-class medicines for serious and rare diseases. We target disease areas where marketed therapies often leave room for improvements in efficacy, safety, and/or dosing convenience. We believe that first-generation medicines rarely represent optimal solutions, especially in rare disease areas, and that there is potential to develop differentiated, best-in-class medicines that could lead to improved patient outcomes, reduced side effects, improved quality of life, expanded market access, and augmented market competition. Our business model is designed to identify and evaluate product opportunities in disease areas where trial data establishes proof-of-concept for a drug target in the clinic, but the competitive evolution of the product life cycle management and number of entrants appears incomplete. We intend to prioritize indications where a fast-follower and a potentially differentiated drug candidate, or overall product profile, could create significant medical benefit for patients. We are engineering product candidates to address unmet medical needs for patients and further advance drug innovation.

Our goal is to identify and evaluate product concepts leveraging clinically validated molecular targets using established therapeutic modalities. We prioritize product concepts that are aligned with clinical and commercial hypotheses, which we expect will provide an attractive balance of risk and opportunity, thereby representing a compelling allocation of our resources. We focus on advancing therapeutic proteins that we either in-license or discover internally, incorporating proprietary therapeutic protein and antibody discovery and optimization platforms to advance clinical candidates with unique characteristics. We have built relevant expertise in protein and antibody discovery and engineering, biologics manufacturing, nonclinical and clinical development, and commercialization for thyroid eye disease ("TED"), development of anti-neonatal Fc receptor ("FcRn") therapies, and nonclinical and clinical development for indications in rare and autoimmune diseases.

Our approach to rapidly discovering and developing novel therapeutics relies on our scientific expertise in evaluating pre-existing clinical proof-of-concept data for the drug targets we are pursuing, and opportunities to improve upon existing investigational and/or approved therapies. This approach informs how we design, select, and develop our product candidates, including in critical areas such as pharmacokinetics, pharmacodynamics, clinical trial design, trial endpoints, and the selection and recruitment of patients. We believe this strategy reduces the risks associated with discovering and developing novel therapeutics.

Development of Therapies to Treat Thyroid Eye Disease (TED)

We are developing therapies for the treatment of TED, a serious and debilitating rare autoimmune disease that causes inflammation within the orbit of the eye that can cause bulging of the eyes, redness and swelling, double vision, pain, and potential blindness. TED significantly impacts quality of life, imposing a high burden on activities of daily living and mental health for patients suffering from the disease. TED is a progressive disease consisting of an initial active phase ("active TED"), followed by a transition to a secondary chronic phase ("chronic TED"). The only medicine approved by the FDA for TED is Tepezza® (teprotumumab), which is an intravenously administered monoclonal antibody that targets insulin-like growth factor 1 receptor ("IGF-1R"). Tepezza is marketed in the United States ("U.S.") by Horizon Therapeutics plc ("Horizon"), which was acquired by Amgen Inc. ("Amgen") in October 2023. In 2024, Amgen gained approval for Tepezza in Japan and submitted a Marketing Authorization Application ("MAA") to the European Medicines Agency ("EMA").

The results from clinical trials of teprotumumab conducted by Horizon provide strong clinical validation linking the targeting of IGF-1R to clinical benefit in patients with TED. However, clinical trials evaluating teprotumumab in patients with TED reported to date used a single dosing regimen, providing little guidance as to the optimal dosing required for clinical activity in TED. We believe that there are multiple opportunities to develop fast-follower therapeutics that improve on teprotumumab's features, including dosing schedule, route of administration, and safety profile.

We are developing two product candidates, veligrotug (formerly known as VRDN-001) for intravenous ("IV") and VRDN-003 for subcutaneous ("SC") administration, to treat patients who suffer from TED. Our most advanced program, veligrotug, is a differentiated humanized monoclonal antibody targeting IGF-1R intravenously administered for the treatment of TED. In previously presented *in vitro* nonclinical data, we showed that veligrotug is a potentially differentiated full antagonist of IGF-1R, compared to teprotumumab's incomplete antagonism of IGF-1R. VRDN-003 has the same binding domain as veligrotug, and was engineered to have a longer half-life. VRDN-003 is designed to be a low-volume, infrequently-dosed subcutaneous IGF-1R for TED, which we plan to launch commercially with an auto-injector to enable at-home patient self-

administration. We believe VRDN-003 has the potential to be the best-in-class subcutaneous anti-IGF-1R product candidate by preserving the efficacy of anti-IGF-1Rs in TED, improving safety and maximizing convenience for patients.

We conducted phase 1/2 clinical trials of veligrotug in patients with active or chronic TED. In the active TED portion of the phase 1/2 clinical trials, data reported from all three dose cohorts of veligrotug (n=21) showed significant and rapid improvement in both the signs and symptoms of TED after two infusions of veligrotug compared to placebo. Across all veligrotug treated patients in the active TED trial, 71% were proptosis responders, 67% were overall responders, 62% achieved a clinical activity score ("CAS") of 0 or 1, and 54% had complete resolution of their diplopia. In the chronic TED portion of the phase 1/2 clinical trials, data reported from both dose cohorts of veligrotug (n=12) showed significant and rapid improvement in the signs and symptoms of TED after two infusions of veligrotug compared to placebo. Across all veligrotug treated patients in the chronic TED trial, 42% were proptosis responders, 40% achieved a CAS of 0 or 1, and no patients had complete resolution of their diplopia. In the phase 1/2 clinical trials of both active and chronic TED, veligrotug had a favorable safety profile and was well-tolerated by all patients treated in all dose cohorts.

We are conducting a global pivotal program for veligrotug, including evaluating its efficacy and safety in two global well-controlled phase 3 clinical trials, THRIVE and THRIVE-2, for the treatment of active and chronic TED, respectively. THRIVE and THRIVE-2 are each designed to compare a five-dose IV treatment arm of veligrotug at 10 mg/kg, dosed three weeks apart, to placebo. This five-dose veligrotug regimen features fewer infusions and a shorter time per infusion compared to teprotumumab, the currently marketed IGF-1R inhibitor. On September 10, 2024, we announced topline data from the THRIVE study, which enrolled 113 patients, randomized to veligrotug (n=75) and placebo (n=38). THRIVE achieved all primary and secondary endpoints with a high level of statistical significance ($p < 0.0001$) and was generally well-tolerated, with no treatment-related serious adverse events ("SAEs"). Veligrotug additionally showed a rapid onset of treatment effect, with the majority (53%) of veligrotug-treated patients achieving a proptosis response as early as three weeks. On December 16, 2024, we announced topline data from the THRIVE-2 study, which enrolled 188 patients, randomized to veligrotug (n=125) and placebo (n=63). THRIVE-2 achieved all primary and secondary endpoints with statistical significance and was generally well-tolerated. Veligrotug continued to demonstrate a rapid onset of treatment effect, with a statistically significant proptosis response as early as three weeks and a statistically significant reduction and resolution of diplopia as early as six weeks. THRIVE-2 is the first global phase 3 study in patients with chronic TED to demonstrate a statistically significant and clinically meaningful diplopia responder rate and rate of diplopia complete resolution. To meet the 300 patient standard safety database requirements for the veligrotug biologics license application ("BLA"), we are conducting our STRIVE clinical trial (safety database inclusive of patients from the THRIVE and THRIVE-2 trials). STRIVE is a global study of veligrotug in TED patients that utilizes broad inclusion criteria (e.g., any severity or duration of disease) and is randomized 3:1 (10 mg/kg IV with an active control of 3 mg/kg IV). In January 2025, we completed enrollment in STRIVE with a total of 231 patients, exceeding the enrollment target of 212 due to patient demand. We have also completed enrollment of the open label extension study for non-responding patients in THRIVE and THRIVE-2. We anticipate submitting a BLA for veligrotug in the second half of 2025 and an MAA to the EMA in the first half of 2026.

In addition to our intravenous veligrotug program, VRDN-003 is our subcutaneous product candidate currently in pivotal development in TED, which we selected in December 2023 following positive data in a phase 1 clinical trial in healthy volunteers.

The VRDN-003 phase 1 clinical study showed VRDN-003 to have a prolonged half-life of 40 to 50 days, which is four to five times that of veligrotug. Because of the healthy volunteer data and the similarities between the veligrotug and VRDN-003 antibodies, we expect VRDN-003 to have similar clinical responses at the exposure levels of veligrotug that led to robust clinical activity in its clinical trials to date in TED. Further, pharmacokinetic modeling of VRDN-003 based on the healthy volunteer data predicted that exposure levels of VRDN-003 could be achieved that are equivalent to exposure levels of veligrotug that produced clinically meaningful results with multiple dosing regimens of VRDN-003, i.e., subcutaneous injection every two, four, or eight weeks.

We are conducting a global pivotal program for VRDN-003, including evaluating its efficacy and safety in two global well-controlled phase 3 clinical trials, REVEAL-1 and REVEAL-2, for the treatment of active and chronic TED, respectively. Both studies will evaluate subcutaneous VRDN-003 administered every four weeks or every eight weeks and will assess outcomes versus placebo. Patient enrollment and dosing continues in both studies. In addition, to enable BLA submission for VRDN-003, we have initiated a safety study to meet the 300 patient standard safety database requirement (to also include patients from the REVEAL-1 and REVEAL-2 trials) and plan to initiate an auto-injector study in 2025 to enable launching VRDN-003 in an auto-injector device, if approved. We anticipate topline data for REVEAL-1 and REVEAL-2 in the first half of 2026, and we anticipate submitting a BLA for VRDN-003 for the treatment of TED by the end of 2026.

Development of FcRn Inhibitors

In addition to developing therapies for TED, we are also developing a portfolio of engineered FcRn inhibitors, including VRDN-006 and VRDN-008. FcRn inhibitors have the potential to treat a broad array of autoimmune diseases, representing a possible significant commercial market opportunity. Our multi-pronged engineering approach has resulted in a portfolio of FcRn-targeting molecules that leverage the clinically and commercially validated mechanism of FcRn inhibition while potentially addressing the limitations of current agents such as incomplete immunoglobulin G ("IgG") suppression, safety, and inconvenience of dosing.

VRDN-006 is a highly selective Fc fragment that inhibits FcRn and is designed to be a convenient subcutaneous and self-administered option for patients. In non-human primate ("NHP") studies, VRDN-006 demonstrated specificity for blocking FcRn-IgG interactions while not showing decreases in albumin or increases in low-density lipoprotein ("LDL") levels, which are known potential side effects associated with certain full-length anti-FcRn monoclonal antibodies. In our head-to-head NHP studies, VRDN-006 demonstrated comparable potency and IgG reductions to efgartigimod, which is the current standard of care in FcRn inhibition, as well as a similar safety profile. We submitted an IND for VRDN-006 in December 2024, which cleared in January 2025, and we expect proof-of-concept IgG reduction data in healthy volunteers in the third quarter of 2025.

VRDN-008 is a half-life extended bispecific FcRn inhibitor comprising an Fc fragment and an albumin-binding domain designed to prolong IgG suppression and provide a potentially best-in-class subcutaneous option for patients. In a single, high-dose, head-to-head study in NHPs, VRDN-008 demonstrated three times the half-life of efgartigimod. Additionally, VRDN-008 showed a deeper and more sustained IgG reduction with peak IgG reductions that were 20% deeper than efgartigimod while not showing decreases in albumin or increases in LDL levels. NHP studies are ongoing to generate additional data for VRDN-008. Once completed, we plan to use the totality of VRDN-008's NHP data to build a robust pharmacokinetic and pharmacodynamic model to predict potential human dosing regimens for VRDN-008. We anticipate submitting an IND for VRDN-008 by the end of 2025.

Our Strategy

Our mission is to create and advance new biologic medicines for patients suffering from serious and rare diseases that are underserved by today's therapies. Key elements of our business strategy are to:

- **Evaluate opportunities to identify, engineer, and develop potential best-in-class therapeutic proteins and antibodies that optimize patient care.** Our pipeline of therapeutic programs represents a patient-centric model of innovation that leverages proven biology and protein and antibody technology to reduce research and development risk, while striving to address strategic gaps related to access, delivery, quality of life, efficacy, and/or safety and tolerability in targeted therapeutic areas. Our multidisciplinary search process evaluates scientific and clinical validation of therapeutic targets, market potential, and feasibility of efficiently developing a competitive product.

- **Our clinical development and commercial focus on thyroid eye disease (TED)**:

    - **Seek marketing approval for veligrotug.** We are evaluating veligrotug in two pivotal global phase 3 clinical trials, THRIVE and THRIVE-2, for the treatment of active and chronic TED, respectively. THRIVE and THRIVE-2 are each designed to compare a five-dose intravenous treatment arm of veligrotug at 10 mg/kg, dosed three weeks apart, to placebo. This five-dose veligrotug regimen features fewer infusions and a shorter time per infusion compared to teprotumumab, the currently marketed IGF-1R inhibitor for TED. We reported positive topline THRIVE and THRIVE-2 data in September 2024 and December 2024, respectively. We expect that the THRIVE and THRIVE-2 phase 3 trials, together with a safety database comprising 300 treated patients (safety database inclusive of patients from the THRIVE and THRIVE-2 trials), will support global health authority registration for marketing approval in both active and chronic TED. We expect to submit a BLA for veligrotug in the second half of 2025 and an MAA to the EMA for veligrotug in the first half of 2026.

    - **Rapidly develop subcutaneous VRDN-003 as our next generation, potential best-in-class IGF-1R antibody.** VRDN-003 is designed to be self-administered subcutaneously at home as an infrequent and low-volume injection to decrease the burden on TED patients. VRDN-003 has the same binding domain as veligrotug and was engineered to have a longer half-life. VRDN-003 is designed to maintain the efficacy of IGF-1Rs as demonstrated by the marketed product, teprotumumab, and by the clinical results for veligrotug in THRIVE and THRIVE-2, while improving on its safety and maximizing patient convenience. We are evaluating VRDN-003 in two global phase 3 clinical trials, REVEAL-1 and REVEAL-2, for the treatment of active and chronic TED, respectively. REVEAL-1 and REVEAL-2 are each designed to evaluate subcutaneous VRDN-003 administered every four weeks or every eight weeks and will assess outcomes

versus placebo. We have initiated a safety study to meet the 300 patient standard safety database requirement (to also include patients from the REVEAL-1 and REVEAL-2 trials) and anticipate initiating an auto-injector study in 2025 to have an auto-injector device available at the time of commercial launch, if approved. We expect to report topline REVEAL-1 and REVEAL-2 data in the first half of 2026. We expect that the REVEAL-1 and REVEAL-2 phase 3 trials, together with a safety database of 300 treated patients (safety database inclusive of patients from the REVEAL-1 and REVEAL-2 trials), will support global health authority registration for marketing approval in both active and chronic TED, respectively.

  - **Be a trusted partner in the care of TED patients.** We plan to cultivate a network across TED stakeholders to inform our patient-centric approach, including with patients and advocacy groups, key opinion leaders, research institutions, healthcare professionals and payers.

  - **Prepare for commercialization of veligrotug and VRDN-003, for the treatment of patients with TED.** We hold worldwide commercialization rights, excluding the greater area of China, to veligrotug and VRDN-003. As a result, we have the flexibility to develop and potentially commercialize products ourselves, or alternatively to enter collaborations with industry partners.

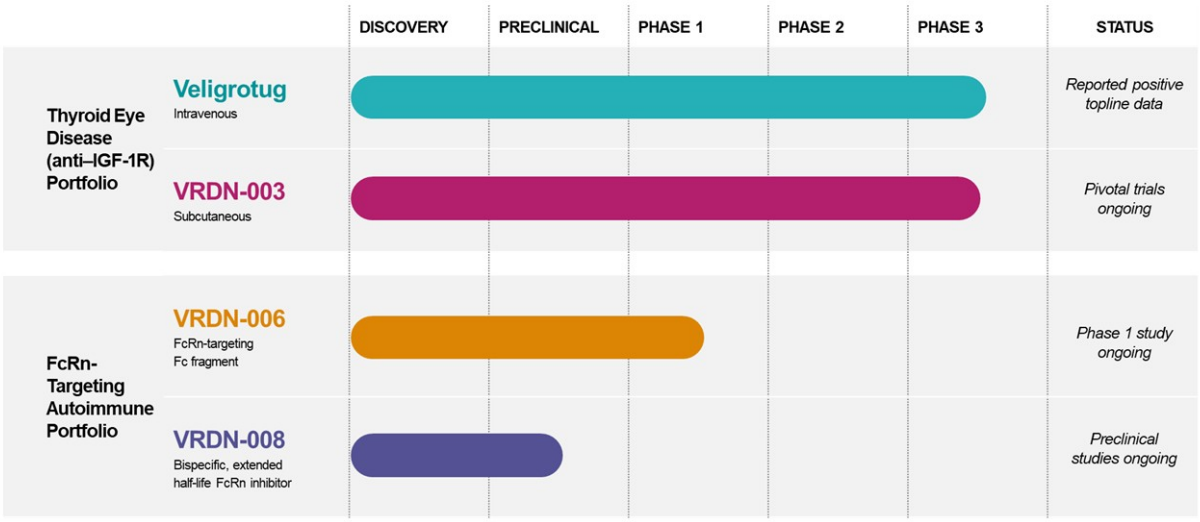
- **Advance our portfolio of FcRn inhibitors with the potential to treat a broad array of autoimmune disorders.** We are developing a portfolio of engineered anti-neonatal FcRn inhibitors, including VRDN-006 and VRDN-008. FcRn inhibitors have the potential to treat a broad array of autoimmune diseases, representing a possible significant commercial market opportunity. Our multi-pronged engineering approach has resulted in a portfolio of FcRn-targeting molecules that leverage the clinically and commercially validated mechanism of FcRn inhibition while potentially addressing the limitations of current agents such as incomplete IgG suppression and safety.

  - **Generate VRDN-006 proof-of-concept IgG reduction data in healthy volunteers.** VRDN-006 is a highly selective Fc fragment that inhibits FcRn and is designed to be a convenient subcutaneous and self-administered option for patients. VRDN-006 received IND clearance from the FDA in January 2025 and we expect proof-of-concept IgG reduction data in healthy volunteers in the third quarter of 2025.

  - **Advance VRDN-008 to the clinic.** VRDN-008 is a half-life extended bispecific FcRn inhibitor comprising an Fc fragment and an albumin-binding domain designed to prolong IgG suppression as a subcutaneous, self-administered and potential best-in-class option for patients. In single, high-dose head-to-head NHP studies, VRDN-008 demonstrated three times the half-life and showed a deeper and more sustained IgG reduction than efgartigimod. NHP studies are ongoing to generate additional data for VRDN-008. Once completed, we plan to use the totality of VRDN-008's NHP data to build a robust pharmacokinetic and pharmacodynamic model to predict potential human dosing regimens for VRDN-008. We anticipate submitting an IND for VRDN-008 by the end of 2025.

- **Leverage our therapeutic protein, antibody, and multi-disciplinary search expertise to continue discovering and developing novel, best-in class product candidates.** We plan to continue to identify and advance novel product candidates and technologies to generate potential best-in-class protein and antibody therapeutics, either internally or through in-licensing.

Our Pipeline



Thyroid Eye Disease (TED)

TED, commonly associated with Graves' Disease, and in some cases referred to as Graves' orbitopathy, is a serious and rare autoimmune disorder affecting the eye and its adjacent tissue. It is characterized by inflammation within the orbit of the eye that can cause bulging of the eyes, redness and swelling, double vision, pain, and potential blindness. TED is a progressive disease consisting of an initial active phase or active TED, followed by a transition to a secondary chronic phase or chronic TED. In the active phase of TED, patients present with several inflammatory signs and symptoms such as pain, redness, swelling, proptosis, diplopia, and eyelid retraction. The active phase is generally defined as the first 18 to 24 months of disease onset and is typically when inflammatory signs and symptoms reach their peak levels. The second, chronic phase of TED is characterized by a reduction in some of the inflammatory signs, such as redness and swelling in the area surrounding the eye, compared to the active phase of the disease. However, proptosis, pain, diplopia, and eyelid retraction often persist throughout life for patients with chronic TED. Patients with active and chronic TED experience significant impairment to their quality of life, including difficulties with the activities of daily living, trouble functioning in social situations, and decreased psychological well-being. About one in every three patients experience anxiety and depression.

Pathologies Leading to the Development of TED

TED develops in parallel with Graves' Disease, an autoimmune disease in which antibodies form against the thyroid-stimulating hormone receptor ("TSHR"), which is present in the thyroid and other cells such as adipocytes and fibroblasts. A close temporal relationship exists between the onset of Graves' Disease and the onset of TED. Regardless of which condition occurs first, the other condition develops within 18 months in 80% of patients. In addition to antibodies against TSHR, patients with TED also develop antibodies against IGF-1R.

Insulin-like growth factor 1 is a hormone similar in molecular structure to insulin with higher growth-promoting activity. IGF-1R, the receptor for IGF-1, is highly expressed in fibrocytes, cells that are derived from the bone marrow and that have the potential to differentiate into either myofibroblasts or fat cells. IGF-1R and TSHR function in concert to regulate the proliferation and differentiation of fibrocytes in the orbital socket.

One potential cause of TED is autoimmune antibodies against IGF-1R that lead to the activation of IGF-1R, resulting in increased proliferation, secretion of extracellular complex carbohydrates, and differentiation into fat cells. These antibodies, and autoimmune antibodies to TSHR, can elicit an immune attack against the fibrocytes that surround the eye triggering the

development of TED. Inflammation associated with this attack combined with activation of IGF-1R leads to the wide spectrum of pathologies seen with this disease.

Exposure to other inflammatory agents, such as cigarette smoke, leads to exacerbation of the disease resulting in more severe symptoms.

Current Treatments for TED

Prior to 2020, moderate to severe cases of TED were treated off-label with steroids such as daily doses of oral prednisone, or in more severe cases, weekly doses of IV methylprednisolone. Treatment with steroids is associated with a wide range of serious complications including high blood pressure, diabetes, psychological effects, personality change, insomnia, skin thinning, immunosuppression, hyperglycemia, and increased risks of infections. Systemic steroids showed limited efficacy for most of the signs and symptoms of TED and are not a sustainable long-range intervention given the side effects. If steroid treatment proved to be inadequate, or could not be tolerated, remaining options for patients include orbital radiation or surgery to reduce swelling, decompress orbital contents, and protect the vision. Again, each of these therapies was considered incomplete or inadequate from the perspective of both the patient and the treating physician.

In January 2020, Tepezza (teprotumumab), an antibody that blocks the activation of IGF-1R, was approved by the FDA for the treatment of TED. The Tepezza labeling was updated in April 2023 to specify its use for the treatment of TED regardless of TED activity or duration. In addition, the labeling was updated in its warnings and precautions, adverse reactions, and patient counseling information sections in December 2022 with additional information on hyperglycemia and in July 2023 to include hearing impairment, its potential severity, and guidance for monitoring.

In two randomized, double-blind placebo-controlled trials, infusions of teprotumumab every three weeks, for a total of eight doses, led to a greater than 2 mm decrease in proptosis in 71% and 83% of patients with active TED, respectively, compared to 20% and 10% with placebo. Combined results from these two studies in patients with active TED showed that treatment with teprotumumab also led to a 53% decrease in diplopia compared to a 25% decrease when patients were treated with placebo control. Thus, these data show that targeting and blockade of IGF-1R in TED provides a clinically meaningful benefit and is a de-risked approach.

Market Potential

We estimate approximately 190,000 TED patients in the United States with moderate to severe TED, which includes patients with either active and chronic TED, and a similar epidemiology in Europe. In 2020, Horizon launched with a price of approximately $16,300 per vial of Tepezza which translates to a list price of approximately $375,000 based on patient weight for a six-month course of therapy. Tepezza's 2024 net sales in the U.S. were approximately $1.8 billion, with the potential for additional revenue in the U.S. with further penetration into the prevalent TED population and more convenient regimens and routes of administration. With Tepezza now approved in multiple countries outside of the U.S., including Japan, and a regulatory submission completed in Europe, we believe there is potential for meaningful additional revenue outside of the U.S., which we believe will further support multiple entrants.

Our Product Candidates

Veligrotug, a potential best-in-class intravenously administered IGF-1R antibody

Veligrotug is a monoclonal antibody that binds to and is believed to act as a full antagonist of IGF-1R signaling pathway. This mechanism of action is clinically and commercially validated by the only FDA product approved for the treatment of TED, Tepezza. Based on our ongoing THRIVE and THRIVE-2 phase 3 clinical trials, our goal is for veligrotug to be second to market in this class of medicine, with the opportunity to offer a differentiated IV product.

We have an exclusive license to the worldwide rights to develop and commercialize veligrotug for all non-oncology indications that do not use radiopharmaceuticals, including the treatment of patients with TED, from ImmunoGen, Inc. ("ImmunoGen"). The antibody sequence that we are developing as veligrotug in TED had previously been developed in oncology as AVE-1642 and studied in over 100 patients. However, development in oncology was stopped in 2009 due to its failure to meet the primary efficacy endpoints in multiple myeloma. As described below, we sublicensed the right to develop, manufacture and commercialize certain IGF-1R directed antibody products for non-oncology indications in the greater area of China to Zenas BioPharma (Cayman) Limited (now Zenas BioPharma, Inc., their successor in interest, "Zenas BioPharma"). In January 2025, Zenas BioPharma sublicensed their rights to Zai Lab (Hong King) Limited ("Zai Lab").

Clinical Trials for veligrotug

Phase 1/2 Trial of veligrotug in Patients with Active TED

In the second half of 2022 and early 2023, we announced data from our phase 1/2 clinical trial evaluating the safety and efficacy of veligrotug in patients with active TED. The proof-of-concept portion of this double-blind, placebo-controlled phase 1/2 trial evaluated two infusions of veligrotug administered intravenously, three weeks apart, with efficacy measured six weeks after the first dose. Veligrotug was evaluated at doses of 3, 10, and 20 mg/kg, with each cohort designed to include six patients randomized to drug, and two patients randomized to placebo. We previously announced positive results from all three dose cohorts, and veligrotug demonstrated a favorable safety profile. In the 3 mg/kg dose cohort, nine patients were randomized to receive veligrotug to enable all consented patients who were eligible following screening to participate in the trial, and two patients were randomized to receive placebo. At week 6, across all three dose groups (n=21), we observed a 71% proptosis responder rate and a 67% overall responder rate. 62% of veligrotug-treated patients achieved a CAS of 0 or 1, and 54% had complete resolution of their diplopia. Veligrotug was generally well-tolerated.

Phase 1/2 Trial of veligrotug in Patients with Chronic TED

In July 2023, we announced data from our phase 1/2 clinical trial evaluating the safety and efficacy of veligrotug in patients with chronic TED. The proof-of-concept portion of this double-blind, placebo-controlled phase 1/2 trial evaluated two infusions of veligrotug administered intravenously, three weeks apart, with efficacy measured six weeks after the first dose. Veligrotug was evaluated at doses of 3 and 10 mg/kg, with each cohort designed to include six patients randomized to drug, and two patients randomized to placebo. We previously announced positive results from both cohorts, and veligrotug demonstrated a favorable safety profile that was generally consistent with the previously reported results in patients with active TED with veligrotug. At week six, across both dose groups (n=12), we observed a 42% proptosis responder rate and 40% of veligrotug-treated patients achieving a CAS of 0 or 1. No patients achieved complete resolution of their diplopia. Veligrotug was generally well-tolerated and demonstrated a safety profile that was generally consistent with the previously reported results in patients with active TED with veligrotug.

Phase 3 Trial (THRIVE) of veligrotug in Patients with Active TED

THRIVE is a global double-masked, placebo-controlled phase 3 clinical trial evaluating the safety and efficacy of veligrotug in patients with active TED. THRIVE evaluated five infusions of veligrotug at 10 mg/kg, dosed three weeks apart. Patients were randomized two to drug and one to placebo.

In September 2024, we announced positive topline data from THRIVE. THRIVE met the primary and all secondary endpoints at fifteen weeks after five infusions of veligrotug, showing highly statistically significant ($p < 0.0001$) improvements on all of the measured signs and symptoms of TED. Veligrotug additionally showed a rapid onset of treatment effect, with the majority (53%) of veligrotug-treated patients achieving a proptosis response as early as three weeks. THRIVE enrolled 113 patients, randomized to veligrotug (n=75) and placebo (n=38).

The following activity was observed in veligrotug-treated patients at week fifteen (n=75):

Proptosis

- 70% proptosis responder rate (“PRR”) (64% placebo-adjusted, $p < 0.0001$), defined as a ≥2-millimeter (“mm”) reduction in proptosis from baseline in the study eye without worsening in the fellow eye (≥2 mm increase), as measured by exophthalmometry. PRR results as measured by MRI/CT were consistent with those measured by exophthalmometry at the primary efficacy analysis timepoint.

- 2.9mm mean reduction in proptosis from baseline (2.4mm placebo-adjusted, $p < 0.0001$), as measured by exophthalmometry

Diplopia

- 63% diplopia responder rate (43% placebo-adjusted, $p < 0.0001$), defined as patients with baseline diplopia who achieved a reduction of at least 1 on the Gorman subjective diplopia scale (76 patients with diplopia at baseline)

- 54% complete resolution of diplopia (43% placebo-adjusted, $p < 0.0001$), defined as patients with baseline diplopia who achieved a score of 0 on the Gorman subjective diplopia scale

CAS

- 64% maximal or near-maximal therapeutic effect on CAS (46% placebo-adjusted, $p < 0.0001$), defined as reaching a CAS of 0 or 1 on the 7-point composite measure of signs and symptoms of TED

- 3.4 point mean reduction in CAS from baseline (1.7-point placebo-adjusted, $p < 0.0001$), on a 7-point measure of signs and symptoms of TED

Overall response

- 67% overall responder rate (61% placebo-adjusted, $p < 0.0001$), defined as a ≥2 mm reduction in proptosis and a ≥2 point reduction in CAS

Veligrotug was generally well-tolerated with a safety profile consistent with previous veligrotug studies. The majority of adverse events ("AEs") were mild, and 96% of veligrotug-treated patients completing all doses. There were no treatment-related serious AEs. A 5.5% placebo-adjusted rate of hearing impairment AEs was observed.

Phase 3 Trial (THRIVE-2) of veligrotug in Patients with Chronic TED

THRIVE-2 is a global double-masked, placebo-controlled phase 3 clinical trial evaluating the safety and efficacy of veligrotug in patients with chronic TED. THRIVE-2 evaluated five infusions of veligrotug at 10 mg/kg, dosed three weeks apart. Patients were randomized two to drug and one to placebo.

In December 2024, we announced positive topline data from THRIVE-2. THRIVE-2 met the primary and all secondary endpoints at fifteen weeks after five infusions of veligrotug, showing statistically significant responses on all of the measured signs and symptoms of TED. Veligrotug continued to demonstrate a rapid onset of treatment effect, with a statistically significant proptosis response as early as three weeks and statistically significant diplopia reduction and resolution as early as six weeks. THRIVE-2 is the first global phase 3 study in patients with chronic TED to demonstrate a statistically significant and clinically meaningful diplopia responder rate and rate of diplopia complete resolution. THRIVE-2 enrolled 188 patients, randomized to veligrotug (n=125) and placebo (n=63). The mean time since onset of TED in patients treated with veligrotug was 69.8 months.

The following activity was observed in veligrotug-treated patients at week fifteen (n=125):

Proptosis

- 56% proptosis responder rate ("PRR") (48% placebo-adjusted; $p < 0.0001$), defined as a ≥2-millimeter ("mm") reduction in proptosis from baseline in the study eye without worsening in the fellow eye (≥2 mm increase), as measured by exophthalmometry. PRR was statistically significant at all time points, including as early as 3 weeks, demonstrating a rapid onset of treatment effect. PRR results as measured by MRI/CT were consistent with those measured by exophthalmometry at the primary efficacy analysis timepoint.

- 2.3mm mean reduction in proptosis from baseline (1.9mm placebo-adjusted, $p < 0.0001$), as measured by exophthalmometry

Diplopia

- 56% diplopia responder rate (31% placebo-adjusted, $p = 0.0006$), defined as patients with baseline diplopia who achieved a reduction of at least 1 on the Gorman subjective diplopia scale. Rapid onset was observed as early as 6 weeks after just two infusions (102 patients with diplopia at baseline)

- 32% complete resolution of diplopia (18% placebo-adjusted, $p = 0.0152$), defined as patients with baseline diplopia who achieved a score of 0 on the Gorman subjective diplopia scale

CAS

- 54% maximal or near-maximal therapeutic effect on CAS (29% placebo-adjusted, $p = 0.006$), defined as reaching a CAS of 0 or 1 on the 7-point composite measure of signs and symptoms of TED, among patients with a CAS of ≥ 3 at baseline (n = 104)

- 2.9 point mean reduction in CAS from baseline (1.6-point placebo-adjusted, $p < 0.0001$), on a 7-point measure of signs and symptoms of TED, among patients with a CAS of ≥ 3 at baseline

- CAS outcomes are exploratory endpoints and p-values are nominally significant.

Overall response

- 56% overall responder rate (50% placebo-adjusted, $p < 0.0001$), defined as a ≥2 mm reduction in proptosis and a ≥1 point reduction in CAS

Veligrotug was generally well-tolerated with a safety profile consistent with previous veligrotug studies, including THRIVE. The majority of AEs were mild, and 94% of veligrotug-treated patients completed their treatment course. A 9.6% placebo-adjusted rate of hearing impairment AEs was observed.

To meet the 300 patient standard safety database requirements for the veligrotug BLA, we are conducting STRIVE, a global clinical study of veligrotug in TED patients that utilizes broad inclusion criteria (e.g., any severity or duration of disease) and is randomized 3:1 (10 mg/kg IV with an active control of 3 mg/kg IV). In January 2025, we completed enrollment in STRIVE with a total of 231 patients, exceeding the enrollment target of 212 due to patient demand. We also completed enrollment of patients in the open label extension study for non-responding patients in THRIVE and THRIVE-2.

Together, THRIVE and THRIVE-2 evaluated veligrotug in the largest and broadest population of active and chronic TED patients studied to date in global phase 3 clinical trials. We believe that these robust and consistent clinical efficacy and safety results, after only five infusions of veligrotug, support a differentiated product profile and the potential for veligrotug to be the IV treatment-of-choice for all forms of active and chronic TED. We expect that the THRIVE and THRIVE-2 phase 3 clinical trials, together with a safety database comprising 300 treated patients, will support global health authority registration for marketing approval in both active and chronic TED, respectively. We expect to submit a BLA in the second half of 2025 and an MAA to the EMA in the first half of 2026.

VRDN-003, a potential best-in-class subcutaneously administered IGF-1R antibody

VRDN-003 is a monoclonal antibody that acts as a full antagonist of IGF-1R. VRDN-003 utilizes the same binding domain as veligrotug and is engineered to extend its half-life, and therefore potentially enabling less frequent and more convenient dosing. VRDN-003 is designed to maintain the clinical response of veligrotug IV while significantly increasing patient convenience.

We believe a later-entrant subcutaneous therapy can convert meaningful portions of an IV market. There is precedent that subcutaneous therapies can quickly command substantial market share even when launching several years after an incumbent IV. Although we have designed VRDN-003 to have a superior dosing profile to its parent molecule, veligrotug, as well as to the currently marketed IV product, teprotumumab, market examples demonstrate that subcutaneous therapies have commanded market share even where such therapies have the same or worse dosing frequency than their IV counterparts. Further, subcutaneous offerings can also grow the overall market size for their class. We believe VRDN-003 has significant potential to capture a meaningful proportion of the IV TED market and to grow the TED market as a convenient, less-frequent, low-volume subcutaneous anti-IGF-1R antibody that patients take at home.

We are conducting a global pivotal program for VRDN-003, including evaluating its efficacy and safety in two global well-controlled phase 3 pivotal clinical trials, REVEAL-1 and REVEAL-2, for the treatment of active and chronic TED, respectively. We selected VRDN-003 for pivotal development in TED following positive data in a phase 1 clinical trial in healthy volunteers. This study showed VRDN-003 to have a prolonged half-life of 40 to 50 days, which is four to five times that of its parent molecule, veligrotug. Because of the similarities of veligrotug and VRDN-003, we expect VRDN-003 to have similar clinical responses at the exposure levels of veligrotug that led to robust clinical activity in its phase 2 clinical study in TED. Further, pharmacokinetic modeling of VRDN-003 predicted that exposure levels of VRDN-003 could be achieved that are equivalent to exposure levels of veligrotug that produced clinically meaningful results with multiple dosing regimens of VRDN-003, i.e., subcutaneous injection every two, four, or eight weeks. Patient enrollment and dosing continues in both REVEAL-1 and REVEAL-2. Both studies will evaluate subcutaneous VRDN-003 administered every four weeks or every eight weeks and will assess outcomes versus placebo. We expect that the REVEAL-1 and REVEAL-2 phase 3 trials, together with a safety database of 300 patients (safety database inclusive of patients from the REVEAL-1 and REVEAL-2 trials), will support global health authority registration for marketing approval in both active and chronic TED, respectively. We also anticipate initiating an auto-injector study in 2025 to have an auto-injector device available at the time of commercial launch, if approved. We anticipate topline data for REVEAL-1 and REVEAL-2 in the first half of 2026, and we anticipate submitting a BLA for VRDN-003 for the treatment of TED by the end of 2026.

Phase 1 Trial of VRDN-003 in Healthy Volunteers

- Study Design: VRDN-003 was dosed in four single dose cohorts of healthy volunteers at a concentration of 150 mg/ml receiving 5 mg/kg IV (n=4), 300 mg SC (n=6), 15 mg/kg IV (n=4), 600 mg SC (n=6) and a fifth cohort of two doses of VRDN-003 (n=4).

- Summary of Results:
  - Extended Half Life: VRDN-003 pharmacokinetics data showed an extended half-life of 40 to 50 days, which is a 4-to-5-fold increase over the half-life of veligrotug (which showed a half-life of 10 to 12 days).

  - Prolonged Pharmacodynamics ("PD"): Following a single subcutaneous dose of VRDN-003, IGF-1 serum levels increased approximately 4-fold at peak. This was consistent with the increases in IGF-1 levels that have been shown in the clinic following a single dose of veligrotug SC and IV. IGF-1 is a PD biomarker for IGF-1R target engagement.

  - Well-Tolerated: VRDN-003 was well tolerated in all subjects with no SAEs. All treatment-related, treatment-emergent adverse events were grade 1 (mild). In the reported dataset, no antidrug antibodies ("ADAs") were detected.

  - Dosing Flexibility for Pivotal Development: VRDN-003 modeling demonstrated dosing flexibility for the program's anticipated global pivotal development. The modeling showed that dosing VRDN-003 every eight weeks, every four weeks, and every two weeks achieved a range of exposures levels that were seen for veligrotug after intravenous doses of 3 mg/kg, 10 mg/kg and 20 mg/kg, respectively.

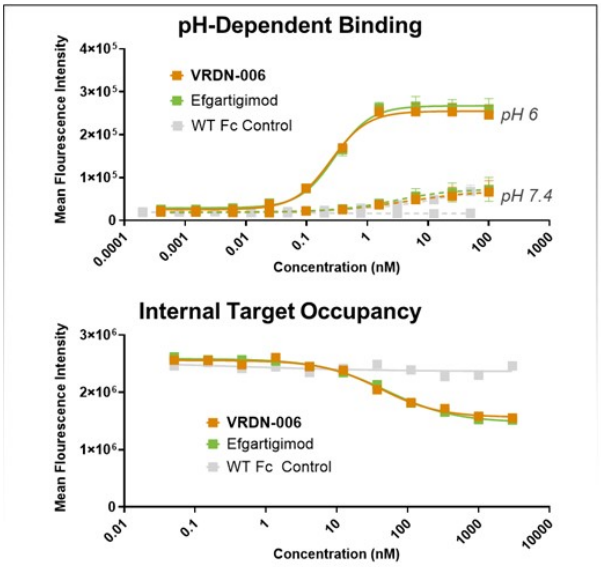
FcRn Inhibitor Portfolio: VRDN-006 and VRDN-008

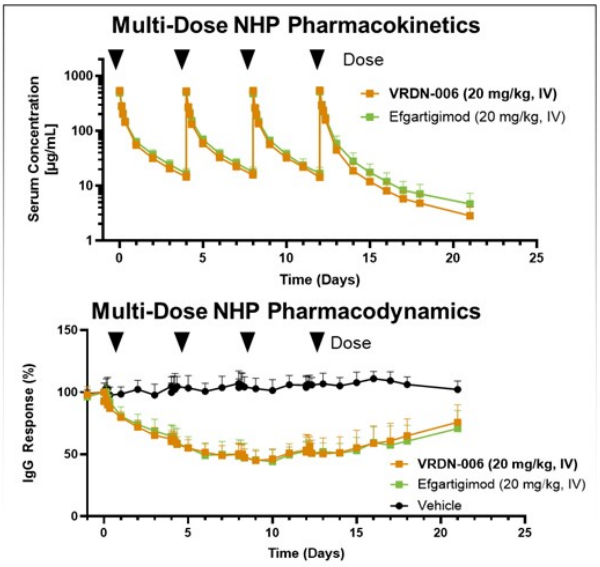
In October 2023, consistent with our vision to develop the next generation of best-in-class products for severe autoimmune and rare diseases, we unveiled VRDN-006 and VRDN-008 from our portfolio of engineered FcRn inhibitors. FcRn inhibitors have the potential to treat a broad array of autoimmune diseases, representing a possible significant commercial market opportunity. Our multi-pronged engineering approach has resulted in a portfolio of FcRn-targeting molecules that leverage the clinically and commercially validated mechanism of FcRn inhibition in myasthenia gravis and chronic inflammatory demyelinating polyneuropathy ("CIDP") while potentially addressing the limitations of current agents such as incomplete IgG suppression and safety. VRDN-006 and VRDN-008 are both designed to be convenient, self-administered, subcutaneous products.

The first FDA-approved FcRn inhibitor, Vyvgart® (efgartigimod), was developed by argenx SE ("Argenx") and is approved for myasthenia gravis and chronic inflammatory demyelinating polyneuropathy. Argenx reported efgartigimod net sales of approximately $2.2 billion in 2024, and it is projected to generate close to $6 billion in annual sales by 2030. Furthermore, FcRn inhibitors have the potential to address additional sizable autoimmune indications such as myositis, membranous nephropathy, Graves' disease, lupus nephritis, and Sjogren's syndrome.

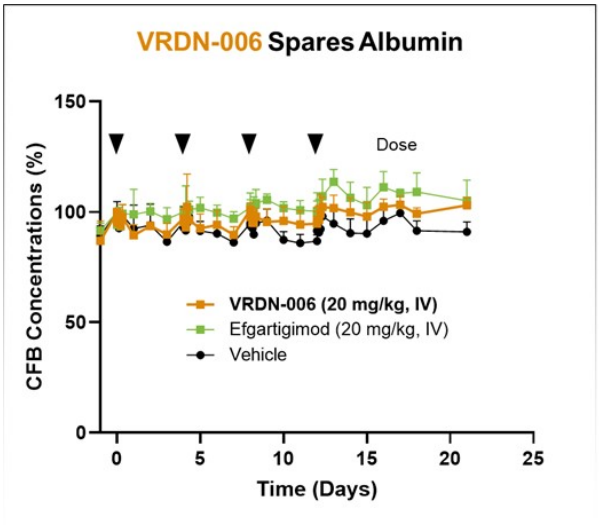
VRDN-006

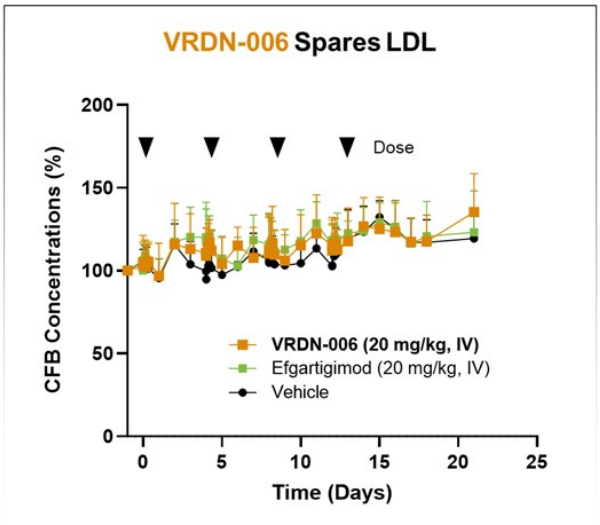
VRDN-006 is a highly-selective Fc fragment. In our NHP studies, VRDN-006 demonstrated specificity for blocking FcRn-IgG interactions while not showing decreases in albumin or increases in LDL levels, which are known potential side effects associated with certain full-length monoclonal anti-FcRn antibodies. With efgartigimod, Argenx has proven that an Fc fragment can achieve clinical efficacy while sparing an effect on albumin or LDL, and shows better tolerability than full length antibodies against FcRn. VRDN-006 is the only other known Fc fragment currently in development. In NHP studies, we showed that VRDN-006 demonstrates comparable potency in vitro and comparable IgG lowering in non-human primates to efgartigimod.





VRDN-006 also shows a similar safety profile to efgartigimod in our head-to-head non-human primate study showing that, comparable to efgartigimod, it did not lower albumin or increase LDL levels.

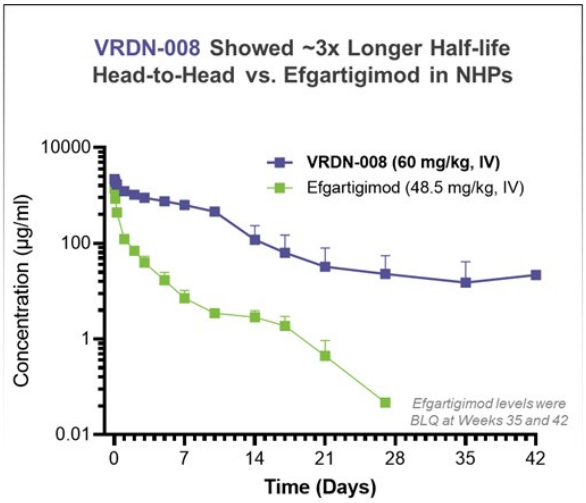


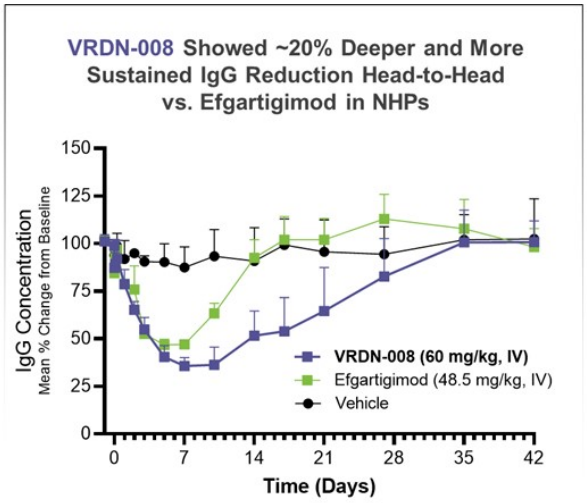


VRDN-006 received IND clearance from the FDA in January 2025 and we expect proof-of-concept IgG reduction data in healthy volunteers in the third quarter of 2025.

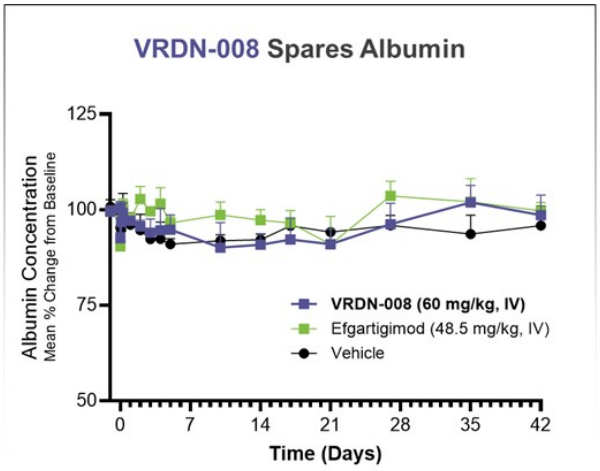
VRDN-008

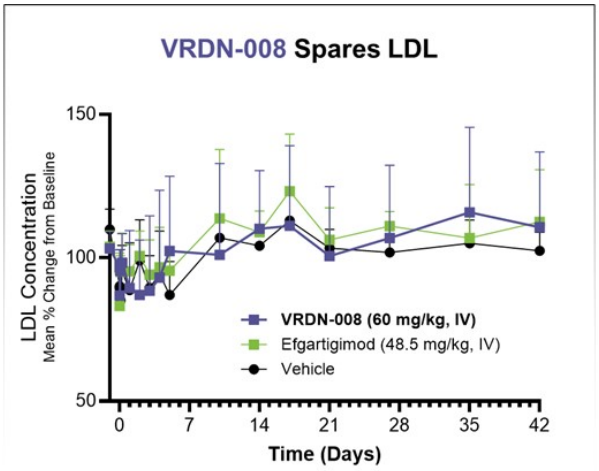
VRDN-008 is a half-life extended bispecific FcRn inhibitor comprising an Fc fragment and an albumin-binding domain designed to prolong IgG suppression and provide a potentially best-in-class subcutaneous option for patients. In a single, high-dose, head-to-head study in NHPs, VRDN-008 demonstrated three times the half-life of efgartigimod and a deeper and more sustained IgG reduction with peak IgG reductions that were 20% deeper than efgartigimod.





VRDN-008 also shows a similar safety profile to efgartigimod in our head-to-head non-human primate study showing that, comparable to efgartigimod, it did not lower albumin or increase LDL levels.





NHP studies are ongoing to generate additional data for VRDN-008. Once completed, we plan to use the totality of VRDN-008's NHP data to build a robust pharmacokinetic and pharmacodynamic model to enable the prediction of potential human dosing regimens for VRDN-008.

Intellectual Property

We have in-licensed and owned patents and patent applications, which include claims directed to compositions, methods of use, dosing and formulations. We possess know-how and trade secrets relating to the development and commercialization of our product candidates, including related manufacturing processes. As of January 15, 2025, our in-licensed and owned patent portfolio consists of approximately one U.S. issued patent, approximately seventeen U.S. pending patent applications, no patents issued in jurisdictions outside of the United States, one allowed patent in China, and approximately seventy-eight patent applications pending in jurisdictions outside of the United States (including approximately seven pending Patent Cooperation Treaty (PCT) applications) that, in many cases, are counterparts to the foregoing U.S. patents and patent applications.

With respect to the product candidates and related manufacturing processes we develop and commercialize, we intend to pursue, when possible, composition, method of use, process, dosing and formulation patent protection. We may also pursue patent protection with respect to manufacturing and drug development processes and technology. When available to expand

market exclusivity, our strategy is to obtain or license additional intellectual property related to core elements of technology and/or product candidates.

Individual patents extend for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance, and the legal term of patents in the countries in which they are obtained. Generally, patents issued for applications filed in the United States are effective for 20 years from the earliest nonprovisional filing date. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the Unites States Patent and Trademark Office (USPTO) in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent or delays on the part of a patentee. In addition, in certain instances, the patent term of a U.S. patent that covers an FDA-approved drug may also be eligible to be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period. The restoration period cannot be longer than five years and the total patent term, including the restoration period, must not exceed 14 years following FDA approval, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. The duration of patents outside of the United States varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest non-provisional filing date. Our patent issued as of January 15, 2025 is expected to expire no earlier than 2041. If patents are issued on our patent applications pending as of January 15, 2025, the resulting patents are projected to expire on dates ranging from 2041 to 2045. However, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country, potential disclaimers of term, and the validity and enforceability of the patent.

Competition

The biotechnology and pharmaceutical industries are characterized by intense and rapidly changing competition to develop new technologies and proprietary products. Our product candidates may address multiple markets. Ultimately, the diseases our product candidates target, and for which product candidates we may receive marketing authorization, will determine our competition. We believe that for most or all of our product development programs, there will be one or more competing programs under development or being marketed by other companies. Any products that we may commercialize will have to compete with existing therapies and new therapies that may become available in the future. We face potential competition from many different sources, including larger and better-funded biotechnology and pharmaceutical companies. In many cases, the companies with competing programs will have access to greater resources and expertise than we do and may be more advanced in those programs.

Amgen's Tepezza is the only FDA-approved medication for TED. Other therapies, such as corticosteroids, have been used on an off-label basis to alleviate some of the symptoms of TED. A non-exhaustive list of companies currently advancing therapies in clinical development for the treatment of TED include:

- Amgen is developing an on-body subcutaneous formulation of Tepezza in a phase 3 study and has an early-stage candidate AMG-732 in TED.
- Argenx is developing efgartigimod (Vyvgart), an antibody fragment to target the FcRn that is subcutaneously delivered and expected to be evaluated in a registrational phase 3 trial in patients with TED.
- Immunovant, Inc. is developing a subcutaneous formulation of batoclimab in phase 3 studies in patients with active TED.
- Roche is developing satralizumab (Enspryng), an anti-1L-6R that is subcutaneously delivered and is being evaluated in a phase 3 trial in patients with active TED.
- Sling Therapeutics, Inc. is developing linsitinib, a small molecule IGF-1R inhibitor currently being evaluated in an ongoing phase 2b/3 study in patients with active TED and currently has plans to initiate a phase 3 trial.
- Tourmaline Bio is developing TOUR006, a subcutaneously delivered anti-IL-6, in an ongoing phase 2b clinical trial in patients with active TED.
- Lassen Therapeutics is developing LASN01, an intravenously delivered anti-1L-11R currently being evaluated in a phase 2 study in active TED.

- ACELYRIN, INC. is developing lonigutamab (VB-421), a subcutaneously delivered anti-IGF-1R currently being evaluated in a phase 1/2 study in patients with TED. On January 6, 2025, ACELYRIN reported partial data from the phase 1/2 study and announced plans to initiate two phase 3 studies in patients with TED in the first quarter of 2025. On February 6, 2025, ACELYRIN announced a decision to re-evaluate the phase 3 development program for lonigutumab.

Argenx's Vyvgart and UCB's Rystiggo® are the only FDA-approved anti-FcRn therapies, each approved in generalized myasthenia gravis. A non-exhaustive list of other companies that are advancing therapies in clinical development for the treatment to target FcRn include:

- Immunovant, Inc. is developing batoclimab (IMVT-1401/HBM9161) and IMVT-1402 with intentions to target generalized myasthenia gravis, CIDP, Graves' disease, and Rheumatoid arthritis ("RA"). Both are monoclonal antibodies targeting FcRn. Batoclimab is currently being evaluated in ongoing phase 3 studies in TED and phase 2 studies in CIDP and Graves' disease. IMVT-1402 is currently being evaluated in a phase 2 study in patients with Graves' disease and RA.

- Johnson and Johnson is developing nipocalimab, which is in ongoing phase 3 trials for a number of indications including generalized myasthenia gravis, CIDP, Sjogren's disease and warm autoimmune hemolytic anemia. Johnson and Johnson submitted a BLA for nipocalimab in generalized myasthenia gravis in August 2024.

- UCB continues to develop Rystiggo in an ongoing phase 3 study in Myelin Oligodendrocyte Glycoprotein Antibody-associated Disease.

License Agreements

License Agreement with Zenas BioPharma

In October 2020, Viridian Therapeutics, Inc. ("Private Viridian") entered a license agreement with Zenas BioPharma to license technology comprising certain materials, patent rights, and know-how to Zenas BioPharma. On October 27, 2020, in connection with the closing of the Private Viridian acquisition, we became party to the license agreement with Zenas BioPharma. Since February 2021, we have entered into several letter agreements with Zenas BioPharma in which we agreed to provide assistance to Zenas BioPharma with certain development activities, including manufacturing. In May 2022, the Company entered into a Manufacturing Development and Supply Agreement with Zenas BioPharma to manufacture and supply, or to have manufactured and supplied, clinical drug product for developmental purposes. The license agreement and subsequent letter agreements and supply agreement (collectively, the "Zenas Agreements") were negotiated with a single commercial objective and are treated as a combined contract for accounting purposes. Under the terms of the Zenas Agreements, we granted Zenas BioPharma an exclusive license to develop, manufacture, and commercialize certain IGF-1R directed antibody products for non-oncology indications in the greater area of China. In January 2025, Zenas BioPharma sublicensed their rights under the license agreement to Zai Lab and assigned the Manufacturing Development and Supply Agreement to Zai Lab in connection with the sublicense transaction.

As consideration for the Zenas Agreements, the transaction price included upfront non-cash consideration and variable consideration in the form of payment for our goods and services provided and milestone payments due upon the achievement of specified events. Under the Zenas Agreements, we are eligible to receive non-refundable milestone payments upon achieving specific milestone events during the contract term. Additionally, we are eligible to receive royalty payments based on a percentage of the annual net sales of any licensed products sold on a country-by-country basis in the greater area of China. The royalty percentage may vary based on different tiers of annual net sales of the licensed products made. Zenas BioPharma is obligated to make royalty payments to us for the royalty term in the Zenas Agreements.

License Agreement with ImmunoGen, Inc.

On October 12, 2020, Private Viridian entered into a license agreement with ImmunoGen (the "ImmunoGen License Agreement"), under which we obtained rights to an exclusive, sublicensable, worldwide license to certain patents and other intellectual property rights to develop, manufacture, and commercialize certain products for non-oncology and non-radiopharmaceutical indications. In consideration for rights granted by ImmunoGen, we are obligated to make certain development milestone payments of up to $48.0 million. In December 2021, we paid a $2.5 million milestone payment to ImmunoGen upon the submission of an IND application for veligrotug with the FDA. In May 2022, we paid a $3.0 million milestone payment to ImmunoGen related to the first patient dosed in the clinical trial for veligrotug. In December 2022, we recorded $10.0 million as research and development expense related to a milestone owed to ImmunoGen related to the first

patient dosed in a pivotal clinical trial for veligrotug, amount which was paid in January 2023, and which was included in accounts payable in the consolidated balance sheet as of December 31, 2022. Additionally, if we successfully commercialize any product candidate subject to the ImmunoGen License Agreement, we are responsible for royalty payments equal to a percentage in the mid-single digits of net sales and commercial milestone payments of up to $95.0 million. We are obligated to make any such royalty payments on a product-by-product and country-by-country basis from the first commercial sale of a specified product in each country until the later of (i) the expiration of the last patent claim subject to the ImmunoGen License Agreement in such country, (ii) the expiration of any applicable regulatory exclusivity obtained for each product in such country, or (iii) the 12th anniversary of the date of the first commercial sale of such product in such country. We assumed the ImmunoGen License Agreement in connection with the merger with Private Viridian in 2020.

Antibody and Discovery Option Agreement and License Agreement with Paragon Therapeutics, Inc.

In January 2022, we entered into an antibody and discovery option agreement (the "Paragon Research Agreement") with Paragon Therapeutics, Inc. ("Paragon") under which we and Paragon will cooperate to develop one or more therapeutic proteins or antibodies. Under the terms of the Paragon Research Agreement, Paragon will perform certain development activities in accordance with an agreed upon research plan, and we will pay Paragon agreed upon development fees in exchange for Paragon's commitment of the necessary personnel and resources to perform these activities. The Paragon Research Agreement stipulates a final deliverable to us comprising of a report summarizing the experiments and processes performed under the research plan (the "Final Deliverable").

Additionally, Paragon agreed to grant us an option for an exclusive license to all of Paragon's right, title and interest in and to certain antibody technology and the Final Deliverable, and a non-exclusive license to certain background intellectual property owned by Paragon solely to research, develop, make, use, sell, offer for sale and import of the licensed intellectual property and resulting products worldwide (each, an "Option" and together, the "Options"). Paragon also granted us a limited, exclusive, royalty-free license, without the right to sublicense, to certain antibody technology and the Final Deliverable, and a non-exclusive, royalty-free license without the right to sublicense, under certain background intellectual property owned by Paragon, solely to evaluate the antibody technology and Option and for the purpose of allowing us to determine whether to exercise the Option with respect to certain programs. We may, at our sole discretion, exercise the Option with respect to specified programs ("Programs") at any time until the date that is 90 days after the Company's receipt of the Final Deliverable the applicable program, or such longer period as agreed upon by the parties ("Option Period") by delivering written notice of such exercise to Paragon. If we fail to exercise an Option prior to expiration of the applicable Option Period, such Option for such Programs will terminate. In consideration for Paragon's grant of the Options to us, we paid to Paragon a non-refundable, non-creditable one-time fee of $2.5 million, which was recorded as research and development expense during the three months ended March 31, 2022. In December 2022, we and Paragon entered into a first amendment to the Paragon Research Agreement, under which we obtained an additional limited license for the purpose of conducting certain activities. In consideration for the rights and licenses obtained under the first amendment, we paid Paragon a non-refundable fee of $2.3 million (the "First Amendment Payment"), which was recorded as research and development expense during the three months ended December 31, 2022. The non-refundable upfront fee and the First Amendment Payment are separate from any development costs or cost advance paid or owing with respect to the specified program.

In October 2023, we entered into a License Agreement with Paragon (the "Paragon License Agreement") as a result of exercising our Option under the Paragon Research Agreement to obtain exclusive licenses to develop, manufacture and commercialize certain therapeutic proteins and antibodies and associated products. In connection with the execution of the Paragon License Agreement, we made an initial payment of $5.3 million, which was recorded as research and development expense during the three months ended December 31, 2023. As further described below, the Paragon License Agreement was amended and restated by the Amended and Restated License Agreement with Paragon in September 2024.

In January 2024, we entered into a letter agreement with Paragon pursuant to which Paragon agreed to continue to perform development activities under the existing Paragon Research Agreement and Paragon License Agreement, which we renewed in July 2024. In consideration for the development activities to be conducted by Paragon, we agreed to reimburse Paragon for actual development costs incurred and agreed upon development fees in exchange for Paragon's commitment of the necessary personnel and resources to perform these activities. In September 2024, we entered into a second amendment to the Paragon Research Agreement to include additional development activities to be performed by Paragon. Under the amended Paragon Research Agreement, we will be obligated to make a one-time non-refundable payment of $3.5 million to Paragon following the achievement of certain research and development objectives. We achieved such objectives in February 2025 and the $3.5 million payment was recorded as research and development expense during the three months ended March 31, 2025.

In September 2024, we entered into the Amended and Restated License Agreement with Paragon (the "Amended Paragon License Agreement") which amended and restated the Paragon License Agreement. In connection with the execution of the

Amended Paragon License Agreement, we paid to Paragon a non-refundable fee of $4.0 million in September 2024, which was recorded as research and development expense during the three months ended September 30, 2024. In consideration for rights granted by Paragon, we are obligated to make certain future milestone payments of up to $16.0 million on a program-by-program basis upon the achievement of specified clinical or regulatory milestones, with total milestone payments under all programs not to exceed $40.0 million. Additionally, if the Company develops a product utilizing certain intellectual property rights granted to it under the Amended Paragon License Agreement, the Company is obligated to pay Paragon potential additional future development milestone payments of up to $3.1 million and commercial milestone payments of up to $17.0 million with respect to such product. If the Company successfully commercializes any product candidate subject to the Amended Paragon License Agreement, it is responsible for royalty payments equal to a percentage in the mid-single digits of such product's net sales. During the year ended December 31, 2024, we recorded $14.2 million in research and development costs related to the Paragon Research Agreement and Amended Paragon License Agreement (collectively the "Paragon Agreements").

Government Regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates.

U.S. Biologics Regulation

In the United States, biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act ("FDCA"), the Public Health Service Act ("PHSA") and other federal, state, local, and foreign statutes and regulations. The process of developing a biologic and obtaining regulatory approvals and compliance with federal, state, and local statutes and regulations, both pre- and post-approval, requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval may subject an applicant to delays in development or approval, administrative action and judicial sanctions. The regulatory requirements applicable to biological product development, approval, and marketing are subject to change, and regulations and administrative guidance often are revised or reinterpreted by the regulatory authorities in ways that may have a significant impact on our business. We cannot predict whether legislative changes will be enacted or if regulatory authorities' guidance or interpretations will change.

The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests, animal studies and formulation studies performed in accordance with the FDA's current Good Laboratory Practices ("GLP") regulation, as applicable;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent institutional review board ("IRB") or ethics committee ("EC") representing each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice ("GCP") requirements to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a biologics license application ("BLA"), requesting approval to market the biological product for one or more proposed indications, and including submission of detailed information on nonclinical and clinical studies, the manufacture and composition of the product and proposed labeling;
- satisfactory completion of an FDA Advisory Committee review, if applicable;

- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities, including those of third-parties, at which the proposed product is produced to assess compliance with cGMPs, and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency;

- satisfactory completion of any FDA inspections of the nonclinical and clinical trial sites and any FDA Bioresearch Monitoring inspections to assure compliance with GLPs and GCPs, respectively, and the integrity of nonclinical and clinical data submitted in support of the BLA;

- payment of the application fee under the Prescription Drug User Free Act ("PDUFA"), unless exempted; and

- FDA review and approval of a BLA to permit commercial marketing of the product for particular indications for use in the United States.

Nonclinical and Clinical Development

Before testing any investigational biological product in humans, the product must undergo nonclinical testing. Nonclinical tests include laboratory evaluations of product chemistry, formulation, and stability, as well as studies to evaluate the potential for efficacy and toxicity in animal studies. The conduct of the nonclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements, including applicable GLP requirements and the U.S. Department of Agriculture's Animal Welfare Act, if applicable.

Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. An IND submission includes the general investigational plan and the protocol or protocols for the proposed clinical trials, as well as results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product, chemistry, manufacturing and controls information, and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, each clinical trial must be reviewed and approved by an IRB or REC either centrally or individually at each institution at which the clinical trial will be conducted before the clinical trial begins at that site, and the IRB/REC must monitor the study until completed.

Regulatory authorities, the IRB/REC or the sponsor may suspend a clinical trial at any time on various grounds, including based on a finding that the subjects are being exposed to an unacceptable health risk, noncompliance with regulatory requirements, or concern that the trial is unlikely to meet its stated objectives. Imposition by the FDA of a partial or complete clinical hold would delay a proposed clinical study or cause suspension of an ongoing study until FDA determines that all outstanding concerns have been adequately addressed, and the FDA has notified the company that investigations may proceed. Imposition of a clinical hold could cause significant delays or difficulties in completing planned clinical studies in a timely manner.

Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap or be combined.

- Phase 1. The investigational product is initially introduced into a limited population of healthy human subjects or, in some circumstances, patients with the target disease or condition. These studies are designed to test the safety, dosage

tolerance, absorption, metabolism and distribution of the investigational product in humans, and the side effects associated with increasing doses.

- Phase 2. The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive phase 3 clinical trials.

- Phase 3. The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product labeling and approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called phase 4 studies may be made a condition to approval of the BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must include methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain FDA regulatory requirements in order to use the study as support for an IND or application for marketing approval or licensure in the United States. Specifically, the FDA requires that the study be conducted in accordance with GCP requirements intended to ensure the protection of human subjects and the quality and integrity of the study data, including review and approval by an independent ethics committee and use of proper procedures for obtaining informed consent from subjects, and that the FDA is able to validate the data from the study through an onsite inspection if the FDA deems such inspection necessary.

In December 2022, with the passage of the Food and Drug Omnibus Reform Act amendments to the FDCA, Congress added a requirement for sponsors to develop and submit a diversity action plan for each phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. Specifically, diversity action plans must include the sponsor's goals for enrollment, the underlying rationale for those goals, and an explanation of how the sponsor intends to meet them. This requirement will apply with respect to clinical investigations for which enrollment commences 180 days after the publication of a final guidance by the FDA on diversity action plans. FDA issued draft guidance addressing diversity action plans in June 2024, and the statute directs FDA to issue final guidance within nine months of closing the comment period on this draft guidance, which is expected to be in June 2025.

Information about certain clinical trials must be submitted within specific timeframes to the NIH for public dissemination on its ClinicalTrials.gov website. Similar requirements for posting clinical trial information in clinical trial registries exist in the European Union and in other countries outside the United States.

BLA Submission and Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent nonclinical 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. The submission of a BLA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

In addition, under the Pediatric Research Equity Act ("PREA"), a BLA or certain supplements to a BLA must contain data that are adequate to assess the safety and effectiveness of the biological product candidate 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, although deferrals or full or partial waivers may be available in some circumstances. A sponsor who is planning

to submit a marketing application for a biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit an initial pediatric study plan, within sixty days after an end-of-phase 2 meeting or as may be agreed between the sponsor and FDA. The FDA must then review the information submitted, consult with the sponsor, and agree upon a final plan. The FDA or the sponsor may request an amendment to the plan at any time. The FDA is required to send a PREA Non-Compliance letter to sponsors who have failed to submit their pediatric assessments required under PREA, have failed to seek or obtain a deferral or deferral extension or have failed to request approval for a required pediatric formulation, and the FDA publicly posts such PREA Non-Compliance letters and the sponsor's response. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. Once a BLA has been accepted for filing, the FDA's goal is to review standard applications within ten months after the filing date, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. A major amendment to a BLA submitted at any time during the review cycle, including in response to a request from the FDA, may extend the goal date by three months. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs.

During its review of a BLA, the FDA may convene an advisory committee to provide clinical insight on application review questions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application 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 a BLA, the FDA will typically inspect one or more clinical trial sites and may also inspect the applicant to assure compliance with GCPs intended to ensure the protection of human subjects and the quality and integrity of the study data.

Under the PHSA, the FDA may approve a BLA if it determines that the product is safe, pure, and potent and that the facility where the product will be manufactured meets standards designed to ensure that it continues to be safe, pure, and potent. On the basis of the FDA's evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities and any FDA inspections of nonclinical and clinical trial sites to assure compliance with GLP or GCP, and the applicant to ensure compliance with GCP, the FDA may issue an approval letter or a complete response letter ("CRL").To reach this determination, the FDA will evaluate whether the proposed new biologic's benefits outweigh its potential risks to patients.

An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. If the application is not approved, the FDA will issue a CRL which will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. Applicants that receive a CRL may submit to the FDA information that represents a complete response to the issues identified by the FDA. The FDA will not approve an application until issues identified in the CRL have been addressed.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy ("REMS") to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, including a more limited indication or addition of warnings, precautions or contraindications, or implementation of testing and surveillance programs to monitor the product after commercialization. The FDA may require one or more phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies Once approved, the FDA may withdraw the product approval if

compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a New Drug Application ("NDA") or BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the marketing application fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

The FDA's interpretation of the scope of orphan drug exclusivity may change. The FDA's longstanding interpretation of the Orphan Drug Act is that exclusivity is specific to the orphan indication for which the drug was actually approved. As a result, the scope of exclusivity has been narrow and protected only against competition from the same "use or indication" rather than the broader "disease or condition." In the September 2021 case *Catalyst Pharmaceuticals, Inc. v. Becerra*, a federal circuit court set aside the FDA's narrow interpretation and ruled that orphan drug exclusivity covers the full scope of the orphan-designated disease or condition regardless of whether the drug obtains approval only for a narrower use. Although the FDA announced in January 2023 that it will not apply the *Catalyst* decision beyond the facts at issue in that case, *Catalyst* could serve as a precedent for future challenges to FDA's orphan drug-related decisions. Legislation has been introduced, but has not been passed, that would codify the scope of orphan drug exclusivity set forth in the FDA's regulations, rather than the interpretation adopted by the Eleventh Circuit in *Catalyst*.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. The fast track program is intended to expedite or facilitate the process for developing new products that meet certain criteria. Specifically, new products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for more frequent interactions with the review team during product development and, once a BLA is submitted, the product may be eligible for priority review. A fast track product may also be eligible for rolling review, where the FDA may review sections of the BLA on a rolling basis before the complete application is submitted, if the applicant provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the applicant pays any required user fees upon submission of the first section of the BLA.

A product intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as phase 1 and an organizational commitment to expedite the development and review of the product, including involvement of senior managers.

Any marketing application for a biologic submitted to the FDA for approval, including a product with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition. For original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to ten months under standard review). Fast track, breakthrough therapy, and priority review designations are not mutually exclusive, and a product may qualify for one or more of these programs. While these programs are intended to expedite product development and approval, they do not alter the standards for FDA marketing approval. Even if designation is granted, FDA may later decide that a product candidate no longer meets the conditions for designation and the designation may be rescinded.

Additionally, the FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022, the FDA may require, as appropriate, that such studies be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Failure to conduct required post-approval studies with due diligence, failure to confirm a clinical benefit during the post-approval studies, or dissemination of false or misleading promotional materials would allow the FDA to withdraw the product approval on an expedited basis. All promotional materials for therapeutic candidates approved under accelerated approval are subject to prior review by the FDA unless FDA informs the BLA holder otherwise.

The Consolidated Appropriations Act, 2023 strengthens the FDA's authority to require and regulate post-approval studies of accelerated approval drugs and to expedite the rescission of accelerated approval based on these post-approval studies.

Regulation of Combination Products

Certain therapeutic products comprise multiple components, such as drug components and device components, that would normally be subject to different regulatory frameworks by the FDA and frequently regulated by different centers at the FDA. These products are known as combination products. Under the FDCA, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The determination of which center will be the lead center is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a drug-device combination product is attributable to the drug product, the FDA center responsible for premarket review of the drug product would have primary jurisdiction for the combination product. The FDA has also established the Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute. A combination product with a primary mode of action attributable to the drug or biologic component generally would be reviewed and approved pursuant to the drug or biologic approval processes set forth in the FDCA. In reviewing the NDA or BLA for such a product, however, FDA reviewers would consult with their counterparts in the FDA's Center for Devices and Radiological Health to ensure that the device component of the combination product met applicable requirements regarding safety, effectiveness, durability and performance. In addition, under FDA regulations, combination products are subject to cGMP requirements applicable to both drugs and devices, including the Quality System Regulation applicable to medical devices.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, manufacturing, testing and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies. BLA holders and their contractors, including third-party manufacturers, are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with

ongoing regulatory requirements, including cGMPs and pharmacovigilance regulations. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

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

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates the marketing, labeling, advertising and promotion of prescription drug products, including biological products. Promotional claims about a product candidate are prohibited before the product is approved. In addition, the NDA or BLA holder of an approved drug, including a biologic, in the United States may not promote that drug for unapproved, or off-label, uses, although a physician may prescribe a drug for an off-label use in accordance with laws and professional standards governing the practice of medicine. If a company is found to have promoted off-label uses for an approved drug, it may become subject to administrative and judicial enforcement by the FDA, the DOJ or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company may promote or distribute drug products in the future. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Biosimilars and Reference Product Exclusivity

The Affordable Care Act ("ACA") includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biosimilar and interchangeable biosimilars. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. A product shown to be biosimilar or interchangeable with an FDA-approved reference biological product may rely in part on the FDA's previous determination of safety and effectiveness for the reference product for approval, which can potentially reduce the cost and time required to obtain approval to market the product.

Upon licensure by the FDA, an interchangeable biosimilar may be substituted for the reference product without the intervention of the health-care provider who prescribed the reference product. The FDA approved the first interchangeable biosimilars in 2021. However, in 2024, the agency updated its policies regarding interchangeable biosimilars to require fewer tests by the applicant to demonstrate interchangeability and to highlight that these products are not safer or more effective than biosimilars that have not been demonstrated "interchangeable" with their reference products. In response to such scientific developments, it is possible that Congress could revisit and amend relevant provisions from the BPCIA as part of the upcoming legislative session.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own nonclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product.

The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. The law also includes an extensive process for the innovator biologic and biosimilar manufacturer to litigate patent infringement, validity, and enforceability prior to the approval of the biosimilar.

As discussed below, the Inflation Reduction Act of 2022 ("IRA") is a significant new law that intends to foster generic and biosimilar competition and to lower drug and biologic costs.

Patent Term Restoration

Some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly referred to as the "Hatch-Waxman Amendments"), which amended the FDCA. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA or BLA, plus the time between the submission date and the approval of that application. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO in consultation with the FDA, reviews and approves the application for any patent term extension. Thus, for each approved product, we may apply for restoration of patent term for one of our related owned or licensed patents to add patent life beyond the original expiration date, depending on the expected length of the clinical studies and other factors involved in the filing of the relevant NDA or BLA.

Foreign Regulation

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, research and development, clinical trials, testing, manufacturing, safety, efficacy, quality control, labeling, packaging, storage, record keeping, distribution, reporting, export and import, advertising, marketing and other promotional practices involving biological products as well as authorization, approval as well as post-approval monitoring and reporting of our products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials.

The requirements and process governing the conduct of clinical trials, including requirements to conduct additional clinical trials, product licensing, safety reporting, post-authorization requirements, marketing and promotion, interactions with healthcare professionals, pricing and reimbursement may vary widely from country to country. No action can be taken to market any product in a country until an appropriate approval application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices may not be approved for such product, which would make launch of such products commercially unfeasible in such countries.

Regulation in the European Union

European Data Laws

We are subject to laws and regulations related to, among other things, privacy, data protection, information security and consumer protection across different markets where we conduct our business. Such laws and regulations are constantly evolving and changing and are likely to remain uncertain for the foreseeable future. Our actual or perceived failure to comply with such obligations could have an adverse effect on our business, operating results and financial operations. Complying with these numerous, complex, and often changing regulations is expensive and difficult, and failure to comply with any data protection, privacy laws or data security laws or any security incident or breach involving the potential or actual misappropriation, loss or other unauthorized processing, use or disclosure of sensitive or confidential patient, consumer or other personal information, whether by us, one of our collaborators or another third-party, could adversely affect our business, financial condition, and results of operations, including but not limited to investigation costs, material fines and penalties, compensatory, special, punitive, and statutory damages, litigation, consent orders regarding our privacy and security practices, requirements that we provide notices, credit monitoring services, and/or credit restoration services or other relevant services to impacted individuals, adverse actions against our licenses to do business, reputational damage and injunctive relief.

The collection and use of personal health data and other personal data in the European Union ("EU") is governed by the provisions of the European General Data Protection Regulation 2016/679 ("GDPR"), which became applicable in May 2018, and related data protection laws in individual EU Member States. The GDPR imposes a number of strict obligations and restrictions on the ability to process, including collecting, analyzing and transferring, personal data of individuals, in particular with respect to health data from clinical trials and adverse event reporting. The GDPR includes requirements relating to the legal basis of the processing (such as consent of the individuals to whom the personal data relates), the information provided to the individuals prior to processing their personal data, the notification obligations to the national data protection authorities, and the security and confidentiality of the personal data. EU Member States may also impose additional requirements in relation to health, genetic and biometric data through their national legislation.

In addition, the GDPR imposes specific restrictions on the transfer of personal data to countries outside of the European Economic Area ("EEA") that are not considered by the European Commission ("EC") to provide an adequate level of data protection. Appropriate safeguards are required to enable such transfers. Among the appropriate safeguards that can be used, the data exporter may use the standard contractual clauses ("SCCs"). When relying on SCCs, the data exporters are also required to conduct a transfer risk assessment to verify if anything in the law and/or practices of the third country may impinge on the effectiveness of the SCCs in the context of the transfer at stake and, if so, to identify and adopt supplementary measures that are necessary to bring the level of protection of the data transferred to the EU standard of essential equivalence. Where no supplementary measure is suitable, the data exporter should avoid, suspend or terminate the transfer. On June 18, 2021, the European Data Protection Board adopted recommendations to assist data exporters with such assessment and their duty to identify and implement supplementary measures where they are needed to ensure compliance with the EU level of protection to the personal data they transfer to third countries. With regard to the transfer of personal data from the EEA to the United States, on July 10, 2023, the European Commission adopted its adequacy decision for the EU-US Data Privacy Framework. On the basis of the new adequacy decision, personal data can flow from the EEA to U.S. companies participating in the framework. Companies that have not signed up to the framework will continue to be subject to the international transfer requirements above, and will need to ensure that adequate safeguards such as the SCCs are implemented for all EEA-US data transfers.

Failure to comply with the requirements of the GDPR and the related national data protection laws of the EU Member States may result in significant monetary fines for noncompliance of up to €20 million or 4% of the annual global turnover of the noncompliant company, whichever is greater, other administrative penalties and a number of criminal offenses (punishable by uncapped fines) for organizations and, in certain cases, their directors and officers, as well as civil liability claims from individuals whose personal data was processed. Data protection authorities from the different EU Member States may still implement certain variations, enforce the GDPR and national data protection laws differently, and introduce additional national regulations and guidelines, which adds to the complexity of processing personal data in the EU. Guidance developed at both the EU level and at the national level in individual EU Member States concerning implementation and compliance practices are often updated or otherwise revised.

Furthermore, there is a growing trend towards the required public disclosure of clinical trial data in the EU, which adds to the complexity of obligations relating to processing health data from clinical trials. Such public disclosure obligations are provided in the new EU Clinical Trials Regulation No.536/2014 ("CTR"), EMA disclosure initiatives and voluntary commitments by industry. Failure to comply with these obligations could lead to government enforcement actions and significant penalties against us, harm to our reputation, and adversely impact our business and operating results. The uncertainty regarding the

interplay between different regulatory frameworks, such as the CTR and the GDPR, further adds to the complexity that we face with regard to data protection regulation.

With regard to the transfer of personal data from the EEA to the United Kingdom ("UK"), personal data may now freely flow from the EEA to the UK since the UK is deemed to have an adequate data protection level. However, the adequacy decisions include a 'sunset clause' which entails that the decisions will automatically expire four years after their entry into force, and so this adequacy decision will be reviewed, and is expected – but not guaranteed - to be renewed, before or during June 2025.

Drug and Biologic Development Process in the EU

In the EU, medicinal products are primarily regulated by EU pharmaceutical law seeking to harmonize the standards for assessing the quality, safety and efficacy of medicinal products. The process of obtaining regulatory approvals and the subsequent compliance with applicable legislation requires the expenditure of substantial time and financial resources. Failure to comply with the applicable EU requirements at any time during the product development and post-approval may attract enforcement actions and sanctions.

The process by which medicinal products may be marketed in the EU generally involves the following:

- completion of nonclinical laboratory tests and animal studies performed consistent with the principles of GLP set out in Directive 2004/9/EC and Directive 2004/10/EC;
- submission to the relevant national competent authorities ("NCA") in each Member State where the trial will be performed of an application for clinical trial authorization ("CTA"), which must be granted prior to the commencement of the clinical trial;
- issuance of a positive opinion on the clinical trial by a research ethics committee ("REC") in each Member State where the trial will be performed;
- performance of adequate and well-controlled clinical trials in accordance with the principles of GCPs set out in the CTR, Directive 2005/28/EC, Commission Implementing Regulation 2017/556 or the equivalent requirements for trials conducted outside the EU, the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use guidelines on GCPs, and the ethical principles set out in the Declaration of Helsinki;
- manufacture and import of the medicinal product in accordance with the principles of GMPs set out in Regulation No. 1252/2014, Directive 2001/83/EC, Directive 2017/1572 and associated legislation;
- preparation of and submission to the EMA, or the relevant NCA, of a marketing authorization application ("MAA") after completion of all pivotal clinical trials, nonclinical studies and chemistry, manufacturing and control information;
- following satisfactory assessment of the MAA dossier, adoption by the EMA, or the relevant NCA, of a positive opinion on the approvability of the medicinal product;
- following EMA's positive scientific assessment or that of a NCA on the approvability of the medicinal product, grant of a marketing authorization in respect of therapeutic indications by either the European Commission for centrally approved medicinal products or NCAs for nationally approved medicinal products;
- national approval for pricing and reimbursement including the need to demonstrate cost-effectiveness in each Member State for a new medicinal product to be adopted for use in the respective national health systems; and
- establishment and implementation of an appropriate pharmacovigilance system which complies with principles of GVP set out in Directive 2010/84/EU, Regulation (EU) No 1235/2010 and Commission Implementing Regulation No 520/2012.

Clinical Development in the EU

Regardless of where they are conducted, all clinical trials included in applications for marketing authorization for human medicines in the EU / EEA must have been carried out in accordance with EU regulations. This means that clinical trials conducted in the EU / EEA have to comply with EU clinical trial legislation but also that clinical trials conducted outside the

EU / EEA have to comply with the principles equivalent to those set out in the EEA, including adhering to GCPs and the ethical principles set out in the Declaration of Helsinki.

In accordance with the CTR, sponsors must submit a single CTA application through a centralized EU clinical trials portal, the Clinical Trials Information System ("CTIS"). The CTA application will generally include the results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product, chemistry, manufacturing and controls information, and any available human data or literature to support the use of the investigational product. The sponsor must propose one NCA to act as reporting member state ("RMS") to lead the validation and evaluation of the application. This RMS will be responsible for consulting and coordinating with the NCAs of the other EU Member States, i.e., Concerned Member States ("CMS"). If an application is rejected, it may be amended and resubmitted through the CTIS. If an approval is issued, the sponsor may start the clinical trial in all CMSs. However, a CMS may in limited circumstances declare an "opt-out" from an approval and prevent the clinical trial from being conducted in such Member State. Consistent with the position in the U.S., NCAs, RECs or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives.

During the development of a medicinal product, the EMA and NCAs provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually achieved in the form of scientific advice, which is given by the Committee for Medicinal Products for Human Use ("CHMP") on the recommendation of the Scientific Advice Working Party. A fee is incurred with each scientific advice procedure but is significantly reduced for designated orphan medicines. Advice from the EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical studies, and pharmacovigilance plans and risk-management programs. Advice is not legally binding with regard to any future MAA of the product concerned.

Drug Marketing Authorization

In the EU, medicinal products are subject to extensive pre- and post-market regulation by regulatory authorities at both the EU and national levels. In the EU and EEA, after completion of all required testing, nonclinical studies, clinical trials and chemistry, manufacturing, and controls information can be included in a MAA requesting approval to market the product for one or more indications. Pharmaceutical products may only be placed on the market after a marketing authorization has been obtained. In the EU and EEA, there are two types of marketing authorization: centralized and national.

Centralized Marketing Authorizations

The centralized procedure provides for the grant of a single marketing authorization that is issued by the EC, following the scientific assessment of the application by the EMA that is valid for all EU Member States as well as in the three additional EEA Member States. The centralized procedure is compulsory for specific medicinal products, including for medicines developed by means of certain biotechnological processes, (recombinant DNA technology, controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells, and hybridoma and monoclonal antibody methods) products designated as orphan medicinal products, advanced-therapy medicinal products (gene-therapies, somatic cell-therapies or tissue-engineered medicines), and medicinal products containing a new active substance indicated for the treatment of certain diseases (AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune, other immune dysfunctions and viral diseases). For medicinal products containing a new active substance not yet authorized in the EEA before May 20, 2004 and indicated for the treatment of other diseases, medicinal products that constitute significant therapeutic, scientific or technical innovations or for which the grant of a marketing authorization through the centralized procedure would be in the interest of public health at EU level, an applicant may request submission of an marketing authorization through the centralized procedure.

Under the centralized procedure, the CHMP established at the EMA, is responsible for conducting the initial assessment of a drug. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure, the timeframe for the evaluation of an MAA by the EMA's CHMP is, in principle, 210 days from receipt of a valid MAA. However, this timeline excludes clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP, so the overall process typically takes a year or more, unless the application is eligible for an accelerated assessment. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. Upon request, the CHMP can reduce the time frame to 150 days if the applicant provides sufficient justification for an accelerated assessment. The CHMP will provide a positive opinion regarding the application only if it meets certain quality, safety and efficacy

requirements. This opinion is then transmitted to the EC, which has the ultimate authority for granting marketing authorization within 67 days after receipt of the CHMP opinion.

National Marketing Authorizations

Medicines that fall outside the mandatory scope of the centralized procedure can be authorized nationally. Where a product already received a national marketing authorization, applicants can request other Member States to recognize the approval via the mutual recognition procedure. If the product has not received a national marketing authorization in any Member State at the time of application, it can be approved simultaneously in various Member States through the decentralized procedure.

The decentralized procedure permits companies to file identical MAAs for a medicinal product to the NCAs of various EU Member States simultaneously. The NCA of a single EU Member State, the reference member state, is appointed to review the application and provide an assessment report. The NCAs of the other Member States, the concerned member states, are subsequently required to grant a marketing authorization for their territories on the basis of this assessment. The only exception to this is where the competent authority of a CMS considers that there are concerns of potential serious risk to public health, the disputed points are subject to a dispute resolution mechanism and may eventually be referred to the EC, whose decision is binding for all EU Member States.

Risk Management Plan

All new MAAs must include a Risk Management Plan ("RMP") describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. RMPs are continually modified and updated throughout the lifetime of the medicine as new information becomes available. An updated RMP must be submitted: (i) at the request of EMA or a NCA, or (ii) whenever the risk-management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit-risk profile or as a result of an important pharmacovigilance or risk-minimization milestone being reached. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization. Since October 30, 2023, all RMPs for centrally authorized products are published by the EMA subject only to limited redactions.

Marketing Authorization Validity Period and Exclusivity

Marketing Authorizations have an initial duration of five years. After these five years have elapsed, the authorization may subsequently be renewed on the basis of a reevaluation of the risk-benefit balance. Once renewed, the marketing authorization is valid for an unlimited period unless the European Commission or the NCA decides, on justified grounds relating to pharmacovigilance, to proceed with only one additional five-year renewal. Applications for renewal must be made to the EMA at least nine months before the five-year period expires.

In the EU, medicinal products containing a new active substance ("NAS"), qualify for eight years of data exclusivity upon the product's first marketing authorization in the EU and an additional two years of market exclusivity. This data exclusivity, if granted, prevents the developers of generic versions of the innovative medicinal product from referencing the innovator's data for eight years. After this period has expired, a generic marketing authorization can be submitted, and the innovator's data may be referenced. During the marketing protection period, even if a generic marketing authorization has been granted, the generic medicinal product cannot be placed on the market until the expiry of a full ten-year period from the initial authorization of the innovative medicinal product. The overall ten-year period can be extended to a maximum of eleven years if, during the first eight of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Products may not be granted data exclusivity since there is no guarantee that a product will be considered by the EU's regulatory authorities to include an NAS. Even if a compound is considered to be a NAS and the marketing authorization applicant is able to gain the prescribed period of data exclusivity, another company could market a version of the medicinal product if such company can compile a full MAA based on its own complete set of chemistry, manufacturing, and controls information, nonclinical studies and clinical trials and obtain marketing authorization of its product.

Conditional Approval

Similar to accelerated approval regulations in the United States, conditional marketing authorizations can be granted in the EU in the interest of public health and patients to address unmet medical needs. A conditional marketing authorization can be granted for medicinal products based on less comprehensive clinical data referring to the safety and efficacy of the medicinal product than normally required. However, for such an approval to be granted a number of criteria should be fulfilled: (i) the

benefit/risk balance of the product is positive, (ii) it is likely that the applicant will be in a position to provide the comprehensive clinical data, (iii) unmet medical needs will be fulfilled by the grant of the marketing authorization and (iv) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorization must be renewed annually.

Orphan Designation and Exclusivity

The criteria for designating an orphan medicinal product in the European Union are similar in principle to those in the United States. The EMA's Committee for Orphan Medicinal Products ("COMP") assesses orphan drug designation if the medicinal product is: (1) intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the European Union when the application is made, or without the incentives derived from orphan status, it is unlikely the medicinal product would generate sufficient return to justify the investment; and (2) there is no other satisfactory method approved in the EU of diagnosing, preventing, or treating the condition, or if such a method exists, the proposed medicinal product is a significant benefit to patients affected by the condition. The COMP's assessment will form the basis for the European Commission to adopt an implementing decision on grant of an orphan designation. An application for orphan drug designation (which is not a marketing authorization, as not all orphan-designated medicines reach the authorization application stage) must be submitted first before an application for marketing authorization of the medicinal product is submitted. The applicant will receive a fee reduction for the MAA if the orphan drug designation is granted, but not if the designation is still pending at the time the MAA is submitted, and applicants must submit an annual report to EMA summarizing the status of development of the medicine. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Designated orphan medicines are eligible for conditional marketing authorization.

The COMP reassesses the orphan drug designation of a product in parallel with the CHMP's review of the MAA. For a product to benefit from market exclusivity it must maintain its orphan drug designation at the time of marketing authorization review by the EMA and approval by the EC. Additionally, any marketing authorization granted for an orphan medicinal product must only cover the therapeutic indication(s) that are covered by the orphan drug designation. Upon the grant of a marketing authorization, orphan drug designation provides up to ten years of market exclusivity in the orphan indication.

During the 10-year period of market exclusivity, with a limited number of exceptions, NCAs and the EMA may not accept MAAs to extend an existing marketing authorization or grant marketing authorizations for other similar medicinal products for the same approved therapeutic indication. A similar medicinal product is defined as a medicinal product containing a similar active substance or substances as contained in a currently authorized orphan medicinal product, and which is intended for the same therapeutic indication. An orphan medicinal product can benefit from an additional two years of market exclusivity for an orphan-designated condition when the results of specific studies are reflected in the Summary of Product Characteristics, addressing the pediatric population and completed in accordance with a fully compliant Pediatric Investigation Plan. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications.

The 10-year market exclusivity period may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation or that the product is sufficiently profitable to justify maintenance of the market exclusivity. When the period of orphan market exclusivity for an indication ends, the orphan drug designation for that indication expires as well. Orphan exclusivity runs in parallel with normal rules on data exclusivity and market protection. Additionally, a marketing authorization may be granted to a similar medicinal product (orphan or not) for the same or overlapping indication subject to certain requirements.

PRIME Designation

In March 2016, the EMA launched an initiative to facilitate development of product candidates in indications, often rare, for which few or no satisfactory therapies currently exist in the EU. The Priority Medicines ("PRIME") scheme is intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation for them to be reviewed under the centralized procedure. Products from small- and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies on the basis of compelling nonclinical data and tolerability data from initial clinical trials. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted. Importantly, once a candidate medicine has been selected for the PRIME scheme, a dedicated contact point and rapporteur from the CHMP or from the Committee for Advanced Therapies ("CAT") are appointed facilitating increased understanding of the product at EMA's Committee level. A kick-off meeting with the CHMP/CAT rapporteur initiates these relationships and includes a team of multidisciplinary experts to provide guidance on the overall development plan and

regulatory strategy. PRIME eligibility does not change the standards for product approval, and there is no assurance that any such designation or eligibility will result in expedited review or approval.

Regulation of Combination Products in the EU

Unlike in the U.S., there is no single definition for a combination product. In the EU, product containing a medical device and a medicinal product are either regulated as a medicinal product or a medical device and the primary mode of action governs the regulatory pathway. If a medical device intended to administer a medicinal product and the medicinal product and medical device are placed on the market in such a way that they form a single integral product which is intended exclusively for use in the given combination and which is not reusable, then the single integral product is regulated as a medicinal product. In that case, the approval must take account of general safety and performance requirements for assessing the medical device component. In contrast, where the medical device and the medicinal product are not presented as an integrated unit, then they will be regulated separately under the medical device legislation and the medicinal product legislation. Any device which incorporates as an integral part, a medicinal substance, including a biological substance, that have an action ancillary to that the device, then the combination product is regulated as a medical device, but the notified body responsible for conformity assessment must consult a medicine authority including the EMA. However, if the action of the medicinal substance including a biological substance is principal and not ancillary to that of the device, then the combination product is regulated as a medicinal product.

Post-Approval Requirements in the EU

EU law requires each marketing authorization holder, NCA, and the EMA to operate a pharmacovigilance system. Collectively, these systems ensure the ongoing monitoring of the safety and benefit-risk profile of approved medicinal products. Key responsibilities of marketing authorization holders include, but are not limited to: the maintenance of a pharmacovigilance system master file that outlines the marketing authorization holder's relevant processes and procedures; the appointment of a Qualified Person for pharmacovigilance who is responsible for overseeing the marketing authorization holder's pharmacovigilance system; the collection, recording and reporting by the marketing authorization holder to the relevant competent authorities of suspected adverse events associated with the use of their medicinal products; the submission by marketing authorization holders of periodic safety update reports to the relevant competent authority and to regular audits and inspections by the relevant regulatory authorities. Post approval, any changes to the approved medicinal product, such as the addition of new indications or changes to the manufacturing process, are subject to prior review and approval by the relevant regulatory authorities. Obtaining and maintaining such approvals requires marketing authorization holders to expend time, money and effort to ensure and demonstrate regulatory compliance.

Similar to the position in the U.S., if a marketing authorization holder does not maintain compliance with applicable regulatory requirements, or if unfavorable signals derived from post-approval use of the medicinal product are identified, the relevant regulatory authority can impose various sanctions/remedial actions, including but not limited to: the suspension or revocation of the underlying approvals; the imposition of market recalls; the performance of post-authorization safety studies; the imposition of changes to the approved labeling; the issuance of warning letters and imposition of fines; restrictions on the marketing of a medicinal product; the issuance of safety alerts including Dear Healthcare Professional letters; injunctions; and the imposition of criminal penalties.

Regulation in the UK

The UK formally left the EU on January 31, 2020. After the expiry of the transition period on December 31, 2020, the UK became a "third country" for the purposes of EU law. Until recently, certain aspects of EU pharmaceutical legislation applied in Northern Ireland by virtue of the Northern Ireland Protocol. However, in accordance with the Windsor Framework, as of January 1, 2025, EU pharmaceutical law no longer applies in Northern Ireland. The Windsor Framework sets out a long-term set of arrangements for the supply of medicines into Northern Ireland. In particular, medicines need to be approved and licensed on a UK-wide basis by the UK's Medicines and Healthcare products Regulatory Agency (the "MHRA"), with medicines using the same packaging and labeling across the UK. The EMA has no role in approving or licensing new drugs for provision in Northern Ireland.

The European Union and the UK have agreed on a trade and cooperation agreement ("TCA"), which includes provisions affecting the life sciences sector (including on customs and tariffs). There are some specific provisions concerning pharmaceuticals, including the mutual recognition of cGMP, inspections of manufacturing facilities for medicinal products and GMP documents issued. The TCA does not, however, contain wholesale mutual recognition of UK and EU pharmaceutical regulations and product standards.

The UK government has adopted the Medicines and Medical Devices Act 2021 ("MMDA") to enable the UK's regulatory frameworks to be updated following the UK's departure from the EU. The MMDA introduces regulation-making, delegated powers covering the fields of human medicines, clinical trials of human medicines, veterinary medicines and medical devices. The MHRA has since been consulting on future regulations for medicines and medical devices in the UK.

The collection and use of personal health data and other personal data in the UK is governed by the provisions of the UK GDPR (as defined by section 3(10) (as supplemented by section 205(4)) of the Data Protection Act 2018 (the "DPA 2018")), the DPA 2018, and related data protection laws in the UK. The UK GDPR imposes a number of strict obligations and restrictions on the ability to process, including collecting, analyzing and transferring, personal data of individuals, in particular with respect to health data from clinical trials and adverse event reporting. The UK GDPR includes requirements relating to the legal basis of the processing (such as consent of the individuals to whom the personal data relates), the information provided to the individuals prior to processing their personal data, the notification obligations to the national data protection authorities, and the security and confidentiality of the personal data. Separately to the fines that can be imposed by the GDPR, the UK regime has the ability to impose fines for failure to comply with the requirements of the UK GDPR and related UK data protection laws up to the greater of £17.5 million or 4% of global turnover.

Following the UK's withdrawal from the EU and the EEA, companies are subject to specific transfer rules under the UK regime; personal data may flow freely from the UK to the EEA, since the EEA is deemed to have an adequate data protection level for purposes of the UK regime. These UK international transfer rules broadly mirror the EU GDPR rules. On February 2, 2022, the UK Secretary of State laid before the UK Parliament the international data transfer agreement ("IDTA") and the international data transfer addendum to the European Commission's standard contractual clauses for international data transfers ("Addendum") and a document setting out transitional provisions. The IDTA and Addendum came into force on March 21, 2022 and replaced the old SCCs for the purposes of the UK regime. However, the transitional provisions, adopted with the IDTA and the Addendum, provide that contracts concluded on or before September 21, 2022 on the basis of any old SCCs continued to provide appropriate safeguards for the purpose of the UK regime until March 21, 2024, provided that the processing operations that are the subject matter of the contract remain unchanged and reliance on those clauses ensures that the transfer of personal data is subject to appropriate safeguards. With regard to the transfer of personal data from the UK to the United States, the UK government has adopted an adequacy decision for the United States, the UK-US Data Bridge, which came into force on October 12, 2023. The UK-US Data Bridge recognizes the United States as offering an adequate level of data protection where the transfer is to a U.S. company participating in the EU-US Data Privacy Framework and the UK Extension. As with the EU equivalent, companies that are not participants in the framework and extension will continue to be subject to the international transfer requirements under the UK GDPR.

Other Regulations

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation: the federal Anti-Kickback Statute ("AKS"); the federal False Claims Act ("FCA"); the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and similar foreign, federal and state fraud, abuse and transparency laws.

The AKS prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under any federal healthcare program. The term remuneration has been interpreted broadly to include anything of value. The AKS has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand, and prescribers and purchasers on the other. The government often takes the position that to violate the AKS, only one purpose of the remuneration need be to induce referrals, even if there are other legitimate purposes for the remuneration. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from AKS prosecution, but they are drawn narrowly and practices that involve remuneration, such as consulting agreements, that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the AKS. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Civil and criminal false claims laws, including the FCA, and civil monetary penalty laws, which can be enforced through civil whistleblower or qui tam actions, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment of federal government funds, including in federal healthcare programs, that are false or

fraudulent. Pharmaceutical and other healthcare companies have been prosecuted under these laws for engaging in a variety of different types of conduct that caused the submission of false claims to federal healthcare programs. Under the AKS, for example, a claim resulting from a violation of the AKS is deemed to be a false or fraudulent claim for purposes of the FCA. The FCA imposes mandatory treble damages and per-violation civil penalties up to approximately $25,000.

HIPAA created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program, including private third-party payors, and making false statements relating to healthcare matters. A person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate the statute in order to have committed a violation.

The FDCA addresses, among other things, the design, production, labeling, promotion, manufacturing, and testing of drugs, biologics and medical devices, and prohibits such acts as the introduction into interstate commerce of adulterated or misbranded drugs or devices. The PHSA also prohibits the introduction into interstate commerce of unlicensed or mislabeled biological products.

The U.S. federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information related to payments or other transfers of value to various healthcare professionals including physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, certified nurse-midwives, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning on January 1, 2023, California Assembly Bill 1278 requires California physicians and surgeons to notify patients of Open Payments.

We are also subject to additional similar U.S. state and foreign law equivalents of each of the above federal laws, which, in some cases, differ from each other in significant ways, and may not have the same effect, thus complicating compliance efforts. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply, we may be subject to penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations.

For other countries outside of the EU, UK and United Stated such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Data Privacy and Security

Numerous United States state, federal, and local laws and regulations, as well as foreign legislation, govern the collection, processing, transfer, disclosure, sharing, storing, dissemination, use, confidentiality, and security of personal information. In the United States, there are several federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations that regulate the collection, use, disclosure, protection and processing of personal information, including medical and health-related information. These laws could apply to our operations or the operations of our partners.

For example, in the United States, at the federal level, the regulations promulgated under the Health Insurance Portability and Accountability Act ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH Act"), and their respective implementing regulations impose data privacy, security, and breach notification obligations with respect to protected health information ("PHI") on certain health-care providers, health plans and health-care clearinghouses, known as "covered entities", as well as on their business associates, which include persons or entities that perform certain services that involve using, disclosing, creating, receiving, maintaining, or transmitting individually identifiable PHI for or on behalf of such covered entities. While we have determined that we are neither a covered entity nor a business associate directly subject to HIPAA, many of the U.S. health-care providers with which we interact are subject to HIPAA, and we may have assumed obligations related to protecting the privacy of personal information.

These requirements imposed by HIPAA and the HITECH Act on covered entities and business associates include, entering into agreements that require business associates protect PHI provided by the covered entity against improper use or disclosure, among other things; following certain standards for the privacy of PHI, which limit the disclosure of a patient's past, present, or future physical or mental health or condition or information about a patient's receipt of health-care if the information identifies, or could reasonably be used to identify, the individual; ensuring the confidentiality, integrity, and availability of all PHI created, received, maintained, or transmitted in electronic form, to identify and protect against reasonably anticipated threats or impermissible uses or disclosures to the security and integrity of such PHI; and reporting of breaches of PHI to individuals and regulators.

Entities that are found to be in violation of HIPAA may be subject to significant civil, criminal, and administrative fines and other penalties and/or additional reporting and oversight obligations, for example, if required to enter into a resolution agreement and corrective action plan with the U.S. Department of Health and Human Services to settle allegations of HIPAA non-compliance. A covered entity or business associate is also liable for civil money penalties for a violation that is based on an act or omission of any of its agents, which may include a downstream business associate, as determined according to the federal common law of agency. The HITECH Act also increased the civil and criminal penalties applicable to covered entities and business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. To the extent that we submit electronic healthcare claims and payment transactions that do not comply with the electronic data transmission standards established under HIPAA and the HITECH Act, payments to us may be delayed or denied.

Even when HIPAA does not apply, according to the Federal Trade Commission, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure, including medical and health-related information, may constitute unfair or deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act.

In addition, there are also several U.S. state privacy laws, such as the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (together, the "CCPA"), that govern the privacy and security of personal information. Some, such as the Washington My Health My Data Act, protect specific medical and health-related information in certain circumstances. Some of these state laws are more stringent than HIPAA and many differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. The CCPA applies to personal data of consumers, business contacts, and employees, and imposes obligations on certain businesses that do business in California, including to provide specific disclosures in privacy notices and rights to California residents in relation to their personal information. Health information may fall under the CCPA's definition of personal information where it identifies, relates to, describes, or is reasonably capable of being associated with or could reasonably be linked with a particular consumer or household—unless it is subject to HIPAA—and is included under a new category of personal information, "sensitive personal information," which is offered greater protection. In addition, almost 20 other states have now passed comprehensive privacy laws that have taken effect or will come into effect at various times over the next few years. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation.

Privacy and security laws, regulations, and other obligations are stringent, constantly evolving and may conflict with each other, which makes compliance difficult and complicated. Actual or alleged noncompliance can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing. Any of these events could have a material adverse effect on our reputation, business, or financial condition. Additionally, our use of artificial intelligence and machine learning may be subject to laws and evolving regulations regarding the use of artificial intelligence/machine learning, controlling for data bias, and anti-discrimination.

Health Reform

The United States and some foreign jurisdictions are considering or have enacted a number of reform proposals to change the healthcare system. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state legislative initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded health-care programs, and increased governmental control of drug pricing.

The ACA, which was enacted in March 2010, substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly affected the pharmaceutical industry. The ACA contains a number of provisions of particular import to the pharmaceutical and biotechnology industries, including, but not limited to, those governing enrollment in federal healthcare programs, a new methodology by which rebates owed by manufacturers under the

Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and annual fees based on pharmaceutical companies' share of sales to federal health-care programs. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future.

Other legislative changes have been proposed and adopted since the ACA was enacted, including automatic aggregate reductions of Medicare payments to providers of 2% per fiscal year as part of the federal budget sequestration under the Budget Control Act of 2011. These reductions went into effect in April 2013 and, due to subsequent legislative amendments, will remain in effect through 2030 with the exception of a temporary suspension from May 1, 2020 through December 31, 2020, unless additional action is taken by Congress. In addition, the Bipartisan Budget Act of 2018, among other things, amended the Medicare Act (as amended by the ACA) to increase the point-of-sale discounts that manufacturers must agree to offer under the Medicare Part D coverage discount program from 50% to 70% off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs being covered under Medicare Part D.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state measures designed to, among other things, reduce the cost of prescription drugs, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, in May 2019, CMS adopted a final rule allowing Medicare Advantage Plans the option to use step therapy for Part B drugs, permitting Medicare Part D plans to apply certain utilization controls to new starts of five of the six protected class drugs, and requiring the Explanation of Benefits for Part D beneficiaries to disclose drug price increases and lower cost therapeutic alternatives, which went into effect on January 1, 2021.

Notwithstanding the IRA, continued legislative and enforcement interest exists in the United States with respect to specialty drug pricing practices. Specifically, we expect regulators to continue pushing for transparency to drug pricing, reducing the cost of prescription drugs under Medicare, reviewing the relationship between pricing and manufacturer patient programs, and reforming government program reimbursement methodologies for drugs.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological product for which we obtain regulatory approval. Sales of any product, if approved, depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement, if any, for such product by third-party payors. Decisions regarding whether to cover any of our product candidates, if approved, the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical or biological products, medical devices and medical services, in addition to questioning safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product that receives approval. Decreases in third-party reimbursement for any product or a decision by a third-party not to cover a product could reduce physician usage and patient demand for the product.

For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Recently, the U.S. government passed the IRA, which includes provisions that authorize the U.S. Department of Health and Human Services to negotiate prices of certain drugs with participating manufacturers in federal healthcare programs. The IRA provides CMS with significant new authorities intended to curb drug costs and to encourage market competition. For the first time, CMS will be able to directly negotiate prescription drug prices and to cap out-of-pocket costs. Each year, CMS will select and negotiate a preset number of high-spend drugs and biologics that are covered under Medicare Part B and Part D that do not have generic or biosimilar competition. These price negotiations will begin in 2023. The IRA also provides a new "inflation rebate" covering Medicare patients that will take effect in 2023 and is intended to counter certain price increases in prescriptions drugs. The inflation rebate provision will require drug manufacturers to pay a rebate to the federal government if the price for a drug or biologic under Medicare Part B and Part D increases faster than the rate of inflation. To support biosimilar competition, beginning in October 2022, qualifying biosimilars may receive a Medicare Part B payment increase for a period of five years. Separately, if a biologic drug for which no biosimilar exists delays a biosimilar's market entry beyond two years, CMS will be authorized to subject the biologics manufacturer to price negotiations intended to ensure fair competition. Notwithstanding these provisions, the IRA's impact on commercialization and competition remains largely uncertain.

Manufacturing

We do not own or operate clinical or commercial manufacturing facilities for the production of our product candidates, which include drug-device combination products that we develop, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently depend on third-party contract manufacturers for all of our required raw materials, active pharmaceutical ingredients, finished product candidates, and any devices or device components that may be used for delivery of our product candidates, for our clinical trials. We do not have any current contractual arrangements for the manufacture of commercial supplies of our product candidates that we develop. We currently employ internal resources and third-party consultants to manage our manufacturing contractors.

Historically, we have relied on third-party contract development and manufacturing organizations ("CDMOs"), to manufacture and supply our nonclinical and clinical materials used during the development of our product candidates. We currently rely on a single multi-site CDMO for manufacturing our clinical materials, WuXi Biologics (Hong Kong) Limited ("WuXi"), although other avenues remain available if our current manufacturer were to be negatively impacted. We maintain a long-term master services agreement with our CDMO pursuant to which the CDMO provides biologics development and manufacturing services on a per-project basis and a related cell line license. We may terminate the master services agreement at any time for convenience in accordance with the terms of the agreement. We may also terminate the master services agreement in the event that the CDMO does not obtain or maintain any material governmental license or approval in accordance with the terms of the agreement. The agreement includes confidentiality and intellectual property provisions to protect our proprietary rights related to our product candidates. We do not currently have arrangements for redundant supply and are working on building our supply chain to put these in place. Any reduction or halt in supply from the CDMO could limit our ability to develop our product candidates until a replacement CDMO is found and qualified, although we believe that we have supply on hand that can partially support our current clinical trial programs until a replacement CDMO is secured. In light of our reliance on WuXi, we are taking several measures to strengthen our supply chain by moving certain CDMO activities outside of WuXi's facilities. See "Risk Factors" for additional information.

Sales and Marketing

We have not yet defined our sales, marketing, or product distribution strategy for our product candidates because our product candidates are still in development. Our commercial strategy may include the use of strategic partners, distributors, a contract sale force, or the establishment of our own commercial and specialty sales force. We plan to further evaluate these alternatives as we continue to advance into later stages of development for each one of our product candidates.

Human Capital Management

As of December 31, 2024, we employed 143 full-time employees located in the U.S., including at our facilities in Waltham, Massachusetts and Boulder, Colorado.

We consider our relationship with our employees to be good. We have never had a work stoppage, and none of our employees is represented by a labor organization or under any collective bargaining arrangements. We track and report internally on key talent metrics including workforce demographics, diversity data and the status of open positions. We are committed to equality, inclusion and diversity in the workplace. As of December 31, 2024, approximately 24% of our workforce identify as members

of underrepresented ethnic communities and approximately 59% identify as female. We strive to develop a diverse slate of candidates to interview for our open positions.

Attracting, developing and retaining talented employees to support the growth of our business is an integral part of our human capital strategy and critical to our long-term success. We continue to seek additions to our staff, although the competition in our industry and in the Greater Boston area, where our headquarters is located, is significant. The principal purpose of our equity incentive and annual bonus programs is to attract, retain and motivate personnel through the granting of stock-based compensation awards and cash-based performance bonus awards. As a biopharmaceutical company, we recognize the importance of access to high quality healthcare and as such we cover 100% of our employees' monthly healthcare premiums. We offer a package of competitive employee benefits, including 401(k) plan matching contributions and an employee stock purchase plan.

We have a performance development review process in which managers provide regular feedback to assist with the development of our employees. We also invest in the growth and development of our employees through various training and development programs that help build and strengthen our employees' leadership and professional skills.

We believe our management team has the experience necessary to effectively execute our strategy and advance our product and technology leadership. A large majority of our employees have obtained advanced degrees in their professions. We support our employees' further development with individualized development plans, mentoring, coaching, group training and conference attendance.

Our Corporate Information

We were initially founded as miRagen Therapeutics, Inc. as a Delaware limited liability company in January 2010 and subsequently incorporated as a Delaware corporation in June 2014. On January 20, 2021, pursuant to a merger agreement under which miRagen Therapeutics, Inc. acquired Viridian Therapeutics, Inc., we changed our name from Miragen Therapeutics, Inc. to Viridian Therapeutics, Inc. Our common stock currently trades on The Nasdaq Capital Market under the ticker symbol "VRDN." Our principal executive office is located at 221 Crescent Street, Suite 103A, Waltham, MA 02453, and our telephone number is (617) 272-4600. Our website address is www.viridiantherapeutics.com. The information contained on, or that can be accessed through, our website is not part of this Annual Report. We have included our website in this Annual Report solely as an inactive textual reference.

This Annual Report contains references to our trademarks and trademarks belonging to other entities that are the property of their respective owners. Solely for convenience, trademarks and trade names referred to in this Annual Report, including logos, artwork, and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other company.

Available Information

Our Annual Reports, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") are available free of charge on our website located at www.viridiantherapeutics.com as soon as reasonably practicable after they are filed with the SEC. The reports are also available at the SEC's internet website at www.sec.gov. A copy of our Corporate Governance Guidelines, Code of Business Conduct and Ethics, and the charters of the Audit Committee, Compensation Committee, Nominating and Corporate Governance Committee, and Science and Technology Committee are posted on our website, www.viridiantherapeutics.com, under "Corporate Governance."

ITEM 1A. RISK FACTORS

Our business, financial condition, and operating results may be affected by a number of factors, whether currently known or unknown, including but not limited to those described below. Any one or more of such factors could directly or indirectly cause our actual results of operations and financial condition to vary materially from past or anticipated future results of operations and financial condition. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, results of operations, and stock price. The following information should be read in conjunction with Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and related notes in Part II, Item 8, "Financial Statements and Supplementary Data" of this Annual Report.

Risks Related to Our Financial Condition and Capital Requirements

We have historically incurred losses, have a limited operating history on which to assess our business, and anticipate that we will continue to incur significant losses for the foreseeable future.

We are a biopharmaceutical company with a limited operating history. We have historically incurred net losses. During the years ended December 31, 2024 and 2023, our net loss was $269.9 million and $237.7 million, respectively. As of December 31, 2024, we had an accumulated deficit of $995.9 million and cash, cash equivalents, and short-term investments of $717.6 million.

We believe that our current cash, cash equivalents and short-term investments will be sufficient to fund our operations, including our clinical development plan described elsewhere in this Annual Report, and enable us to fund our operating expenses and capital expenditure requirements into the second half of 2027. We will need to raise substantial additional capital to continue to fund our operations in the future. The amount and timing of our future funding requirements will depend on many factors, including the pace, results and costs of our clinical development efforts and macroeconomic conditions affecting our business and industry.

Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to develop our product candidates. Changing circumstances may cause us to consume capital significantly faster or slower than we currently anticipate. If we are unable to acquire additional capital or resources, we will be required to modify our operational plans to complete future milestones. We have based these estimates on assumptions that may prove to be wrong, and we could exhaust our available financial resources sooner than we currently anticipate. We may be forced to reduce our operating expenses and raise additional funds to meet our working capital needs, principally through the additional sales of our securities or debt financings or entering into strategic collaborations.

We have devoted substantially all of our financial resources to identify, acquire, and develop our product candidates, including conducting clinical trials and providing general and administrative support for our operations. To date, we have financed our operations primarily through the sale of equity securities, convertible promissory notes and the Hercules Loan and Security Agreement. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity, debt financings or other non-dilutive sources of capital, or strategic collaborations. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We expect our losses to increase as our product candidates continue advancing through clinical development and as new product candidates enter clinical trials and then advance through clinical development. It may be several years, if ever, before we complete pivotal clinical trials or have a product candidate approved for commercialization. We expect to invest significant funds into the research and development of our current product candidates to determine the potential to advance these product candidates to regulatory approval.

If we obtain regulatory approval to market a product candidate, our future revenue will depend upon the size of any markets in which our product candidates may receive approval, and our ability to establish and maintain a commercial supply chain in each market, achieve sufficient market acceptance, pricing, coverage, and adequate reimbursement from third-party payors, and adequate market share for our product candidates in those markets. Additionally, patients and physicians may not use our products as intended, if approved, which could impact the pricing and reimbursement of our products.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future and our expenses will increase substantially if and as we:

- continue the development of our product candidates;
- continue efforts to discover and develop new product candidates;
- continue the manufacturing of our product candidates or increase volumes manufactured by third parties;
- continue to advance our programs into large, expensive clinical trials;
- initiate additional nonclinical studies or clinical trials for our product candidates;
- seek regulatory and marketing approvals, pricing, and reimbursement for our product candidates;

- establish a sales, marketing, and supply chain and distribution infrastructure to commercialize any products for which we may obtain marketing approval and market for ourselves;
- seek to identify, assess, acquire, and/or develop other product candidates;
- make milestone, royalty, or other payments under third-party license agreements or enter into additional third-party license agreements;
- seek to maintain, protect, and expand our intellectual property portfolio;
- seek to attract and retain skilled personnel; and
- experience any delays or encounter issues with the development and potential for regulatory approval of our clinical and product candidates such as safety issues, manufacturing delays, clinical trial accrual delays, longer follow-up for planned studies or trials, additional major studies or trials, or supportive trials necessary to support marketing approval.

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

If we are unable to raise capital when needed, we would be forced to delay, reduce, or eliminate our research and product development programs or future commercialization efforts.

As of December 31, 2024, we had $717.6 million of cash, cash equivalents, and short-term investments. We believe that our current cash, cash equivalents and short-term investments will be sufficient to fund our operations, including our clinical development plan described elsewhere in this Annual Report, into the second half of 2027. We will need to raise additional capital to continue to fund our operations and service our obligations in the future. If we are unable to raise additional capital when needed, we will not be able to continue as a going concern.

Developing our product candidates requires a substantial amount of capital. We expect our research and development expenses to increase in connection with our ongoing activities, particularly as we advance our product candidates through clinical trials and pre-commercial and commercial activities. We will need to raise additional capital to fund our operations and such funding may not be available to us on acceptable terms, or at all.

We do not currently have any products approved for sale and do not generate any revenue from product sales. Accordingly, we expect to rely primarily on equity and/or debt financings or other non-dilutive sources of capital to fund our continued operations. Our ability to raise additional funds will depend, in part, on the success of our nonclinical studies and clinical trials and other product development activities, regulatory events, our ability to identify and enter into licensing or other strategic arrangements, and other events or conditions that may affect our value or prospects, as well as factors related to financial, economic and market conditions, many of which are beyond our control. For example, even if our clinical trials generate data that we view favorably, investors may not share our interpretation of these data, and we may be unable to raise additional funds. There can be no assurances that sufficient funds will be available to us when required or on acceptable terms, if at all.

If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- significantly delay, scale back, or discontinue the development or commercialization of our product candidates;
- seek strategic alliances, or amend existing alliances, for research and development programs at an earlier stage than otherwise would be desirable or that we otherwise would have sought to develop independently, or on terms that are less favorable than might otherwise be available in the future;
- dispose of technology assets, or relinquish or license on unfavorable terms, our rights to technologies or any of our product candidates that we otherwise would seek to develop or commercialize ourselves;
- pursue the sale of our company to a third-party at a price that may result in a loss on investment for our stockholders; or
- file for bankruptcy or cease operations altogether.

Any of these events could have a material adverse effect on our business, operating results, and prospects.

We have never generated any revenue from product sales and may never be profitable.

We have no products approved for commercialization and have never generated any revenue from product sales. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaborators, to successfully complete the development of, obtain the regulatory and marketing approvals, and build and maintain a commercial supply chain necessary to commercialize one or more of our product candidates. We do not anticipate generating revenue from product sales for the foreseeable future. Our ability to generate future revenue from product sales depends heavily on our success in many areas, including but not limited to:

- completing research and development of our product candidates;
- obtaining regulatory and marketing approvals for our product candidates;
- manufacturing product candidates and establishing and maintaining supply and manufacturing relationships with third parties that are commercially feasible, meet regulatory requirements and our supply needs in sufficient quantities to meet market demand for our product candidates, if approved;
- establishing and maintaining a commercial supply chain for our product candidates in the countries or regions in which we obtain regulatory approval for them, including receipt and maintenance of necessary licenses, permits, or similar permissions, either directly or with a collaborator or distributor;
- marketing, launching, and commercializing product candidates for which we obtain regulatory and marketing approval, either directly or with a collaborator or distributor;
- gaining market acceptance of our product candidates as treatment options;
- addressing any competing products;
- developing, protecting and enforcing our intellectual property rights, including patents, trade secrets, and know-how;
- our ability to avoid or defend third-party patent infringement claims
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- obtaining coverage and adequate reimbursement from third-party payors and receiving and maintaining pricing for our product candidates that supports profitability; and
- attracting, hiring, and retaining qualified personnel.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Portions of our current pipeline of product candidates have been in-licensed from third parties, which make the commercial sale of such in-licensed products potentially subject to additional royalty and milestone payments to such third parties. We will also have to develop or acquire manufacturing capabilities or continue to contract with contract manufacturers in order to continue development and potential commercialization of our product candidates. For instance, if the costs of manufacturing our drug product are not commercially feasible, we will need to develop or procure our drug product in a commercially feasible manner in order to successfully commercialize a future approved product, if any.

Additionally, if we are not able to generate revenue from the sale of any approved products, we may never become profitable.

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

Until such time, if ever, as we can generate substantial revenue from the sale of our product candidates, we expect to finance our cash needs through a combination of equity offerings, debt financings, and license and development agreements. To the extent that we raise additional capital through the sale of equity securities or convertible debt securities, or other non-dilutive sources of capital, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, making additional product acquisitions, or declaring dividends.

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

To the extent that we raise additional capital through the sale of equity, including pursuant to any sales under our September 2022 ATM Agreement with Jefferies, convertible debt, or other securities convertible into equity, the ownership interest of our stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our stockholders. Any additional sales of our capital stock by us will dilute the ownership interest of our stockholders and may cause the price per share of our common stock to decrease. In addition, any exercise of outstanding warrants will dilute the ownership interest of our stockholders and may cause the price per share of our common stock to decrease. Debt financing, including under our Hercules Loan and Security Agreement, may include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, making additional product acquisitions, or declaring dividends.

We cannot be assured that we will be able to obtain additional funding, if and when necessary, to fund our entire portfolio of product candidates to meet our projected plans. If we are unable to obtain funding on a timely basis, we may be required to delay or discontinue one or more of our development programs or the commercialization of any product candidates or be unable to expand our operations or otherwise capitalize on potential business opportunities, which could materially harm our business, financial condition, and results of operations.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our third-party research institution collaborators, contract research organizations ("CROs"), contract manufacturing operations ("CDMOs"), and other contractors and consultants, could be subject to acts of war, wildfires, earthquakes, power shortages, information technology and telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, governmental actions, medical pandemics or epidemics, and other natural or man-made disasters or business interruptions, for which we are partly uninsured. In addition, we rely or may rely in the future on our third-party research institution collaborators for conducting research and development of our product candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Risks Related to the Discovery and Development of Our Product Candidates

Clinical trials are costly, time consuming, and inherently risky, and we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Clinical development is expensive, time consuming, and involves significant risk. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of development. Events that may prevent successful or timely completion of clinical development include but are not limited to:

- inability to generate satisfactory nonclinical, toxicology, or other in vivo or in vitro data or diagnostics to support the initiation or continuation of clinical trials;
- delays in reaching agreement on acceptable terms with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, clinical trial sites, and in countries or regions where our trials are conducted;
- delays in obtaining required approvals from institutional review boards or independent ethics committees at each clinical trial site;
- failure to permit the conduct of a clinical trial by regulatory authorities;
- delays in or inability to recruit a sufficient number of eligible patients and/or subjects in our clinical trials;
- failure by clinical sites, CROs, or other third parties to adhere to clinical trial requirements or to perform their obligations related to the clinical development of our product candidates;

- failure of CDMOs, shipping logistics providers or other third parties to deliver necessary clinical material;
- failure by our clinical sites, CROs, or other third parties to perform in accordance with current good clinical practice ("cGCP"), current good laboratory practice ("cGLP"), current good manufacturing practice ("cGMP") or other applicable requirements of the FDA or applicable foreign regulatory authorities;
- patients and/or subjects dropping out of our clinical trials;
- adverse events or tolerability or animal toxicology issues significant enough in our studies, in studies of third parties, or as reported for marketed products for the FDA or other regulatory agencies to put any or all clinical trials on hold, require us to change how we conduct our IND-enabling studies or our ongoing or future trials, including amending or submitting new clinical protocols or additional safety monitoring or measurements;
- occurrence of adverse events associated with our product candidates;
- changes in regulatory requirements or guidance that require amending or submitting new clinical protocols;
- geopolitical unrest and adverse regulatory or other actions taken against us, or third parties on whom we relay, by foreign governments or entities, including in Israel and China, where we have current or planned clinical trial operations;
- significant costs of clinical trials of our product candidates, including manufacturing activities;
- negative or inconclusive results from our clinical trials or the trials of third parties with related or similar product candidates, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development programs in other ongoing or planned indications for a product candidate, or change how we conduct our IND-enabling studies or our ongoing or future trials, including amending or submitting new clinical protocols or additional safety monitoring or measurements; and
- delays in reaching agreement on acceptable terms with third-party manufacturers and the time to manufacture sufficient quantities of our product candidates acceptable for use in clinical trials.

We expect that the THRIVE and THRIVE-2 phase 3 clinical trials, together with a safety database comprising 300 treated patients (safety database inclusive of THRIVE and THRIVE-2 patients), will support global health authority registration for veligrotug for marketing approval in both active and chronic TED, respectively. However, the FDA or other regulatory authorities may require additional patients in this safety database or may require us to take other additional steps. We are also conducting a global pivotal program for VRDN-003. We may be required to take other additional steps in the course of development and regulatory interaction regarding our product candidates, including veligrotug, VRDN-003, and VRDN-006. Such additional steps may include, without limitation, initiating new trials, starting at an earlier phase of clinical trial, conducting bridging studies, enrolling more patients, amending trial protocols, or requiring us to assess additional parameters related to safety or efficacy. For example, we may make adjustments to the VRDN-003 clinical trial designs as a result of the additional data or feedback from regulatory authorities. These additional requirements or steps could increase the cost of development of our product candidates, negatively affect our anticipated timelines, delay our time to market with our product candidates, if approved, and could harm our business.

The FDA or other regulatory authorities may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or non-compliance with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions, for example, under a Risk Evaluation Mitigation Strategy ("REMS") program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market, or product recalls;
- fines, warning letters, or holds on post-approval clinical studies;

- refusal of the FDA or other regulatory authorities to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;

- product seizure or detention, or refusal of the FDA or other regulatory authorities to permit the import or export of products; or

- injunctions or the imposition of civil or criminal penalties.

Any inability to successfully complete clinical development and obtain regulatory approval for our product candidates could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional clinical or nonclinical studies and the results obtained, including from studying such new formulation may not be consistent with previous results obtained. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow competitors to develop and bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Even if we obtain regulatory approval for a product candidate, we will remain subject to ongoing regulatory requirements.

If any of our product candidates are approved, we will be subject to ongoing regulatory requirements with respect to manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing clinical trials, and submission of safety, efficacy, and other post-approval information, including both federal and state requirements in the United States, and requirements of the EMA and comparable foreign regulatory authorities. See "Business—Government Regulation—Expedited Development and Review Programs" and "Business—Government Regulation—Regulation in the European Union."

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the marketed product. We will be required to report adverse reactions and production problems, if any, to the FDA, EMA, and any relevant comparable foreign regulatory authorities. Any new legislation could result in delays in product development or commercialization, or increased costs to assure compliance. If our original marketing approval for a product candidate was granted accelerated approval by the FDA, we could be required to conduct a successful post-marketing clinical trial in order to confirm the clinical benefit of our products. Other regulatory authorities outside of the U.S. may have similar requirements. An unsuccessful post-marketing clinical trial or failure to complete such a trial could result in the withdrawal of marketing approval. We and any of our suppliers or collaborators, including our CDMOs, would be subject to periodic inspections by the FDA, EMA, and, as applicable, comparable foreign regulatory authorities to monitor compliance with cGMPs and other FDA, EMA, and, as applicable, any comparable foreign regulatory requirements. Application holders must further notify the FDA, and any comparable foreign regulatory authorities, as applicable, and depending on the nature of the change, obtain FDA pre-approval or pre-approval from other comparable foreign regulatory authorities, as applicable, for product and manufacturing changes.

We must comply with requirements concerning advertising and promotion for any product candidates for which we seek or obtain marketing approval. Promotional communications with respect to drugs and biologics are subject to a variety of legal and regulatory restrictions by the FDA and comparable foreign regulatory authorities. When the FDA or comparable foreign regulatory authorities issue regulatory approval for a product candidate, the regulatory approval is limited to those specific uses and indications for which a product is approved. If we are not able to obtain FDA or comparable foreign regulatory authority approval for desired uses or indications for our product candidates, we may not market or promote them for those indications and uses, and our business, financial condition, results of operations, prospects and reputation may be materially harmed. We also must sufficiently substantiate any claims that we make for our products, including claims comparing our products to other companies' products, and must abide by the FDA or comparable foreign regulatory authority's strict requirements regarding the content of promotion and advertising.

Any government investigation or enforcement action concerning alleged violations of law, including with respect to promotional requirements, would be expected to require us to expend significant time and resources in response and could result in significant liability, including civil and administrative remedies as well as criminal sanctions and fines. Even if it is later determined that we were not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our actions and have to divert significant management resources from other matters. Any non-compliance with ongoing regulatory requirements may significantly and adversely affect our ability to develop and commercialize our products, and the value of the company and our operating results would be adversely affected.

Regulatory approval processes are lengthy, time-consuming and inherently unpredictable. Failure to obtain regulatory approval for our product candidates would have a material adverse effect upon our business and business prospects.

In connection with the advancement of our clinical programs and before we can commercialize any of our current or future product candidates, we must obtain marketing approval from regulatory authorities. We may not be able to receive approval to market any of our current or future product candidates from regulatory authorities in our desired indications in any jurisdiction, and it is possible that none of our product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. We may need to rely on third-party CROs and regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive nonclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish a product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the biologic manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authorities, who may deny approval based on the results of such submissions and inspections. Our current or future product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The FDA and other regulatory authorities have substantial discretion in the approval process, including determining when or whether regulatory approval will be obtained for a product candidate. Even if we believe the data collected from clinical trials are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority or such authorities may request additional information that may be difficult to generate or provide. Further, following approval, the FDA or other regulatory authorities may conduct additional inspections and, based on the results of such inspections, deem the inspected manufacturing facilities to be deficient, suspending our ability to manufacture our product candidates until we can secure satisfactory alternative manufacturing facilities. Additionally, given the second Trump Administration and the prospect of potential downsizing, reforming and restructuring of federal health agencies, there may be substantial loss of key FDA staff. If there are significant gaps in subject matter expertise, FDA may not be able to meet certain timelines, and review and approval of any of our regulatory submissions to the FDA may be delayed or extended.

In addition to the United States, we may seek regulatory approval to commercialize our product candidates in Europe. While the scope of regulatory approval is similar in many countries, to obtain separate regulatory approval in multiple countries will require us to comply with numerous and varying regulatory requirements of each such country or jurisdiction regarding safety, efficacy and quality, and governing, among other things, clinical trials, commercial sales, pricing and distribution, and we cannot predict success in any such jurisdictions, even if we were to receive approval in the United States.

The process of obtaining regulatory approvals, both in the United States and in other countries, is time consuming, expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted BLA, or equivalent application types, may cause delays in the approval or rejection of an application.

Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional nonclinical studies or clinical or other trials for our current or future product candidates. Our current and future product candidates could be delayed in receiving, or fail to receive, regulatory approval or we may fail or cease to advance their development for many reasons, including the following:

- regulatory authorities may disagree with the number, design or implementation of our clinical trials to support further development or approval;
- we may be unable to demonstrate to the satisfaction of regulatory authorities that a product candidate is safe and effective for its proposed indication or that its clinical and other benefits outweigh its safety risks;
- regulatory authorities could require us to collect additional data or conduct additional clinical trials, which could include a requirement to compare our products or product candidates to other therapies for the treatment of the same indication;
- regulatory authorities, following the discovery of adverse safety signals or side effects from approved therapeutics or therapeutics in development in the same or related class as our products or product candidates, could require us to collect additional data or conduct additional clinical trials;

- the results of clinical trials may produce negative, inconclusive or uncompetitive results, which may result in us deciding, or regulatory authorities requiring us, to conduct additional clinical trials or to modify or cease development programs for our product candidates;

- the results of clinical trials may not meet the primary or secondary endpoints of the applicable trial or the level of statistical significance required by regulatory authorities;

- regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;

- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA, supplementary BLA or other submission or to obtain regulatory approval in the United States or elsewhere;

- the number of participants required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate or we may fail to recruit suitable participants for a trial;

- our third-party contractors may fail to comply with data quality and regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- regulatory authorities may believe that we have not sufficiently demonstrated our ability to manufacture our candidates to the requisite level of quality standards, including that such material is sufficiently comparable to material used in previous clinical trials, or they may fail to approve our manufacturing processes or facilities, or the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;

- regulatory authorities may conclude that on-site inspections and data audits have not sufficiently demonstrated the quality and integrity of the clinical trial conduct and of data submitted to regulatory authorities in support of our new product approvals and marketing applications;

- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;

- our product candidates may have undesirable side effects, toxicities or other unexpected characteristics, causing us or our investigators, regulatory authorities, institutional review boards or ethics committees to reject, suspend or terminate the clinical trials; and

- the approval policies or regulations of regulatory authorities may significantly change in a manner rendering our clinical data, biologic manufacturing process and other supporting information insufficient for approval.

In addition, even if we were to obtain approval for one or more of our current or future product candidates, regulatory authorities may approve such product candidates for fewer indications or more limited patient populations than we request. Furthermore, regulatory authorities or payers may not approve the price we intend to charge, may grant approval contingent on the performance of costly post-marketing clinical trials, may impose certain post-marketing requirements that impose limits on our marketing and distribution activities, or may approve a product candidate with labeling that does not include the claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our current or future product candidates.

Failure to obtain regulatory approval for our product candidates would have a material adverse effect upon our business and business prospects.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial viability of approved labeling, or result in significant negative consequences following marketing approval, if any.

We are or may develop our product candidates in areas with existing investigational and/or approved products where such products may have known risk profiles. Undesirable side effects caused by our product candidates, or other product candidates, including in the TED space or FcRn inhibitor space, could cause us or regulatory authorities to interrupt, delay, or terminate clinical trials. Such side effects additionally may result in a delay or denial of regulatory approval by the FDA, EMA, or comparable foreign authorities, or, even in the instance that an affected product candidate is approved, may result in restrictive drug labeling. For example, hearing impairment observed in Tepezza, or other negative side effects of other IGF-1R antagonists

in development, may negatively affect clinical trials for our product candidates, delay regulatory approval or result in restrictive drug labeling, if approved.

Even if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may withdraw approvals of such products;
- regulatory authorities may require additional warnings on the drug labeling;
- we may be required to create a REMS, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients or subjects; and
- our reputation may suffer.

Clinical trials by their nature utilize a sample of the potential patient population. But, with a limited number of subjects and limited duration of exposure, we cannot be fully assured that rare and severe side effects of our product candidates will be uncovered. Such rare and severe side effects may only be uncovered with a significantly larger number of patients or subjects exposed to the drug. If such safety problems occur or are identified after our product candidates reach the market, the FDA or other regulatory authorities may require that we amend the labeling of the product, implement a REMS, recall the product, conduct a post-approval study or studies, implement surveillance measures, or may even withdraw approval for the product. Later discovered undesirable side effects could further result in reduced market acceptance and utilization of our product or potential product liability claims. Any of these occurrences may materially harm our business, financial condition, results of operations and prospects.

Any of these events could prevent us from achieving or maintaining market acceptance of a product candidate, even if approved, and could significantly harm our business, results of operations, and prospects.

Additional time may be required to obtain marketing authorizations for certain of our product candidates because they are, or are anticipated to be, combination products.

Some of our product candidates, including VRDN-003, VRDN-006 and VRDN-008, are or are anticipated to be combination products that will require coordination within the FDA and similar foreign regulatory agencies for review of their device and drug components. Although the FDA and similar foreign regulatory agencies have systems in place for the review and approval of combination products, such as drugs that utilize delivery systems like auto-injectors or prefilled syringes, we may experience delays in the development and commercialization of our product candidates due to complexities arising from them being combination products and associated regulatory timing constraints and uncertainties in the product development and approval process. Of note, prior clearance or approval of one component of a combination product does not increase the likelihood that the FDA will approve a later product combining the previously cleared product or approved active ingredient with a novel active ingredient. See “Business—Government Regulation—Regulation of Combination Products.”

Product development involves a lengthy and expensive process with an uncertain outcome, and results of earlier nonclinical studies and clinical trials may not be predictive of future clinical trial results.

Clinical testing is expensive and generally takes many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of nonclinical studies and early clinical trials of our product candidates may not be predictive of the results of larger, later-stage controlled clinical trials. Product candidates that have shown promising results in early-stage clinical trials may still suffer significant setbacks in subsequent clinical trials. In addition, from time to time, we may publicly disclose interim, topline, or preliminary data from our nonclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change as more patient data become available. The interim, topline, or preliminary results that we report may differ from final results upon study completion, or different conclusions or considerations may qualify such results.

We will have to conduct well-controlled trials in our proposed indications to support any regulatory submissions for further clinical development. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles despite promising results in earlier, smaller clinical trials. Larger scale clinical trials for our product candidates may generate additional data that raise issues regarding the safety and efficacy of

our product candidates that were not observed in smaller clinical trials. Certain approaches that we take in our clinical trials with respect to measurement of safety and efficacy outcomes may differ in important respects as compared to the trials of our competitors, which may lead to negative regulatory and/or commercial outcomes.

Moreover, both nonclinical and clinical data are often susceptible to varying interpretations and analyses. Third parties upon whom we rely may analyze data differently than others, or differently than we do. As a result, they or we may reach different conclusions regarding the results of our studies, including our clinical studies.

We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate safety and efficacy of our product candidates, with respect to the proposed indication for use, sufficient to receive regulatory approval to market our drug candidates. Failure to demonstrate safety and efficacy of our product candidates, and failure to obtain regulatory approval, would have a material adverse effect upon our business and business prospects. Additionally, differences in our clinical trial designs as compared to those of our competitors could render our product candidates less attractive than those of our competitors.

Preliminary data from our clinical trials that we announce or publish are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we publish preliminary data from our clinical trials. On December 18, 2023, we reported clinical data from our phase 1 clinical study in healthy volunteers and announced the selection of VRDN-003 as our lead subcutaneous product candidate for TED. Based on the comparable pharmacology of VRDN-003 to veligrotug, we believe VRDN-003 has the potential to maintain the clinical response of veligrotug while significantly increasing patient convenience. However, we are conducting a global pivotal program for VRDN-003 in patients with TED, and results of any clinical trials conducted in TED patients with VRDN-003 may not demonstrate safety or efficacy comparable to veligrotug or at all.

On September 10, 2024, we announced topline data from the phase 3 THRIVE trial of veligrotug in patients with active TED. On December 16, 2024, we announced topline data from the phase 3 THRIVE-2 trial in patients with chronic TED. While THRIVE and THRIVE-2 met all primary and secondary endpoints at 15 weeks with a generally well-tolerated safety profile, this data may not be fully reflective of the final results for the THRIVE and THRIVE-2 trials, respectively. If final results from the THRIVE and THRIVE-2 trials are not positive or favorable, it could negatively impact or alter the development of veligrotug and could materially harm our business prospects. If clinical data from the veligrotug trials are not positive or favorable, it could negatively impact or alter the development of VRDN-003 and could materially harm our business prospects. Similarly, negative or unfavorable clinical data from our VRDN-003 product candidate could negatively impact veligrotug and could materially harm our business prospects.

Topline or preliminary data from our clinical trials that we announce or publish from time to time, including the data from our phase 1 study in healthy volunteers, the data for veligrotug from our ongoing trials, and topline data may change as more patient data become available and we become subject to audit and verification procedures that could result in material changes in the final data. This creates a risk that the final results could be materially different from the preliminary results reported, including those reported to date. Additionally, differences in patient populations across our clinical trials may lead to inconsistent or unrepresentative data.

Significant adverse differences between preliminary data and final, audited and verified data could negatively affect the prospect of regulatory approval for our product candidates and could materially harm our reputation and business prospects.

We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and human resources, we may forgo or delay the pursuit of opportunities with some programs or 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 more profitable market opportunities. Our spending on current and future research and development programs and future product candidates for specific indications may not yield any commercially viable products. We may also enter into additional strategic collaboration agreements to develop and commercialize some of our programs and potential product candidates in indications with potentially large commercial markets. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaborations, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and

commercialization rights to such product candidate. We may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a collaboration arrangement.

We may face liability for our products, if approved, and for our product candidates, and if successful claims are brought against us, we may incur substantial liability and costs. If the use or misuse of our approved products, if any, or product candidates harm patients or subjects, or is perceived to harm patients or subjects even when such harm is unrelated to our approved products, if any, or product candidates, our regulatory approvals, if any, could be revoked or otherwise negatively impacted, and we could be subject to costly and damaging product liability claims. If we are unable to obtain adequate insurance or are required to pay for liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage, a material liability claim could adversely affect our financial condition.

The use or misuse of our product candidates in clinical trials and the sale of any products for which we may obtain marketing approval exposes us to the risk of potential product liability claims. There is a risk that our product candidates may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. Patients with the diseases targeted by our product candidates may already be in severe and advanced stages of disease and have both known and unknown significant preexisting and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may or may not be related to our product candidates. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact, or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which an adverse event is unrelated to our product candidates, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may delay our regulatory approval process or impact and limit the type of regulatory approvals our product candidates receive or maintain.

As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition, or results of operations.

Although we have product liability insurance, which covers our historical clinical trials, for up to $10.0 million per occurrence, up to an aggregate limit of $10.0 million, our insurance may be insufficient to reimburse us for any expenses or losses we may suffer. We will also likely be required to increase our product liability insurance coverage for any future clinical trials that we may initiate. If we obtain marketing approval for any of our product candidates, we will need to expand our insurance coverage to include the sale of commercial products. There is no way to know if we will be able to continue to obtain product liability coverage and obtain expanded coverage, if we require it, in sufficient amounts to protect us against losses due to liability, on acceptable terms, or at all. We may not have sufficient resources to pay for any liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage. Where we have provided indemnities in favor of third parties under our agreements with them, there is also a risk that these third parties could incur liability and bring a claim under such indemnities. An individual may bring a product liability claim against us alleging that one of our product candidates causes, or is claimed to have caused, an injury or is found to be unsuitable for consumer use. Any such product liability claims may include allegations of defects in manufacturing, defects in design, failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. Any product liability claim brought against us, with or without merit, could result in:

- inability to recruit clinical trial volunteers, investigators, patients or subjects, or trial sites;
- withdrawal of clinical trial volunteers, investigators, patients or subjects, or trial sites, or limitations on approved indications;
- delay in the development of product candidates;
- the inability to commercialize, or if commercialized, decreased demand for, our product candidates;
- if commercialized, product recalls, labeling, marketing or promotional restrictions, or the need for product modification;
- initiation of investigations by regulators;
- loss of revenue;
- substantial costs of litigation, including monetary awards to patients or other claimants;

- liabilities that substantially exceed our product liability insurance, which we would then be required to pay ourselves;
- an increase in our product liability insurance rates or the inability to maintain insurance coverage in the future on acceptable terms, if at all;
- the diversion of management's attention from our business; and
- damage to our reputation and the reputation of our products and our technology.

Product liability claims may subject us to the foregoing and other risks, which could have a material adverse effect on our business, financial condition, or results of operations.

Risks Related to Commercialization of Our Product Candidates

If we are unable to establish commercial manufacturing, sales and marketing capabilities or enter into agreements with third parties to commercially manufacture, market and sell our product candidates, we may be unable to generate any revenue.

Although some of our employees may have been employed at companies that have launched pharmaceutical products in the past, we have no experience establishing commercial manufacturing relationships for or selling and marketing our product candidates and we are currently building our commercial manufacturing relationships, marketing, and sales organizations. To successfully commercialize any products that may result from our development programs, we may need to find one or more collaborators to commercialize our products or invest in and develop these capabilities, either on our own or with others, which would be expensive, difficult, and time consuming. Any failure or delay in entering into agreements with third parties to market or sell our product candidates or in the timely development of our internal commercialization capabilities could adversely impact the potential for the launch and success of our products.

If commercialization collaborators do not commit sufficient resources to commercialize our future products and we are unable to develop the necessary marketing and sales capabilities on our own, we will be unable to generate sufficient product revenue to sustain or grow our business. We may be competing with companies that currently have extensive and well-funded marketing and sales operations, particularly in the markets our product candidates are intended to address. Without appropriate capabilities, whether directly or through third-party collaborators, we may be unable to compete successfully against these more established companies.

We may attempt to form collaborations in the future with respect to our product candidates, but we may not be able to do so, which may cause us to alter our development and commercialization plans.

We may attempt to form strategic collaborations, create joint ventures, or enter into licensing arrangements with third parties with respect to our programs that we believe will complement or augment our existing business. We may face significant competition in seeking appropriate strategic collaborators, and the negotiation process to secure appropriate terms is time consuming and complex. We may not be successful in our efforts to establish such a strategic collaboration for any product candidates and programs on terms that are acceptable to us, or at all. This may be because our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort, our research and development pipeline may be viewed as insufficient, the competitive or intellectual property landscape may be viewed as too intense or risky, and/or third parties may not view our product candidates and programs as having sufficient potential for commercialization, including the likelihood of an adequate safety and efficacy profile.

Even if we are able to successfully enter into a collaboration regarding the development or commercialization of our product candidates, we cannot guarantee that such a collaboration will be successful. Any delays in identifying suitable collaborators and entering into agreements to develop and/or commercialize our product candidates could delay the development or commercialization of our product candidates, which may reduce their competitiveness even if they reach the market. Absent a strategic collaborator, we would need to undertake development and/or commercialization activities at our own expense. If we elect to fund and undertake development and/or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we are unable to do so, we may not be able to develop our product candidates or bring them to market and our business may be materially and adversely affected.

We face substantial competition, and our competitors may discover, develop, or commercialize products faster or more successfully than us.

The development and commercialization of new drug products is highly competitive, particularly in the treatment of TED and FcRn inhibitor therapeutics. We face competition from major pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, universities, and other research institutions worldwide with respect to our product candidates. We are aware that the following companies, among others, have therapeutics marketed or in development for TED: Amgen, Argenx, Immunovant, Inc., Roche Holdings AG, ACELYRIN, Inc., Tourmaline Bio, Inc., Lassen Therapeutics, and Sling Therapeutics, Inc. Other companies such as Kriya Therapeutics, Inc., Septerna and Crinetics Pharmaceuticals, Inc. among others, have earlier stage products in development which, if successfully developed, may impact the value of our product candidates over their lifecycle. If approved, veligrotug and VRDN-003 will also compete against generic medications, such as corticosteroids, and surgical procedures that are prescribed for the treatment of TED. We are also aware that the following companies, among others, may have anti-FcRn therapeutics marketed or in development: Argenx, UCB S.A., Johnson & Johnson, Immunovant, Inc. and AstraZeneca. Moreover, there are more than 20 indications announced or in development across the FcRn class. Depending on the indications in which we choose to develop VRDN-006 and VRDN-008, there may be further competition from marketed and in-development therapeutics targeting other mechanisms such as complement inhibition, T-cell inhibitors, anti-1L-6 and other mechanisms of action.

Our product candidates may demonstrate inferior efficacy and safety profiles as compared to currently approved drugs, or product candidates currently in development by our competitors. Our competitors may succeed in developing, acquiring, or licensing technologies and drug products that are more effective or less costly than our product candidates that we are currently developing or that we may develop, which could render our product candidates obsolete and noncompetitive. Our competitors may also adopt a similar licensing and development strategy as ours with regard to the development of an existing anti-IGF-1R monoclonal antibody for the treatment of TED. If any competitor was able to effect this strategy in a more efficient manner, there may be less demand for our product candidates, if any are approved.

Many of our competitors have substantially greater financial, technical, and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Third-party payors, including governmental and private insurers, may also encourage the use of generic products. For example, if veligrotug is approved, it may be priced at a significant premium over other competitive products. This may make it difficult for veligrotug or any other future products to compete with these products.

If our competitors obtain marketing approval from the FDA, EMA, or comparable foreign regulatory authorities for their product candidates more rapidly than us, it could result in our competitors establishing a strong market position before we are able to enter the market.

Many of our competitors have materially greater name recognition and financial, manufacturing, marketing, research, and drug development resources than we do. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. For example, in October 2023, Amgen completed its acquisition of Horizon, which could have a significant impact on the competitive landscape for clinical trials and therapeutics for TED. Large pharmaceutical companies, in particular, have extensive expertise in developing and commercializing drugs, including nonclinical and clinical testing, and in obtaining regulatory approvals, pricing and reimbursement for drugs. In addition, academic institutions, government agencies, and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies. These organizations may also establish exclusive collaborative or licensing relationships with our competitors. If our product candidates fail to compete effectively against established treatment options or future products currently in development, this would harm our business, financial condition, results of operations and prospects.

Our products may not be widely adopted by patients, payors or healthcare providers, which would adversely impact our potential profitability and future business prospects.

If approved, the commercial success of our products, particularly in the U.S., depends upon the level of market adoption by patients, payors and healthcare providers. If our products do not achieve an adequate level of market adoption for any reason, or if market adoption does not persist, our potential profitability and our future business prospects will be severely adversely impacted. The degree of market acceptance of our products depends on a number of factors, including:

- our ability to demonstrate to the clinicians and payors, the clinical efficacy, effectiveness and safety of our products as the prescription products of choice for their respective indications;

- the effectiveness of our sales and marketing organizations and distribution networks;

- the ability of patients or providers to be adequately reimbursed for our products in a timely manner from government and private payors;

- the actual and perceived efficacy and safety profile of our products, particularly if unanticipated adverse events related to our products' treatment arise and create safety concerns among potential patients or prescribers or if new data and analyses we obtain for our products do not support, or are interpreted by some parties to not support, the efficacy of our products; and

- the efficacy and safety of therapies developed by our competitors.

If we are unable to successfully commercially launch any of our product candidates, there would be an adverse effect on our business, financial condition, and results of operations.

Failure to obtain or maintain adequate pricing, reimbursement or insurance coverage for our products, if any, could limit our ability to market those products and decrease our ability to generate revenue.

The pricing, as well as the coverage, and reimbursement of our approved products, if any, must be sufficient to support our commercial efforts and other development programs, and the availability of coverage and adequacy of reimbursement by third-party payors, including government healthcare programs, health maintenance organizations, private insurers, and other healthcare management organizations, are essential for most patients to be able to afford expensive treatments. Sales of our approved products, if any, will depend substantially, both domestically and abroad, on the extent to which the costs of our approved products, if any, will be paid for or reimbursed by third-party payors. If coverage and reimbursement are not available, or are available only in limited amounts, we may have to subsidize or provide products for free, or we may not be able to successfully commercialize our products. See "Business—Coverage and Reimbursement."

The pricing of our approved products may be impacted by the pricing of other approved products, including those in the disease areas, drug class, and different drug classes in which we are commercializing our products. In addition, the prices of existing drugs (both inside and outside of the country of regulatory approval or sale) may be used as reference prices for new entrants, including in the same class, which may negatively impact the pricing of such new entrants. If the pricing of our approved products is impacted in these ways, the profitability of our products, if any, may be more difficult to achieve even if they receive regulatory approval or we may not be able to successfully commercialize our products.

Outside the U.S., international operations are generally subject to extensive governmental price controls and other price-restrictive regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, and other countries has and will continue to put pressure on the pricing and usage of products. In many countries, the prices of products are subject to varying price control mechanisms as part of national health systems. Price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products, if any. Accordingly, in markets outside the U.S., the potential revenue may be insufficient to generate commercially reasonable revenue and profits.

We expect to experience pricing pressures in connection with products due to the increasing trend toward managed healthcare, including the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs, has increased and is expected to continue to increase in the future. As a result, profitability of our products, if any, may be more difficult to achieve even if they receive regulatory approval.

If we are unable to successfully develop internal commercialization capabilities, sales of our future products may be negatively impacted.

We are hiring and training a commercial team and created the organizational infrastructure we believe we need to support the future commercial success of our products, if approved. Factors that may inhibit our efforts to maintain and further develop commercial capabilities include:

- an inability to retain an adequate number of effective commercial personnel;

- an inability to train sales personnel, who may have limited experience with our company or our products, to deliver a consistent message regarding our products and be effective in educating clinicians on how to prescribe our products;

- an inability to equip sales personnel with compliant and effective materials, including medical and sales literature to help them educate physicians and our healthcare providers regarding our products and their proper administration and

educate payors on the safety, efficacy and effectiveness profile of our products to support favorable coverage decisions;

- unforeseen costs and expenses associated with maintaining and further developing an independent sales and marketing organization; and
- an inability to develop effective commercial, sales and marketing infrastructure to support new product launches.

If we are not successful in establishing an effective commercial, sales and marketing infrastructure, we will encounter difficulty in achieving, maintaining or increasing projected sales of our products, if approved, which would adversely affect our business and financial condition.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our nonclinical development activities and clinical trials, manufacture our product candidates, and perform other services. If these third parties do not successfully perform and comply with regulatory requirements, we may not be able to successfully complete clinical development, obtain regulatory approval, or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party CROs to conduct, monitor, and manage nonclinical and clinical programs. Adding or changing CROs for our clinical programs carries implementation risk and may delay advancement of our clinical programs. We rely on these parties for execution of clinical trials, and we manage and control only some aspects of their activities. We remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with all applicable laws, regulations, and guidelines, including those required by the FDA, EMA, and comparable foreign regulatory authorities for all of our product candidates in clinical development. If we or any of our CROs or vendors fail to comply with applicable and evolving laws, regulations, and guidelines, the results generated in our clinical trials may be deemed insufficient or unreliable, and the FDA, EMA, or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. For example, we are aware of certain instances of non-compliance with GCP regulations. While we believe that we have made significant progress in remediating these deficiencies, we cannot be assured that our CROs, clinical sites, and other vendors will fully remediate any deficiencies and will meet these requirements on an ongoing basis, or that upon inspection by any regulatory authority, such regulatory authority will determine that efforts, including any of our clinical trials, comply with applicable requirements. Any non-compliance with these laws, regulations and guidelines may negatively impact the integrity of the data collected in our clinical trials and may prevent approval or require us to repeat clinical trials or add patients to ongoing clinical trials, which would be costly and delay the regulatory submission and/or approval process.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs in a timely manner or do so on commercially reasonable terms. In addition, our CROs may not prioritize our clinical trials relative to those of other customers, and any turnover in personnel or delays in the allocation of CRO employees by the CRO may negatively affect our clinical trials. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, our clinical trials may be delayed or terminated, and we may not be able to meet our current plans with respect to our product candidates. Additionally, regional disruptions, including natural disasters, geopolitical unrest, or health emergencies (such as novel viruses or pandemics), could significantly disrupt the timing of clinical trials. CROs may also involve higher costs than anticipated, which could negatively affect our financial condition and operations.

Shortages and governmental restrictions resulting from pandemics or other public health crises may disrupt the ability of or increase the cost for our clinical trial sites and other CROs to procure items that are essential for our research and development activities, including animals that are used for nonclinical studies. For example, the COVID-19 pandemic and resulting disruptions to the global supply chain caused shortages of various animals used in research studies, such as several types of monkeys, which are typically sourced from China.

We do not currently have, nor do we currently plan to establish, the capability to manufacture product candidates for use in the conduct of our clinical trials, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale without the use of third-party manufacturers. We rely, and plan to continue to rely, on third-party manufacturers whose responsibilities include purchasing from third-party suppliers the materials necessary to produce our product candidates for our clinical trials and regulatory approval. There are expected to be a limited number of suppliers for the active ingredients and other materials, including devices and device components, that we expect to use to manufacture and deliver our product candidates, including those of our product candidates that are anticipated to be combination products. We

may not be able to identify alternative suppliers to prevent a possible disruption of the manufacture of our product candidates for our clinical trials, and, if approved, ultimately for commercial sale. Although we generally do not expect to begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the trial, any significant delay or discontinuity in the supply of a product candidate, or the active ingredient or other material components in the manufacture or administration of the product candidate, could delay completion of our clinical trials and potential timing for regulatory approval of our product candidates, which would harm our business and results of operations.

Our manufacturing processes are complex, and we may encounter difficulties in production, which would delay or prevent our ability to provide a sufficient clinical or commercial supply of our product candidates or products.

The process of manufacturing our biologic product candidates is complex, highly regulated, variable, and subject to numerous risks. Our manufacturing process is susceptible to product loss or failure, or product variation that may negatively impact patient outcomes, due to logistical issues associated with preparing the product for administration, administering the product to patients, manufacturing issues, or different product characteristics resulting from changing a manufacturer, changing a manufacturing location, the inherent differences in starting materials, variations between reagent lots, interruptions in the manufacturing process, contamination, equipment or reagent failure, improper installation or operation of equipment and/or programs, vendor or operator error, loss of product during shipment or storage and variability in product characteristics. Some of our product candidates, including VRDN-003, VRDN-006 and VRDN-008, are or are anticipated to be combination products. In particular, we anticipate using devices in connection with our product candidates VRDN-003 and VRDN-006. Combination products are complex to manufacture, and this manufacturing complexity could lead to delays in manufacturing and product candidate availability for our clinical trials. In addition, combination products typically have a longer and more complex supply chain that increases the risk of supply interruptions and could negatively impact product candidate availability.

Even minor variations in starting reagents and materials, deviations from normal manufacturing processes, changing a manufacturer, or changing a manufacturing location could result in reduced production yields, product shortages, product defects, manufacturing failure, changes in product characteristics and other supply disruptions. If microbial, viral, or other contaminations are discovered in our product candidates or in any of the manufacturing facilities in which products or other materials are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Any failure in the foregoing processes could render a batch of product unusable, could affect the regulatory approval of such product candidate, could cause us to incur fines or penalties, or could harm our reputation and that of our product candidates.

We may make changes to our manufacturing process for various reasons, such as to control costs, increase yield or dose, achieve scale, decrease processing time, increase manufacturing success rate, availability of raw materials, or for other reasons. Changes to our process made during the course of clinical development could require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial. Other changes to our manufacturing process made before or after commercialization could require us to show the comparability of the resulting product to the product candidate used in the clinical trials using earlier processes. Such showings could require us to collect additional nonclinical or clinical data from any modified process prior to obtaining marketing approval for the product candidate produced with such modified process. If such data are not ultimately comparable to that seen in the earlier trials or earlier in the same trial in terms of safety or efficacy, we may be required to make further changes to our process and/or undertake additional clinical testing, either of which could significantly delay the clinical development or commercialization of the associated product candidate, which could materially adversely affect our business, financial condition, results of operations and growth prospects.

We rely and expect to continue to rely on third parties to manufacture our clinical product supplies, including Chinese manufacturer WuXi, for drug substance and drug product, and other third parties for devices and device components. If we are unable to source these supplies on a timely basis, at sufficient quantities, or at acceptable quality or prices, establish longer term contracts with our suppliers, or if our third-party manufacturers fail to comply with applicable regulatory requirements, the development and, if approved, commercialization of our product candidates could be stopped, delayed, or made less profitable.

We do not currently have, nor do we currently plan to develop, the infrastructure or capability internally to manufacture our clinical supplies for use in the conduct of our clinical trials, and we lack the resources and the capability to manufacture any of our product candidates, devices, or device components on a clinical or commercial scale. We currently rely on outside vendors to manufacture our clinical supplies of our product candidates and plan to continue relying on third parties to manufacture our product candidates, devices, or device components on a commercial scale, if approved. In particular, we rely upon single-sourced manufacturing with one CDMO for manufacturing our product candidates, including drug substance and drug product. We also rely on single-sourced manufacturing for various elements of our combination products.

We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing of our product candidates and our current cost to manufacture our drug products may not be commercially feasible. Additionally, the actual cost to manufacture our product candidates could materially and adversely affect the commercial viability of our product candidates. As a result, we may never be able to develop a commercially viable product.

In addition, our reliance on third-party manufacturers exposes us to the following additional risks:

- We may be unable to identify additional manufacturers of our product candidates, including combination product candidates, on acceptable terms or at all.
- Our third-party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any.
- Contract manufacturers may not be able to execute our manufacturing process or procedures appropriately.
- Our future third-party manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our commercial products, if approved.
- Our reliance on single-sourced manufacturing with our CDMOs increases the risk that any problems or delays a CDMO could materially, negatively affect the development of our product candidates, or their commercialization, if approved.
- Manufacturers are subject to ongoing periodic unannounced inspection by the FDA, applicable foreign regulatory authorities and some state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.
- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates.
- Our third-party manufacturers could breach or terminate their agreement with us.
- Our third-party manufacturers' performance, available capacity and ability to manufacture clinical or commercial products may be impacted by mergers and or acquisitions.
- We or our third-party manufacturers may experience labor disputes or shortages, raw material shortages or manufacturing capacity shortages, including from the effects of health emergencies (such as novel viruses or pandemics) and natural disasters.
- We and our third-party manufacturers may be impacted by global conflicts, including any potential conflict involving China and Taiwan, and any resulting trade sanctions or regulatory actions.
- We are heavily reliant on third-party manufacturing operations in China, and any regional or geopolitical disruption, including as a result of the escalation of tariffs or other trade restrictions, could negatively impact our clinical trials and development or commercialization of our product candidates, which would harm our business.
- Foreign third-party manufacturers may be subject to U.S. legislation, regulatory actions, or investigations, including legislation similar to the proposed BIOSECURE Act, trade restrictions and other U.S. or foreign regulatory requirements, which could increase the cost or reduce the supply of material available to us, delay or prevent the procurement or supply of such material, delay clinical trials, delay commercial launch, affect the ability to transfer to different manufacturers or have an adverse effect on our ability to secure commitments from governments to purchase our potential therapies.

Each of these risks could delay our clinical trials, as well as the approval, if any, of our product candidates by the FDA or other regulatory authorities, or the commercialization of our product candidates, or could result in higher costs, or could deprive us of potential product revenue.

In addition, we rely on third parties to perform release testing on our product candidates prior to delivery to patients. If these tests are not appropriately conducted and test data are not reliable, patients could be put at risk of serious harm, and this could result in product liability suits.

As we currently rely upon single suppliers for the development and manufacture of our product candidates, we are working closely with our third-party manufacturers, distributors, and other partners to manage and build our supply chain activities and mitigate potential disruptions. In connection with those efforts, we are currently evaluating options and taking steps to establish the development and/or manufacture of our product candidates at new manufacturers. If we encounter any material problems in connection with that process, we may be delayed in the development or commercialization of our product candidates, including veligrotug, and our business could be harmed.

The manufacture of drug products, including combination products that comprise a biological drug product and a device, is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques, process controls and product testing methods. Manufacturers of medical products often encounter difficulties in production, particularly in scaling up and validating initial production and absence of contamination. These problems include difficulties with raw material supply, production costs and yields, quality control, stability of the product, quality assurance testing, operator error, shortages of qualified personnel, logistical problems or delays encountered when using multiple sites for manufacturing and testing, as well as compliance with strictly enforced federal, state, and foreign regulations. These problems may be more likely, or worse, in cases where the products candidates being manufactured are combination products, like certain of our product candidates, due to the increased complexity in their manufacture and associated supply chain. Furthermore, if contaminants are discovered in our supply of our product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot be assured that any stability issue or other issues relating to the manufacture of our product candidates will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes, shortages, including from the effects of heath emergencies (such as novel viruses or pandemics), natural disasters, or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our product candidates to patients or subjects in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the initiation or completion of clinical trials, increase the costs associated with initiating or maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

We currently rely on the Chinese CDMO WuXi Biologics (Hong Kong) Limited ("WuXi") and other CDMOs, to develop and manufacture our product candidates, and will likely continue to rely on them in the future. There has been increased governmental focus in the United States on the role of Chinese companies in the life sciences industry. This focus has included U.S. legislative proposals, such as the proposed BIOSECURE Act, which has been passed by the U.S. House of Representatives and is pending before the U.S. Senate. If enacted, the BIOSECURE Act would, among other things, prohibit U.S. federal agencies from entering into or renewing any contract with any entity that uses biotechnology equipment or services produced or provided by a "biotechnology company of concern" to perform that contract with the government. Although the proposed Act has not been enacted and thus is subject to change through the legislative process, a version of the Act passed by the U.S. House of Representatives defines a "biotechnology company of concern" to include WuXi Biologics and WuXi AppTec. If adopted, the BIOSECURE Act could cause us to seek to exit some or all of our arrangements with WuXi (or any other China-based service provider determined to be "biotechnology companies of concern") and accelerate the transition of these services to alternative companies or continue to engage redundant suppliers for the U.S. market. Additionally, the legislation could adversely impact WuXi's operations or financial position which, in turn, could impact their ability to perform under our agreements with it. Our reliance on Chinese-based contract research organizations, such as WuXi, may also cause us to face additional risks due to geopolitical tensions between the U.S. and China and related legal and regulatory restrictions and requirements, including measures directly affecting WuXi.

In addition, these entities or materials sourced from these entities may be subject to other U.S. legislation, sanctions, investigations, regulations, trade restrictions, tariffs, regulatory actions, or ex-U.S. legislation, regulatory actions or requirements, that could increase the cost or reduce the supply of material available to us, delay or prevent the procurement or supply of such material, delay or impact the availability of our product candidates, delay or impact clinical trials, availability of commercial supply, or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies. Any of the foregoing outcomes could adversely affect our financial condition and business prospects.

For example, in February 2024, the chair and ranking member of the House Select Committee on the Chinese Communist Party, along with certain Senators, sent a letter to the Biden administration requesting that certain WuXi related entities be added to the Department of Defense's Chinese Military Companies List (pursuant to Section 1260H of the National Defense Authorization Act for Fiscal Year 2021), the Department of Commerce's Bureau of Industry and Security Entity List, and the

Department of Treasury's Non-SDN Chinese Military-Industrial Complex Companies List. While the Biden administration did not take action on this letter, adding either or both previously mentioned WuXi entities on any or all of the aforementioned lists could materially impact our agreements with WuXi and could delay the initiation or completion of clinical trials, increase the costs associated with starting or maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely or adversely impact our financial condition and business prospects. Furthermore, we are not able to predict how the second Trump Administration may respond to this or similar requests.

Furthermore, the biopharmaceutical industry in China is strictly regulated by the Chinese government, including Chinese collaborators and service providers such as CROs and CDMOs. Changes to Chinese regulations or government policies affecting biopharmaceutical companies are unpredictable and may adversely impact or have a material adverse effect on us or on our collaborators in China. Such changes may also adversely impact the management of data generated in China, the availability of data generated with Chinese collaborators or in studies in China and the availability of data or records generated by service providers, which could have an adverse effect on our business, the development of our product candidates, our financial condition, results of operations and business prospects. In addition, it may be difficult or impossible to obtain certain source documentation from Chinese entities, which may adversely affect our business where such source documentation is required.

Evolving changes in China's economic, political, and social conditions and the uncertainty around China's relationship with other governments, such as the U.S. and the U.K., could also negatively impact our ability to use Chinese companies to manufacture our product candidates for our clinical trials or have an adverse effect on our ability to secure commitments from governments to purchase our potential therapies, which could cause us to delay our clinical development programs or adversely affect our financial condition.

If it becomes necessary to shift our operations away from reliance upon WuXi or other non-US based CROs and CDMOs, we will need to find suitable replacements for their services. We may encounter significant difficulty in finding suitable replacement partners and vendors, difficulties in transferring our programs or processes from one CRO or CDMO to another, and such parties may have limited capacity due to the influx of demand from other companies, including other biotechnology and biopharmaceutical companies in a position similar to ours. Inability to find suitable replacements for these necessary services could increase the cost or reduce or eliminate the supply of material available to us, delay or prevent the procurement or supply of such material, delay or impact the availability of our product candidates, delay or impact clinical trials, availability of commercial supply, or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies. Any of the foregoing outcomes could adversely affect our financial condition and business prospects.

We may be unable to realize the potential benefits of any collaboration.

Even if we are successful in entering into additional future collaborations with respect to the development and/or commercialization of one or more product candidates, there is no guarantee that the collaboration will be successful. Collaborations may pose a number of risks, including:

- collaborators often have significant discretion in determining the efforts and resources that they will apply to the collaboration and may not commit sufficient resources to the development, marketing, or commercialization of the product or products that are subject to the collaboration;
- collaborators may not perform their obligations as expected;
- any such collaboration may significantly limit our share of potential future profits from the associated program and may require us to relinquish potentially valuable rights to our current product candidates, potential products, proprietary technologies, or grant licenses on terms that are not favorable to us;
- collaborators may cease to devote resources to the development or commercialization of our product candidates if the collaborators view our product candidates as competitive with their own products or product candidates;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation, or the course of development, might cause delays or termination of the development or commercialization of product candidates, and might result in legal proceedings, which would be time consuming, distracting, and expensive;
- collaborators may be impacted by changes in their strategic focus or available funding, or business combinations involving them, which could cause them to divert resources away from the collaboration;

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability, which would be time consuming, distracting, and expensive;

- the collaborations may not result in us achieving revenue to justify such transactions; and

- collaborations may be terminated and, if terminated, may result in a need for us to raise additional capital to pursue further development or commercialization of the applicable product candidate.

As a result, a collaboration may not result in the successful development or commercialization of our product candidates.

Risks Related to Our Intellectual Property

We rely on patent rights, trade secret protections and confidentiality agreements to protect the intellectual property related to our product candidates and any future product candidates. If we are unable to obtain or maintain exclusivity from the combination of these approaches, we may not be able to compete effectively in our markets.

We rely or will rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect the intellectual property related to our technologies and product candidates. Our success depends in large part on our ability to obtain regulatory exclusivity and our and our licensors' ability to maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technologies and product candidates.

We have sought to protect our proprietary position by filing and licensing the rights to patent applications in the United States and abroad related to our technologies and product candidates that are important to our business. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles continue to evolve and may remain unresolved. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our product candidates, third parties may challenge their validity, enforceability, or scope, which may result in such patents being narrowed, found unenforceable, unpatentable, or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates, or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

We, independently or together with our licensors, have filed patent applications covering various aspects of our product candidates, including compositions of matter and their methods of use. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent, or whether any issued patents will be found invalid and unenforceable or unpatentable following a challenge by third parties. Any successful post-grant review proceeding or litigation with respect to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

If we cannot obtain and maintain effective protection of exclusivity from our regulatory efforts and intellectual property rights, including patent protection or data exclusivity, for our product candidates, we may not be able to compete effectively, and our business and results of operations would be harmed.

We may not have sufficient patent term protections for our product candidates to effectively protect our business.

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

Patent term extensions ("PTEs") under the Hatch-Waxman Act in the United States and under supplementary protection certificates in Europe may be available to extend the patent exclusivity terms of our product candidates. We will likely rely on PTEs, and we cannot provide any assurances that any such PTEs will be obtained and, if so, for how long. As a result, we may not be able to maintain exclusivity for our product candidates for an extended period after regulatory approval, if any, which would negatively impact our business, financial condition, results of operations, and prospects. If we do not have sufficient patent terms or regulatory exclusivity to protect our product candidates, our business and results of operations will be adversely affected.

Changes in patent laws in the U.S. and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products, and recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and is therefore costly, time-consuming, and inherently uncertain. In addition, in 2011 the U.S. enacted the Leahy-Smith America Invents Act (the "Leahy-Smith Act") and is still currently implementing wide-ranging patent reform legislation. Recent rulings from the U.S. Supreme Court and the Court of Appeals for the Federal Circuit have narrowed the scope of patent protection available in specified circumstances and weakened the rights of patent owners in specified situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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

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

An important change introduced by the Leahy-Smith Act is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either: (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications until these filings are no longer confidential.

Among some of the other changes introduced by the Leahy-Smith Act are changes that limit where a patentee may file a patent infringement suit and new post-grant review procedures providing opportunities for third parties to challenge any issued patent in the USPTO. Included in these new procedures is a process known as Inter Partes Review, which has been generally used by many third parties since the enactment of the Leahy-Smith Act to render patents unpatentable. These post-grant review procedures are and continue to be an evolving and developing area of law.

Geopolitical actions in the U.S. and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of patent applications and the maintenance, enforcement or defense of issued patents. For example, the U.S. and foreign government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions

could result in abandonment or lapse of patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have predominately primary place of business or profit-making activities in the United States and other countries that Russia has deemed unfriendly without consent or compensation. Consequently, we would not be able to prevent third parties from practicing its inventions in Russia or from selling or importing products made using its inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, operations and prospects may be adversely affected.

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

If we are unable to maintain effective proprietary rights for our product candidates or any future product candidates, we may not be able to compete effectively in our proposed markets.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, such as processes for which patents are difficult to enforce, other elements of our product candidate discovery and/or development processes that involve proprietary know-how, information, or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, collaborators, contractors and other third parties. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations, and systems, the agreements or security measures may be breached, and we may not have adequate remedies for such a breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors, and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed, or that our trade secrets and other confidential proprietary information will not be disclosed, or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business, financial condition, or results of operations. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our ability to develop, manufacture, market, and sell our product candidates and use our proprietary technology without infringing the intellectual property or other exclusive rights of third parties. Numerous third-party U.S. and non-U.S. issued patents and pending applications exist or may be filed in the area of our product candidates. From time to time, we may also monitor these patents and patent applications. For example, we are aware of and monitoring certain patent applications in which third-parties are seeking to obtain patent claims related to our product candidates for treating TED. We are also aware of and monitoring certain third-party patent families, some of which include granted patents, that could be relevant to product candidates in our FcRn inhibitor portfolio. We may in the future pursue available proceedings in the U.S. and foreign patent offices to challenge these patents and patent applications. In addition, or alternatively, we may consider whether to seek to negotiate a license of rights to technology covered by one or more of such third-party patents and patent applications. If any patents or patent applications cover our product candidates or technologies, we may not be free to

manufacture or market our product candidates as planned, absent such a license, which may not be available to us on commercially reasonable terms, or at all.

It is also possible that we have failed to identify relevant third-party patents or applications. For example, applications filed before November 29, 2000 remain confidential until patents issue, and applications filed after that date that will not be filed outside the United States can elect to remain confidential until patents issue.

Moreover, it is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to our product candidates and technologies because patent searching is imperfect due to differences in terminology among patents, incomplete databases, and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale, or use of a current or future product candidate, or we may incorrectly conclude that a third-party patent is invalid, unenforceable, unpatentable, or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to specified limitations, be later amended in a manner that could cover our technologies, our product candidates, or the use of our product candidates.

There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits in federal courts, and interferences, oppositions, inter partes reviews, post-grant reviews, and reexamination proceedings before the USPTO and corresponding foreign patent offices. Numerous U.S. and foreign-issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products, cease development or commercialization, or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We are dependent on intellectual property licensed from third parties. We may not be successful in meeting our obligations under our existing license agreements necessary to maintain our product candidate licenses in effect. In addition, if required in order to commercialize our product candidates, we may be unsuccessful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

We currently have rights to certain intellectual property, through licenses from third parties and under technology and patents that we do not own, to develop and commercialize our product candidates. Because our programs may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to maintain in effect these proprietary rights. Mergers and acquisitions involving the third parties from whom we license intellectual property may negatively impact our rights. Any termination of license agreements with third parties with respect to our product candidates would be expected to negatively impact our business prospects.

We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. 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 their patent rights to us. Even if we are able to license or acquire third-party intellectual property rights that are necessary for our product candidates, there can be no assurance that they will be available on favorable terms.

If we are unable to successfully obtain and maintain rights to required third-party intellectual property, we may have to abandon development or commercialization of that product candidate or pay additional amounts to the third-party, and our business and financial condition could suffer.

The patent protection and patent prosecution for some of our product candidates are dependent on third parties.

While we normally seek and gain the right to fully prosecute the patents relating to our product candidates, there may be times when the prosecution and maintenance of patent applications and patents relating to our product candidates are controlled by our licensors. In these instances, we normally seek a right to participate in such prosecution or maintenance, which is not always granted. If any of our licensors fail to appropriately follow our instructions or consider our comments with regard to the prosecution and maintenance of patent protection for patents covering any of our product candidates, it may result in patent rights that do not or do not sufficiently cover products. If this happens, our ability to develop and commercialize those product candidates may be adversely affected, and we may not be able to prevent competitors from making, using, importing, and selling competing products. In addition, even where we now have the right to control patent prosecution of patents and patent applications, we have licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensors in effect from actions prior to us assuming control over patent prosecution.

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

The USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent prosecution and post grant or issuance. We employ reputable law firms and other professionals to help us comply. Additionally, periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or patent applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or patent applications. We rely on our outside counsel or our agents to pay these fees when due. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. 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. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If such an event were to occur, it could have a material adverse effect on our business. In addition, we may be responsible for the payment of patent fees for patent rights that we license from third parties. If any licensor of these patents does not itself elect to make these payments, and we fail to do so, we may be liable to the licensor for any costs and consequences of any resulting loss of patent rights. If we or our existing or future licensors fail to maintain the patents and patent applications covering our product candidate, our competitors might be able to enter the market, which would have an adverse effect on our business.

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

We are a party to intellectual property licenses and supply agreements that are important to our business and expect to enter into additional license agreements in the future. Our existing agreements impose, and we expect that future license agreements will impose, various diligence, milestone payments, royalties, purchasing, and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, our agreements may be subject to termination by the licensor, in which event we would not be able to develop, manufacture, or market products covered by the license or subject to supply commitments. Further, these agreements are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. If material disputes with respect to these agreements prevent or impair our ability to maintain our current arrangements on acceptable terms, or are insufficient to provide us the necessary rights to use the intellectual property or supply our needs, we may be unable to successfully develop and commercialize the affected product candidates. Any material disputes with our licensors or suppliers or any termination of the agreements on which we depend could have a material adverse effect on our business, financial conditions, results of operations and prospects.

We may be involved in lawsuits or post-grant review proceedings to defend, protect, or enforce our patents or the patents of our licensors, which could be expensive, time consuming, and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. If we, or one of our licensing partners, were to initiate legal proceedings against a third-party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable or file a post-grant review proceeding to challenge the patentability of the patent. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability and post-grant review proceeding to challenge the patentability of the patent are commonplace. Grounds for these challenges could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description, clarity, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material information from the USPTO, or made a

misleading statement, during prosecution. The outcome following legal assertions of invalidity, unenforceability, and patentability is unpredictable.

Interference proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to us from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or offer us a license at all. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation or post-grant review proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our product candidates to market.

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 this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

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

We employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we have written agreements and make every effort to ensure that our employees, consultants, and independent contractors do not use the proprietary information or intellectual property rights of others in their work for us, we may in the future be subject to any claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arising from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors 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, intellectual property that is important to our product candidates. 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. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop our own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries, particularly some developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology and therapeutic

products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters

We expect the product candidates we develop will be regulated as biologics, and they may be subject to competition from biosimilar and interchangeable biological products.

The BPCIA was enacted as part of the ACA to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

We believe that any of the product candidates we develop that is approved in the United States as a biological product under a BLA should qualify for the current 12-year period of exclusivity provided law. However, there is a risk that this exclusivity could be shortened in the future due to congressional action or otherwise, that the FDA will not consider approval or a product candidate to be a "first licensure" that gives rise to an exclusivity period, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

In addition, the first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitted under the abbreviated approval pathway for the lesser of (i) one year after the first commercial marketing, (ii) 18 months after approval if there is no legal challenge, (iii) 18 months after the resolution in the applicant's favor of a lawsuit challenging the biologics' patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period. The approval of a biologic product biosimilar to one of our product candidates could have a material adverse impact on our business as it may be significantly less costly to bring to market and may be priced significantly lower than our product candidates.

We may seek orphan drug designation for our product candidates, but we might not receive such designation.

We are no longer pursuing orphan drug designation for veligrotug for thyroid eye disease in the U.S., but we may seek orphan drug designation for veligrotug in other indications and/or territories and for our other product candidates in various indications and/or territories.

Even if we obtain orphan drug designation for any of our current and potential future product candidates, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Exclusive marketing right in the U.S. also may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for an existing or future product candidate, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties still can be approved for the same condition even with an orphan drug designation. Additionally, even after an orphan drug is approved, the FDA can subsequently approve the same 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 safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug or biologic nor gives the drug or biologic any advantage in the regulatory review or approval process.

In addition, the regulatory agency responsible for the granting of orphan drug exclusivity may change their interpretation of the scope of orphan drug exclusivity. For example, the FDA's longstanding interpretation of the Orphan Drug Act is that exclusivity is specific to the orphan indication for which the drug was actually approved. As a result, the scope of exclusivity has been narrow and protected only against competition from the same "use or indication" rather than the broader "disease or condition." Our ability to obtain and maintain orphan drug designation and the benefits thereof, including orphan drug exclusivity, may materially impact our financial performance. See "Business—Government Regulation—Orphan Drug Designation."

We may seek Fast Track, Breakthrough Therapy, and/or Priority Review designations for one or more of our product candidates, but we might not receive such designation(s), and even if we do, such designation(s) may not actually lead to a faster development or regulatory review or approval process.

If a product candidate is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for this condition, a product sponsor may apply for FDA Fast Track designation, or a product can receive Breakthrough Therapy designation if preliminary clinical evidence indicates that the product, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. If we seek Fast Track or Breakthrough Therapy designation for a product candidate, we may not receive it from the FDA. However, even if we receive Fast Track or Breakthrough Therapy designation, it does not ensure that we will receive marketing approval in any particular timeframe or at all. We may not experience a faster development or regulatory review or approval process with Fast Track or Breakthrough Therapy designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track or Breakthrough Therapy designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track or Breakthrough Therapy designation alone does not guarantee qualification for the FDA's priority review procedures. See "Business—Government Regulation—Expedited Development and Review Programs."

We may attempt to obtain accelerated approval of our product candidates. If we are unable to obtain accelerated approval, we may be required to conduct clinical trials beyond those that we contemplate, or the size and duration of our pivotal clinical trials could be greater than currently planned, which could increase the expense of obtaining, reduce the likelihood of obtaining, and/or delay the timing of obtaining necessary marketing approvals. Even if we receive accelerated approval from the FDA, the FDA may require that we conduct confirmatory trials to verify clinical benefit. If our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-approval requirements, the FDA may seek to withdraw accelerated approval.

We may seek accelerated approval for our product candidates. The FDA may grant accelerated approval to a product designed to treat a serious or life-threatening condition that provides meaningful therapeutic advantage over available therapies and demonstrates an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease. If granted, accelerated approval may be contingent on the applicant's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's predicted effect on irreversible morbidity or mortality or other clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022, the FDA may require, as appropriate, that such confirmatory studies be underway prior to approval for a product granted accelerated approval. If such post-approval studies fail to confirm the drug's clinical benefits relative to its risks, the FDA may withdraw its approval of the drug. If we choose to pursue accelerated approval, there can be no assurance that the FDA will agree that our proposed primary endpoint is an appropriate surrogate endpoint. Similarly, there can be no assurance that after subsequent FDA feedback that we will continue to pursue accelerated approval or any other form of expedited development, review, or approval, even if we initially decide to do so. Furthermore, if we submit an application for accelerated approval, there can be no assurance that such application will be accepted or that approval will be granted on a timely basis, or at all. The FDA also could require us to conduct further studies or trials prior to considering our application or granting approval of any type. We might not be able to fulfill the FDA's requirements in a timely manner, which would cause delays, or approval might not be granted because our submission is deemed incomplete by the FDA.

Even if we receive accelerated approval from the FDA, we will be subject to rigorous post-approval requirements, including submission to the FDA of all promotional materials prior to their dissemination. The FDA may require us to conduct a confirmatory study to verify the predicted clinical benefit. The FDA could withdraw accelerated approval for multiple reasons, including our failure to conduct any required post-approval study with due diligence, or the inability of such study to confirm the predicted clinical benefit. A failure to obtain accelerated approval or any other form of expedited review or approval for a product candidate could result in a longer time period prior to commercializing such product candidate, increase the cost of development of such product candidate, and harm our competitive position in the marketplace.

Healthcare legislative reform measures may have a material adverse effect on our business, financial condition, or results of operations, and current and future legislation may increase the difficulty and cost for us, and any collaborators, to obtain marketing approval of and commercialize our drug candidates and affect the prices we, or they, may obtain.

In the United States, there have been and continues to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA was passed, which was intended to substantially change the way healthcare is financed by both governmental and private insurers, and significantly impact the U.S. pharmaceutical industry. On August 16, 2022, Congress passed the IRA, which, among other provisions, included several measures intended to lower the cost of prescription drugs and related healthcare reforms. It is possible that the IRA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the second Trump Administration will impact the IRA and our business. See "Business—Health Reform."

Heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. We expect that additional state and federal healthcare reform measures will be adopted in the future, particularly in light of the second Trump Administration, any of which could limit the amounts that federal and state governments will pay for healthcare therapies, which could result in reduced demand for our product candidates or additional pricing pressures. We cannot be sure whether additional legislation or rulemaking related to the IRA will be issued or enacted, or what impact, if any, such changes will have on the profitability of any of our drug candidates, if approved for commercial use, in the future.

We may be subject, directly or indirectly, to foreign, federal, and state healthcare fraud and abuse laws, false claims laws, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties, sanctions, or other liability.

Our operations may be subject to various foreign, federal, and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and Physician Payments Sunshine Act, the European General Data Protection Regulation 2016/679, the UK Bribery Act 2010, and other regulations. These laws may impact, among other things, our relationships with healthcare professionals and our proposed sales, marketing, and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. See "Business—Other Regulations."

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including significant civil, criminal, and administrative penalties, disgorgement, damages, fines, contractual damages, reputational harm, diminished profits and future earnings, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

If we fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business, financial condition, or results of operations.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use, and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling, and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts, and business operations, and cause environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by us and our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources, and state or federal or other applicable authorities may curtail our use of specified materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are

complex, change frequently, and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

Non-compliance with existing or future laws and regulations related to privacy or data security could lead to government enforcement actions (which could include civil or criminal fines or penalties), private litigation, other liabilities, and/or adverse publicity. Compliance or non-compliance with such laws could increase the costs of our products and services, could limit their use or adoption, and could otherwise negatively affect our operating results and business.

We may collect, use, transfer, or otherwise process proprietary, confidential, and sensitive information, including personal information and health-related data, which subjects us to numerous evolving and complex data privacy and security obligations, including various laws, regulations, guidance, and industry standards. Regulation of personal information processing is evolving, as federal, state, and foreign governments continue to adopt new, or modify existing, laws and regulations addressing data privacy and security, and the collection, processing, storage, transfer, and use of such data. We, our collaborators, and our service providers may be subject to current, new, or modified federal, state, and foreign data protection laws and regulations (e.g., laws and regulations that address data privacy and data security, including, without limitation, health data). These new or proposed laws and regulations are subject to differing interpretations and may be inconsistent among jurisdictions, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data. These and other requirements could require us or our collaborators to incur additional costs to achieve compliance, limit our competitiveness, necessitate the acceptance of more onerous obligations in our contracts, restrict our ability to use, store, transfer, and process data, impact our or our collaborators' ability to process or use data in order to support the provision of our products or services, affect our or our collaborators' ability to offer our products and services or operate in certain locations, cause regulators to reject, limit, or disrupt our clinical trial activities, result in increased expenses, reduce overall demand for our products and services and make it more difficult to meet expectations of or commitments to customers or collaborators. See "Business—Other Regulations."

Within the U.S., there are numerous federal and state laws and regulations related to the privacy and security of personal information. For example, at the federal level, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended, and its implementing regulations establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information. While we have determined that we are neither a "covered entity" nor a "business associate" directly subject to HIPAA, many of the U.S. health-care providers with which we interact are subject to HIPAA, and we may have assumed obligations related to protecting the privacy of personal information. States are increasingly regulating the privacy and security of personal information. In some states, such as California and Washington, state privacy laws are even more protective than HIPAA. For example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act (together, the "CCPA"), regulates companies' use and disclosure of the personal information of California residents and grants California residents several rights with respect to their personal information. The CCPA also provides for civil penalties for violations, including statutory fines for noncompliance, as well as a limited private right of action in connection with certain data breaches, and establishes a new regulatory agency to implement and enforce the law. In addition, almost 20 other states have now passed comprehensive privacy laws that have taken effect or will come into effect at various times over the next few years. All of these evolving compliance and operational requirements impose significant costs that are likely to increase over time, may require us to modify our data processing practices and policies, divert resources from other initiatives and projects and could restrict the way services involving data are offered, all of which may adversely affect our results of operations. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, than federal or other state laws, and such laws may differ from each other, which may complicate compliance efforts. State laws are changing rapidly and there is ongoing discussion in Congress of a new federal data protection and privacy law to which we may be subject. We will continue to monitor and assess the impact of these state laws, which may impose substantial penalties for violations, impose significant costs for investigations and compliance, and carry significant potential liability for our business.

Outside of the U.S., data protection laws, including the E.U. General Data Protection Regulation (the "GDPR"), which also forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018 and as amended by the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019 (SI 2019/419) ("UK GDPR"), also apply to some of our operations. The GDPR and UK GDPR increase our obligations with respect to the processing of personal data in relation to clinical trials conducted in the member states of the EEA and the UK, including by expanding the definition of personal data to include coded (pseudonymized) data and requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators. In addition, the GDPR and the UK GDPR increase the scrutiny that clinical trial sites located in the EEA and UK should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection. The GDPR and UK GDPR impose substantial fines for breaches of data protection requirements, which can be up to four percent of

global revenue or 20 million Euros (£17.5 million in the U.K.), whichever is greater, and they also confer a private right of action on data subjects for breaches of data protection requirements. Compliance with these laws is a rigorous and time-intensive process that requires review and updates that may increase our cost of doing business, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm in connection with our European and UK activities. Other governmental authorities around the world are considering and, in some cases, have enacted, similar privacy and data security laws.

Non-compliance with U.S. and foreign data protection laws and regulations could result in government investigations and enforcement actions (which could include civil or criminal penalties, fines, or sanctions), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, patients or subjects about whom we or our collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights or failed to comply with data protection laws or applicable privacy notices even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business. Any failure by our third-party collaborators, service providers, contractors, or consultants to comply with applicable law, regulations, or contractual obligations related to data privacy or security could result in proceedings against us by governmental entities or others.

We may publish privacy policies and other documentation regarding our collection, processing, use, and disclosure of personal information and/or other confidential information. Although we endeavor to comply with our published policies and other documentation, we may at times fail to do so or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees or vendors fail to comply with our published policies and documentation. Such failures can subject us to potential foreign, local, state, and federal action if they are found to be deceptive, unfair, or misrepresentative of our actual practices. Moreover, subjects about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights or failed to comply with data protection laws or applicable privacy notices even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business. Any of these matters could materially adversely affect our business, financial condition, or operational results.

Our use of artificial intelligence (AI) or other emerging technologies could adversely impact our business and financial results.

Some of our employees may utilize AI and other emerging technologies in various facets of their responsibilities. The rapid advancement of these technologies entails risks, including that use of AI could make it more difficult for us to maintain confidential information if our employees share our confidential information with AI programs.

Effective development, management, and use of AI technologies is novel and complex, and there are technical challenges associated with achieving desired levels of accuracy, efficiency, and reliability. There are significant risks involved in the development, adoption, use, deployment and maintenance of AI, such as an increase in intellectual property infringement or misappropriation, privacy, data protection, cybersecurity, confidentiality, operational and technological risks, as well as risks associated with harmful content, accuracy, bias and discrimination, any of which could affect our further development, adoption, use, deployment and maintenance of AI, and may cause us to incur additional costs to resolve any issues arising from such risks.

Legal and regulatory frameworks related to the use of AI are rapidly evolving, as regulation of the use of AI continues to be considered and adopted by various U.S. and international governmental and regulatory entities, including the EU, the SEC and the FTC. Several jurisdictions have also passed, or are considering, new laws and regulations relating to the use of AI. For example, in 2024, the EU adopted the EU AI Act and Colorado adopted the Consumer Protections for Artificial Intelligence Act. While these new laws have not yet impacted our use of AI, the future impact on us of these or other new laws or regulations is uncertain. Any failure by us to comply with current, new and proposed AI-related laws and regulations could result in fines and negative publicity, which could result in reputational harm and damage to our business. We may not be able to adequately anticipate or respond to new laws and regulations, and we may need to expend additional resources to adjust our offerings in certain jurisdictions if applicable legal frameworks are inconsistent across jurisdictions. The cost to comply with such laws or regulations could be significant and would increase our operating expenses, which could adversely affect our business, financial condition and results of operations.

Risks Related to Our Business Operations

Our future success depends in part on our ability to attract, retain, and motivate qualified personnel. If we lose key personnel, or if we fail to recruit additional highly skilled personnel, our ability to develop our product candidates will be impaired and our business may be harmed.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends greatly upon our ability to attract and retain highly qualified managerial, scientific and medical personnel with particular subject matter expertise. We are highly dependent on our management team. The loss of the services of key personnel, and our inability to find suitable replacements, could result in delays in the development of our product candidates and harm our business.

Unless we are able to replace departed employees effectively, we may require current employees to fill additional roles, and this could overextend their responsibilities. As a result, we may experience increased turnover due to employees being overworked. Employees also may be unable to perform these multiple roles effectively due to time and resource constraints. Additionally, if we are unable to retain key personnel, we may be required to cover the roles previously performed by such employees with consultants. These consultants may lack the same skills and performance of departed employees and, as a result, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business.

We primarily conduct our business in Massachusetts. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. There is currently a shortage of highly qualified personnel in our industry, which is likely to continue. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we may grant equity awards that vest over time or vest upon the achievement of certain pre-established milestones. The value to employees of equity awards has been, and may continue to be, significantly affected by movements in our stock price that are beyond our control, and these equity awards may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, they may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees.

We utilize shares under our Amended and Restated 2016 Equity Incentive Plan (the “2016 Plan”) to issue equity awards, in order to induce new employees to join our Company and to retain existing employees. We historically seek stockholder approval to increase the number of shares issuable under the 2016 Plan. If stockholders do not approve future increases to the number of shares issuable under the 2016 Plan, however, our ability to attract and retain employee talent, and our ability to compete for talent, may be adversely affected, which could negatively affect our ability to attract and retain talent and negatively affect our business and business prospects.

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

We expect to continue to develop our company and expand the scope of our operations. As our development and commercialization plans and strategies develop and our geographical footprint expands, we expect to need additional managerial, operational, sales, marketing, financial, legal, and other resources. Our management may need to divert a disproportionate amount of our attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees, and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Unstable market and economic conditions, inflation, increases in interest rates, tariffs and trade dispute with other countries, natural disasters, public health crises, political crises, geopolitical events, such as the crisis in Ukraine, or other macroeconomic conditions, may have serious adverse consequences on our business and financial condition.

The global economy, including credit and financial markets, have experienced extreme volatility and disruptions at various points over the last few decades, including, among other things, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates, increased trade tariffs and trade disputes with other countries, and uncertainty about economic stability. The Federal Reserve has raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets, and the potential for increased U.S. trade tariffs and trade disputes with other countries may increase economic uncertainty, increase operating costs, and affect consumer spending. Similarly, the ongoing military conflict between Russia and Ukraine, the rising tensions between China and Taiwan, the conflict in Israel and surrounding area and domestic tensions within the U.S. have created, or may create, significant volatility in the capital markets and may have further global economic consequences, including disruptions of the global supply chain. Any such volatility and disruptions may adversely affect our clinical trials, our business and the third parties on whom we rely.

If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and share price and could require us to delay or abandon development or commercialization plans. In addition, there is a risk that one or more of our service providers, manufacturers or other partners would not survive or be able to meet their commitments to us under such circumstances, which could directly affect our ability to attain our operating goals on schedule and on budget.

We have experienced and may in the future experience disruptions as a result of such macroeconomic conditions, including delays or difficulties in initiating or expanding clinical trials and manufacturing sufficient quantities of materials. Any one or a combination of these events could have a material and adverse effect on our results of operations and financial condition.

The Hercules Loan and Security Agreement contains certain covenants that could adversely affect our operations and, if an event of default were to occur, we could be forced to repay any outstanding indebtedness sooner than planned and possibly at a time when we do not have sufficient capital to meet this obligation.

Pursuant to the Hercules Loan and Security Agreement, we have pledged substantially all of our assets, other than our intellectual property rights. Additionally, the Hercules Loan and Security Agreement contains certain affirmative and negative covenants that could prevent us from taking certain actions without the consent of our lenders. These covenants may limit our flexibility in operating our business and our ability to take actions that might be advantageous to us and our stockholders. The Hercules Loan and Security Agreement also contains customary affirmative and negative covenants that, among other things, limit our ability, subject to certain exceptions, to incur indebtedness, grant liens, enter into a merger or consolidation, enter into transactions with affiliates, or sell all or a portion of our property, business or assets. The Hercules Loan and Security Agreement contains customary events of default. Upon the occurrence and continuation of an event of default, all amounts due under the Hercules Loan and Security Agreement become (in the case of an insolvency or bankruptcy event), or may become (in the case of all other events of default and at the option of Hercules), immediately due and payable. If an event of default under the Hercules Loan and Security Agreement should occur, we could be required to immediately repay any outstanding indebtedness. If we are unable to repay such debt, the lenders would be able to foreclose on the secured collateral, including our cash accounts, and take other remedies permitted under the Hercules Loan and Security Agreement. Even if we are able to repay any indebtedness on an event of default, the repayment of these sums may significantly reduce our working capital and impair our ability to operate as planned.

Failure in our information technology and storage systems, or those of third parties upon whom we rely, could significantly disrupt the operation of our business and adversely impact our financial condition.

Our ability to execute our business plan and maintain operations depends on the continued and uninterrupted performance of our information technology (“IT”) systems and those of third parties upon whom we rely. IT systems are vulnerable to risks and damages from a variety of sources, including telecommunications or network failures, malicious human acts, and natural disasters (such as a tornado, an earthquake, or a fire). Moreover, despite network security and back-up measures, some of our and our vendors’ servers are potentially vulnerable to physical or electronic break-ins, including cyber-attacks, computer viruses, and similar disruptive problems. The techniques used by criminal elements to attack computer systems are sophisticated, change frequently, and may originate from less regulated and remote areas of the world. As a result, we may not be able to address these techniques proactively or implement adequate preventative measures. If the IT systems are compromised, we could be subject to fines, damages, litigation, and enforcement actions, and we could lose trade secrets, the occurrence of which could harm our business. Despite precautionary measures designed to prevent unanticipated problems that could affect the IT systems, sustained or repeated system failures that interrupt our ability to generate and maintain data could adversely affect our ability to operate our business. In addition, the failure of our systems, maintenance problems, upgrading or

transitioning to new platforms, or a breach in security could result in delays and reduce efficiency in our operations. Remediation of such problems could result in significant, unplanned capital investments.

Furthermore, parties in our supply chain may be operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen, and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business.

A data breach, security incident, or other unauthorized network intrusion or access may allow unauthorized access to our network or data, which could result in a material disruption of our clinical trials, harm our reputation, harm our business, create additional liability and adversely impact our financial results or operational results.

Cybersecurity threats to our information networks and systems, and those of our service providers or collaborators have generally increased in sophistication, scale, and frequency in recent years. In addition to threats from natural disasters, telecommunications and electrical failures, traditional computer hackers, malicious code (such as malware, viruses, worms, and ransomware), employee error, theft or misuse, password spraying, phishing, and distributed denial-of-service attacks, we also face threats from sophisticated nation-state and nation-state supported actors who engage in attacks (including advanced persistent threat intrusions) that add to the risks to our internal networks and systems, our third-party service providers, our collaborators and the information that they store and process. Despite having implemented technical and organizational security measures, it is not possible to entirely mitigate these risks. The security measures we have integrated into our internal networks and systems, which are designed to detect unauthorized activity and prevent or minimize security incidents or breaches, may not function as expected or may not be sufficient to protect our internal networks and platform against certain threats. In addition, techniques used to obtain unauthorized access to networks in which data is stored or through which data is transmitted change frequently. As a result, we may be unable to anticipate these techniques or implement adequate preventative measures to prevent such an event.

In addition, security incidents or breaches affecting us or our current or future collaborators or third-party service providers could result in the unauthorized access to, or disclosure or loss of information, including information that we process. This, in turn, could require notification under applicable data privacy regulations or contracts, and could lead to financial losses, litigation, governmental audits, investigations, fines, penalties, and other possible liability, damage our relationships with our collaborators, trigger indemnification and other contractual obligations, cause us to incur investigation, mitigation and remediation expenses, have a negative impact on our ability to conduct clinical trials, and cause reputational damage. For example, the loss of clinical trial data for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

We may not have adequate insurance coverage for security incidents or breaches or information system failures. The successful assertion of one or more large claims against us that exceeds our available insurance coverage or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that any existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators, or other third-party service providers to comply with our data privacy, security, protection, or confidentiality obligations, or to respond to any data security incidents, breaches or other unauthorized access, acquisition, or disclosure of sensitive information (including, without limitation personal information), may result in financial losses, additional cost and/or liability to us, including costs from governmental investigations, enforcement actions, regulatory fines, litigation, costs of doing business, or damage to our reputation. Any of these events could cause harm to our reputation, business, financial condition, or operational results.

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

Our net operating loss ("NOL") carryforwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. Our NOLs generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 years under applicable U.S. tax law. Under the Tax Act, our federal NOLs generated in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of federal NOLs generated in tax years beginning after December 31, 2017 is limited. It is uncertain if and to what extent various states will conform to the Tax Act.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. Our most recent analysis of possible ownership changes was completed for certain tax periods ending through December 31, 2024. It is possible that we have in the past undergone and may in the future undergo, additional ownership changes that could result in additional limitations on our NOL and tax credit carryforwards. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. Consequently, even if we achieve profitability, we may not be able to utilize a material portion of our NOL carryforwards and certain other tax attributes, which could have a material adverse effect on cash flow and results of operations.

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

New income, sales, use, or other tax laws, statutes, rules, regulations, or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations, or ordinances could be interpreted, changed, modified, or applied adversely to us. For example, the Tax Act enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to the Tax Act or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts.

We are subject to taxation in numerous U.S. states and territories and non-U.S. jurisdictions. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors including the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes, and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

Risks Related to Ownership of our Common Stock

Anti-takeover provisions in our charter documents and under Delaware law and the terms of some of our contracts could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our management.

Provisions in our Certificate of Incorporation and Bylaws may delay or prevent an acquisition or a change in management. These provisions include a prohibition on actions by written consent of our stockholders and the ability of our board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us, unless certain conditions are met. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

In addition, the Certificate of Designation of our Series A Convertible Preferred Stock may delay or prevent a change in control of our company. At any time while at least 30% of the originally issued Series A Convertible Preferred Stock remains issued and outstanding, we may not consummate a Fundamental Transaction (as defined in the Certificate of Designation of the Series A Convertible Preferred Stock) or any merger or consolidation of the Company with or into another entity or any stock sale to, or other business combination in which the stockholders of the Company immediately before such transaction do not hold at least a majority of the capital stock of the Company immediately after such transaction, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series A Convertible Preferred Stock. As of December 31, 2024, a

majority of the then outstanding shares of Series A Convertible Preferred Stock was held by entities affiliated with one stockholder. This provision of the Certificate of Designation may make it more difficult for us to enter into any of the aforementioned transactions.

Our Bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or other employees.

Our Bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders, any action asserting a claim against us arising pursuant to any provisions of the Delaware General Corporation Law, our certificate of incorporation or our Bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. Our Bylaws further provide that, unless we consent in writing to an alternative forum, federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended (the "Securities Act").

While these choice of forum provisions do not apply to suits brought to enforce a duty or liability created by the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction, the choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage such lawsuits against our and our directors, officers, and other employees. If a court were to find the choice of forum provision contained in the bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

We do not anticipate that we will pay any cash dividends in the foreseeable future.

The current expectation is that we will retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain, if any, for the foreseeable future.

Future sales of shares by existing stockholders could cause our stock price to decline.

If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after legal restrictions on resale lapse, the trading price of our common stock could decline. In addition, shares of our common stock that are subject to our outstanding options will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act.

Future sales and issuances of equity and debt could result in additional dilution to our stockholders.

We expect that we will need significant additional capital to fund our current and future operations, including to complete potential clinical trials for our product candidates. To raise capital, we may sell common stock, convertible securities, or other equity securities in one or more transactions at prices and in a manner we determine from time to time. As a result, our stockholders may experience additional dilution, which could cause our stock price to fall.

In addition, pursuant to our equity incentive plans, we may grant equity awards and issue additional shares of our common stock to our employees, directors, and consultants, and the number of shares of our common stock reserved for future issuance under certain of these plans will be subject to automatic annual increases in accordance with the terms of the plans. To the extent that new options are granted and exercised, or we issue additional shares of common stock in the future, our stockholders may experience additional dilution, which could cause our stock price to fall.

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

Our directors, officers, 5% stockholders, and their affiliates currently beneficially own a substantial portion of our outstanding voting stock. Therefore, these stockholders have the ability and may continue to have the ability to influence us through this ownership position. These stockholders may be able to determine some or all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

General Risk Factors

The market price of our common stock has historically been volatile, and the market price of our common stock may drop in the future.

The market price of our common stock has been, and may continue to be, subject to significant fluctuations. Market prices for securities of early-stage pharmaceutical, biotechnology, and other life sciences companies have historically been particularly volatile. In addition to the factors described elsewhere in this "Risk Factors," some of the factors that may cause the market price of our common stock to fluctuate greatly, and to decline significantly, include:

- failure to meet or exceed financial and development projections we may provide to the public and the investment community;
- failure of investors to view the clinical trial data that we generate favorably, even if we view the data favorably;
- negative outcomes, or perceived negative outcomes, from our interactions with regulatory authorities in connection with the development of our product candidates;
- the perception of the pharmaceutical and biotechnology industries by the public, legislatures, regulators, and the investment community;
- announcements of significant acquisitions, strategic collaborations, joint ventures, or capital commitments by us or our competitors;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our business and stock;
- changes in the market valuations of similar companies;
- changes in the possible market size, or perceived market size, for our product candidates;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships, or capital commitments;
- the introduction of technological innovations or new therapies that compete with our potential products;
- changes in the structure of health-care payment systems; and
- period-to-period fluctuations in our financial results.

Moreover, the capital markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies, including volatility resulting from general global macroeconomic conditions. These broad market fluctuations may also adversely affect the trading price of our common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our business and reputation.

We may be subject to risks related to litigation and other legal proceedings that may materially adversely affect our business, operating results or financial condition.

From time to time in the ordinary course of its business, we and our directors and officers may become involved in various legal proceedings, including commercial, employment, intellectual property, and other litigation and claims, as well as governmental and other regulatory investigations and proceedings. Such matters can be time-consuming, divert management's attention and resources and cause us to incur significant expenses. Litigation is inherently unpredictable, the results of any such actions may have a material adverse effect on our business, operating results or financial condition.

We incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies.

We incur significant legal, accounting, and other expenses associated with public company reporting requirements. We also incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), as well as rules implemented by the SEC and The Nasdaq Stock Market LLC ("Nasdaq"). These rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. These rules and regulations may also make it difficult and expensive for us to obtain directors' and officers' liability insurance. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as our executive officers, which may adversely affect investor confidence and could cause our business or stock price to suffer.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business, or our market, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our* common stock *may be negatively affected.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our annual report filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. This requires that we incur substantial professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We may experience difficulty in meeting these reporting requirements in a timely manner for each period.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if we are unable to maintain proper and effective internal controls, it could result in a material misstatement of our financial statements that would not be prevented or detected on a timely basis, which could require a restatement, cause us to be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities, cause investors to lose confidence in our financial information, or cause our stock price to decline.

As a public company, we incur significant legal, accounting, insurance, and other expenses, and our management and other personnel have and will need to continue to devote a substantial amount of time to compliance initiatives resulting from operating as a public company. We also anticipate that these costs and compliance initiatives will continue to increase as a result of ceasing to be a "smaller reporting company," as defined in Rule 12b-2 of the Exchange Act.

Our inability to maintain effective internal control over financial reporting in the future could result in investors losing confidence in the accuracy and completeness of our financial reports and negatively affect the market price of our common stock.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act requires our independent registered public accounting firm to attest to the effectiveness of our internal control over financial reporting.

If we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. If we identify material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, if we are unable to assert that our internal controls over financial reporting is effective or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, and the market price of our common stock could be negatively affected. In addition, we could become subject to investigations by any stock exchange on which our securities are listed, the SEC or other regulatory authorities, which could require additional financial and management resources, which could have an adverse impact on our business.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

We have developed and implemented a cybersecurity risk management program that is designed to assess, identify, and manage material risks from cybersecurity threats and to protect the security, confidentiality, integrity and availability of our critical systems and information. These processes are managed and monitored by our information technology team, which is led by our Vice President, Information Technology & Facilities, and include mechanisms, controls, technologies, systems, and other processes designed to prevent or mitigate data loss, theft, misuse, or other security incidents or vulnerabilities affecting our data and information technology environment. For example, we conduct cybersecurity audits, and ongoing risk assessments, including due diligence on and audits of our key technology vendors, CROs, and other contractors and suppliers. We also conduct periodic employee trainings on cyber and information security, among other topics. In addition, we consult with outside advisors and experts, when appropriate, to assist with assessing, identifying, and managing cybersecurity risks, including to anticipate future threats and trends, and their impact on the Company's risk environment.

Our Vice President, Information Technology & Facilities, who reports directly to the Chief Operating Officer and has over 15 years of experience managing information technology and cybersecurity matters, together with our senior leadership team, is responsible for assessing and managing cybersecurity risks. We consider cybersecurity, along with other significant risks that we face, within our overall enterprise risk management framework that is overseen by our Audit Committee of our board of directors and our board of directors. In the last fiscal year, we have not experienced any cybersecurity incidents that resulted in a material effect on our business strategy, results of operations, or financial condition, but we cannot provide assurance that we will not be materially affected in the future by such risks or any future material incidents See "Risk Factors" for additional information on cybersecurity risks we face.

Our Audit Committee has been designated by our Board to oversee cybersecurity risks. The Audit Committee receives biannual updates on cybersecurity and information technology matters and related risk exposures from members of the senior leadership team. The Board also receives updates from management and the Audit Committee on cybersecurity risks on at least an annual basis.

ITEM 2. PROPERTIES

We are party to a multi-year, non-cancelable lease agreement for our office space in Waltham, Massachusetts (as subsequently amended in July 2021, April 2022, July 2022, and April 2024, the "Massachusetts Lease"). In April 2024, we entered into a fourth amendment to the Massachusetts Lease (the "Fourth Amendment"). The Fourth Amendment makes certain modifications to the Massachusetts Lease, including (i) securing 10,427 sq. ft. of office space in the same building (the "New Premises"), (ii) the termination of the 10,956 sq. ft. of leased space under the Massachusetts Lease (the "Original Premises"), and (iii) the extension of the expiration date of the New Premises to July 2029. Under the Fourth Amendment, we have the option to extend the lease term for an additional period of three years upon notice to the landlord. In September 2024, we entered into a fifth amendment to the Massachusetts Lease (the "Fifth Amendment"). The Fifth Amendment makes certain modifications to both the Massachusetts Lease and the Fourth Amendment, including the addition of 2,788 sq. ft. of office space in the same building (the "September 2024 Expansion Premises").

Additionally, we leased approximately 27,128 sq. ft. of office and laboratory space in Boulder, Colorado under a lease that expired in December 2024. In September 2024, we entered into a new, multi-year lease agreement for 7,117 sq. ft. of office and laboratory space in Boulder, Colorado that expires in December 2026. We have the option to extend the lease term for an additional period of five years upon notice to the Landlord.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may be involved in legal proceedings in the ordinary course of business. We are currently not a party to any legal proceedings that we believe would have a material adverse effect on our business, financial condition, or results of operations.

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

Our common stock is traded on The Nasdaq Capital Market under the symbol "VRDN."

Holders

As of February 20, 2025, we had 14 registered holders of record of our common stock. A substantially greater number of holders of our common stock are in "street name" or beneficial holders, whose shares of record are held by banks, brokers, other financial institutions, and registered clearing agencies.

Dividend Policy

We historically have not paid, and do not anticipate in the future paying, dividends on our common stock. We currently intend to retain all of our future earnings, as applicable, to finance the growth and development of our business. In addition to legal restrictions under applicable law, we are subject to certain dividend-related limitations under the Hercules Loan and Security Agreement. Subject to these limitations, any future determination as to the payment of cash dividends on our common stock will be at our board of directors' discretion and will depend on our financial condition, operating results, capital requirements, and other factors that our board of directors considers to be relevant.

Unregistered Sales of Equity Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

ITEM 6. RESERVED

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read together with our consolidated financial statements and the related notes thereto included elsewhere in this Annual Report. This discussion and other parts of this report contain forward-looking statements reflecting our current expectations that involve risks and uncertainties, such as our plans, objectives, expectations, intentions, and beliefs. See "Forward-Looking Statements" for a discussion of the uncertainties, risks, and assumptions associated with these statements. Actual results and the timing of events could differ materially from those discussed in these 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 entitled "Risk Factors" included elsewhere in this Annual Report.

This section discusses 2024 and 2023 items and year-to-year comparisons between the years ended December 31, 2024 and 2023. Discussions of the year ended December 31, 2022 and year-to-year comparisons between the years ended December 31, 2023 and 2022 have been excluded from this Form 10-K and can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on February 27, 2024.

Overview

We are a biopharmaceutical company focused on discovering, developing and commercializing potential best-in-class medicines for serious and rare diseases. We target disease areas where marketed therapies often leave room for improvements in efficacy, safety, and/or dosing convenience. We believe that first-generation medicines rarely represent optimal solutions, especially in rare disease areas, and that there is potential to develop differentiated, best-in-class medicines that could lead to improved patient outcomes, reduced side effects, improved quality of life, expanded market access, and augmented market competition. Our business model is designed to identify and evaluate product opportunities in disease areas where trial data

establishes proof-of-concept for a drug target in the clinic, but the competitive evolution of the product life cycle management and number of entrants appears incomplete. We intend to prioritize indications where a fast-follower and a potentially differentiated drug candidate, or overall product profile, could create significant medical benefit for patients. We are engineering product candidates to address unmet medical needs for patients and further advance drug innovation.

Our goal is to identify and evaluate product concepts leveraging clinically validated molecular targets using established therapeutic modalities. We prioritize product concepts that are aligned with clinical and commercial hypotheses, which we expect will provide an attractive balance of risk and opportunity, thereby representing a compelling allocation of our resources. We focus on advancing therapeutic proteins that we either in-license or discover internally, incorporating proprietary therapeutic protein and antibody discovery and optimization platforms to advance clinical candidates with unique characteristics. We have built relevant expertise in protein and antibody discovery and engineering, biologics manufacturing, nonclinical and clinical development, and commercialization for thyroid eye disease ("TED"), development of anti-neonatal Fc receptor ("FcRn") therapies, and nonclinical and clinical development for indications in rare and autoimmune diseases.

Our approach to rapidly discovering and developing novel therapeutics relies on our scientific expertise in evaluating pre-existing clinical proof-of-concept data for the drug targets we are pursuing, and opportunities to improve upon existing investigational and/or approved therapies. This approach informs how we design, select, and develop our product candidates, including in critical areas such as pharmacokinetics, pharmacodynamics, clinical trial design, trial endpoints, and the selection and recruitment of patients. We believe this strategy reduces the risks associated with discovering and developing novel therapeutics.

Development of Therapies to Treat Thyroid Eye Disease (TED)

We are developing two product candidates, veligrotug (formerly known as VRDN-001) for intravenous and VRDN-003 for subcutaneous administration, to treat patients who suffer from TED. Our most advanced program, veligrotug, is a differentiated humanized monoclonal antibody targeting IGF-1R intravenously administered for the treatment of TED. In previously presented *in vitro* nonclinical data, we showed that veligrotug is a potentially differentiated full antagonist of IGF-1R, compared to teprotumumab's incomplete antagonism of IGF-1R. VRDN-003 has the same binding domain as veligrotug, and was engineered to have a longer half-life. VRDN-003 is designed to be a low-volume, infrequently-dosed subcutaneous IGF-1R for TED, which we plan to launch commercially with an auto-injector to enable at-home patient self-administration. We believe VRDN-003 has the potential to be the best-in-class subcutaneous anti-IGF-1R product candidate by preserving the efficacy of anti-IGF-1Rs in TED, improving safety and maximizing convenience for patients.

We conducted phase 1/2 clinical trials of veligrotug in patients with active or chronic TED. In the active TED portion of the phase 1/2 clinical trials, data reported from all three dose cohorts of veligrotug (n=21) showed significant and rapid improvement in both the signs and symptoms of TED after two infusions of veligrotug compared to placebo. Across all veligrotug treated patients in the active TED trial, 71% were proptosis responders, 67% were overall responders, 62% achieved a clinical activity score ("CAS") of 0 or 1, and 54% had complete resolution of their diplopia. In the chronic TED portion of the phase 1/2 clinical trials, data reported from both dose cohorts of veligrotug (n=12) showed significant and rapid improvement in the signs and symptoms of TED after two infusions of veligrotug compared to placebo. Across all veligrotug treated patients in the chronic TED trial, 42% were proptosis responders, 40% achieved a CAS of 0 or 1, and no patients had complete resolution of their diplopia. In the phase 1/2 clinical trials of both active and chronic TED, veligrotug had a favorable safety profile and was well-tolerated by all patients treated in all dose cohorts.

We are conducting a global pivotal program for veligrotug, including evaluating its efficacy and safety in two global well-controlled phase 3 clinical trials, THRIVE and THRIVE-2, for the treatment of active and chronic TED, respectively. THRIVE and THRIVE-2 are each designed to compare a five-dose IV treatment arm of veligrotug at 10 mg/kg, dosed three weeks apart, to placebo. This five-dose veligrotug regimen features fewer infusions and a shorter time per infusion compared to teprotumumab, the currently marketed IGF-1R inhibitor. On September 10, 2024, we announced topline data from the THRIVE study, which enrolled 113 patients, randomized to veligrotug (n=75) and placebo (n=38). THRIVE achieved all primary and secondary endpoints with a high level of statistical significance ($p < 0.0001$) and was generally well-tolerated, with no treatment-related serious adverse events ("SAEs"). Veligrotug additionally showed a rapid onset of treatment effect, with the majority (53%) of veligrotug-treated patients achieving a proptosis response as early as three weeks. On December 16, 2024, we announced topline data from the THRIVE-2 study, which enrolled 188 patients, randomized to veligrotug (n=125) and placebo (n=63). THRIVE-2 achieved all primary and secondary endpoints with statistical significance and was generally well-tolerated. Veligrotug continued to demonstrate a rapid onset of treatment effect, with a statistically significant proptosis response as early as three weeks and a statistically significant reduction and resolution of diplopia as early as six weeks. THRIVE-2 is the first global phase 3 study in patients with chronic TED to demonstrate a statistically significant and clinically meaningful diplopia responder rate and rate of diplopia complete resolution. To meet the 300 patient standard safety database

requirements for the veligrotug biologics license application ("BLA"), we are conducting our STRIVE clinical trial (safety database inclusive of patients from the THRIVE and THRIVE-2 trials). STRIVE is a global study of veligrotug in TED patients that utilizes broad inclusion criteria (e.g., any severity or duration of disease) and is randomized 3:1 (10 mg/kg IV with an active control of 3 mg/kg IV). In January 2025, we completed enrollment in STRIVE with a total of 231 patients, exceeding the enrollment target of 212 due to patient demand. We have also completed enrollment of the open label extension study for non-responding patients in THRIVE and THRIVE-2. We anticipate submitting a BLA for veligrotug in the second half of 2025 and an MAA to the EMA in the first half of 2026.

In addition to our intravenous veligrotug program, VRDN-003 is our subcutaneous product candidate currently in pivotal development in TED, which we selected in December 2023 following positive data in a phase 1 clinical trial in healthy volunteers.

The VRDN-003 phase 1 clinical study showed VRDN-003 to have a prolonged half-life of 40 to 50 days, which is four to five times that of veligrotug. Because of the healthy volunteer data and the similarities between the veligrotug and VRDN-003 antibodies, we expect VRDN-003 to have similar clinical responses at the exposure levels of veligrotug that led to robust clinical activity in its clinical trials to date in TED. Further, pharmacokinetic modeling of VRDN-003 based on the healthy volunteer data predicted that exposure levels of VRDN-003 could be achieved that are equivalent to exposure levels of veligrotug that produced clinically meaningful results with multiple dosing regimens of VRDN-003, i.e., subcutaneous injection every two, four, or eight weeks.

We are conducting a global pivotal program for VRDN-003, including evaluating its efficacy and safety in two global well-controlled phase 3 clinical trials, REVEAL-1 and REVEAL-2, for the treatment of active and chronic TED, respectively. Both studies will evaluate subcutaneous VRDN-003 administered every four weeks or every eight weeks and will assess outcomes versus placebo. Patient enrollment and dosing continues in both studies. In addition, to enable BLA submission for VRDN-003, we have initiated a safety study to meet the 300 patient standard safety database requirement (to also include patients from the REVEAL-1 and REVEAL-2 trials) and plan to initiate an auto-injector study in 2025 to enable launching VRDN-003 in an auto-injector device, if approved. We anticipate topline data for REVEAL-1 and REVEAL-2 in the first half of 2026, and we anticipate submitting a BLA for VRDN-003 for the treatment of TED by the end of 2026.

Development of FcRn Inhibitors

In addition to developing therapies for TED, we are also developing a portfolio of engineered FcRn inhibitors, including VRDN-006 and VRDN-008. FcRn inhibitors have the potential to treat a broad array of autoimmune diseases, representing a possible significant commercial market opportunity. Our multi-pronged engineering approach has resulted in a portfolio of FcRn-targeting molecules that leverage the clinically and commercially validated mechanism of FcRn inhibition while potentially addressing the limitations of current agents such as incomplete immunoglobulin G ("IgG") suppression, safety, and inconvenience of dosing.

VRDN-006 is a highly selective Fc fragment that inhibits FcRn and is designed to be a convenient subcutaneous and self-administered option for patients. In non-human primate ("NHP") studies, VRDN-006 demonstrated specificity for blocking FcRn-IgG interactions while not showing decreases in albumin or increases in low-density lipoprotein ("LDL") levels, which are known potential side effects associated with certain full-length anti-FcRn monoclonal antibodies. In our head-to-head NHP studies, VRDN-006 demonstrated comparable potency and IgG reductions to efgartigimod, which is the current standard of care in FcRn inhibition, as well as a similar safety profile. We submitted an Investigational New Drug Application ("IND") for VRDN-006 in December 2024, which cleared in January 2025, and we expect proof-of-concept IgG reduction data in healthy volunteers in the third quarter of 2025.

VRDN-008 is a half-life extended bispecific FcRn inhibitor comprising an Fc fragment and an albumin-binding domain designed to prolong IgG suppression and provide a potentially best-in-class subcutaneous option for patients. In a single, high-dose, head-to-head study in NHPs, VRDN-008 demonstrated three times the half-life of efgartigimod. Additionally, VRDN-008 showed a deeper and more sustained IgG reduction with peak IgG reductions that were 20% deeper than efgartigimod while not showing decreases in albumin or increases in LDL levels. NHP studies are ongoing to generate additional data for VRDN-008. Once completed, we plan to use the totality of VRDN-008's NHP data to build a robust pharmacokinetic and pharmacodynamic model to predict potential human dosing regimens for VRDN-008. We anticipate submitting an IND for VRDN-008 by the end of 2025.

Global Economic Considerations

The global macroeconomic environment is uncertain, and could be negatively affected by, among other things, increased U.S. trade tariffs and trade disputes with other countries, instability in the global capital and credit markets, supply chain weaknesses, and instability in the geopolitical environment, including as a result of the Russian invasion of Ukraine, the rising tensions between China and Taiwan, the conflict in Israel and surrounding area and other political tensions. Such challenges have caused, and may continue to cause, recession fears, concerns regarding potential sanctions, high interest rates, foreign exchange volatility and inflationary pressures. At this time, we are unable to quantify the potential effects of this economic instability on our future operations.

Financial Operations Overview

Revenue

Our revenue has historically consisted primarily of up-front payments for licenses, milestone payments, and payments for other research and development services earned under license and collaboration agreements as well as for amounts earned under certain grants we have been awarded.

In October 2020, we became party to a license agreement with Zenas BioPharma. Since February 2021, we have entered into several letter agreements with Zenas BioPharma in which we agreed to provide assistance to Zenas BioPharma with certain development activities, including manufacturing (collectively with the license agreement, the "Zenas Agreements"). Under the terms of the Zenas Agreements, we granted Zenas BioPharma an exclusive license to develop, manufacture, and commercialize certain IGF-1R directed antibody products for non-oncology indications in the greater area of China in exchange for upfront non-cash consideration and non-refundable milestone payments upon achieving specific milestone events during the contract term. Zenas BioPharma announced that it had obtained IND approval in China in July 2022. Under the license agreement, we received a $1.0 million milestone payment from Zenas BioPharma. Additionally, we are eligible to receive royalty payments based on a percentage of the annual net sales of any licensed products sold on a country-by-country basis in the greater area of China. The royalty percentage may vary based on different tiers of annual net sales of the licensed products made. Zenas BioPharma is obligated to make royalty payments to us for the royalty term in the Zenas Agreements. In May 2022, we entered into a Manufacturing Development and Supply Agreement with Zenas BioPharma to manufacture and supply, or have manufactured and supplied, clinical drug product for development purposes. In January 2025, Zenas BioPharma sublicensed their rights under the license agreement to Zai Lab and assigned the Manufacturing Development and Supply Agreement to Zai Lab in connection with the sublicense transaction.

In the future, we expect to continue to generate revenue from a combination of license fees and other up-front payments, payments for research and development services, milestone payments, product sales, and royalties in connection with strategic alliances. We expect that any revenue we generate could fluctuate from quarter to quarter as a result of the timing of our achievement of development and commercial milestones, the timing and amount of payments relating to such milestones and the extent to which any of our product candidates are approved and successfully commercialized by us or our strategic alliance collaborators, if any. If we or our strategic alliance collaborators, if any, fail to develop product candidates in a timely manner or to obtain regulatory approval for them, then our ability to generate future revenue, and our results of operations and financial position would be adversely affected.

Research and Development Expenses

Research and development expenses consist of costs incurred for the research and development of our therapeutic programs and product candidates, which include:

- employee-related expenses, including salaries, severance, retention, benefits, insurance, and share-based compensation expense;
- expenses incurred under agreements with CROs, investigative sites that conduct our clinical trials, and other clinical trial-related vendors, and consultants;
- the costs of acquiring, developing, and manufacturing and testing clinical and nonclinical materials, including costs incurred under agreements with CDMOs;
- costs associated with nonclinical activities and regulatory operations;
- license fees and milestone payments related to the acquisition and retention of certain licensed technology and intellectual property rights; and

- facilities, depreciation, market research, and other expenses, which include allocated expenses for rent and maintenance of facilities, depreciation of leasehold improvements and equipment, and laboratory supplies.

We make non-refundable advance payments for goods and services that will be used in future research and development activities. These payments are recorded as expense in the period in which we receive or take ownership of the goods or when the services are performed.

We record up-front and milestone payments to acquire and retain contractual rights to in-licensed technology and intellectual property rights as research and development expenses when incurred if there is uncertainty in our receiving future economic benefit from the acquired contractual rights. We consider future economic benefits from acquired contractual rights to licensed technology to be uncertain until such a drug candidate is approved by the FDA or other regulatory authorities, or when other significant risk factors are abated.

We expect that our research and development expenses will increase as we expand our clinical development programs and initiate new clinical trials. The process of conducting clinical trials and nonclinical studies necessary to obtain regulatory approval is costly and time consuming. We, or our strategic alliance collaborators, if any, may never succeed in achieving marketing approval for any of our product candidates. The probability of success for each product candidate may be affected by numerous factors, including clinical data, nonclinical data, competition, manufacturability and commercial viability of our product candidates.

Successful development of future product candidates is highly uncertain and may not result in approved products. Completion dates and completion costs can vary significantly for each future product candidate and are difficult to predict. We anticipate we will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis in response to our ability to maintain or enter into new strategic alliances with respect to each program or potential product candidate, the scientific and clinical success of each future product candidate, and ongoing assessments as to each future product candidate's commercial potential. We will need to raise additional capital and may seek additional strategic alliances in the future in order to advance the various clinical trials that are part of our clinical development program described above.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related benefits, including share-based compensation, and severance and retention benefits related to our finance, accounting, human resources, legal, business development, and other support functions, professional fees for auditing, tax, and legal services, market research and other professional and consulting fees to prepare for commercial activities, as well as insurance, board of director compensation, consulting, and other administrative expenses.

Other Income, net

Other income, net consists primarily of interest income, net of fees, and various income items of a non-recurring nature. Interest expense consists of cash and non-cash interest expense on our long-term debt. We earn interest income from interest-bearing accounts, money market funds, and short-term investments.

Critical Accounting Policies and Estimates

This discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). The preparation of financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses. On an ongoing basis, we evaluate these estimates and judgments. We base our estimates on historical experience and on various assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially from these estimates. We believe that the accounting policy discussed below is critical to understanding our historical and future performance, as this policy relates to the more significant areas involving our judgments and estimates.

Clinical Trial and Nonclinical Study Accruals

We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on certain facts and circumstances at that time. Our accrued expenses for nonclinical studies and clinical trials are based on estimates of costs incurred for services provided by external service providers and for other trial-related activities. The timing

and amount of expenses we incur through our external service providers depend on a number of factors, such as site initiation, patient screening, enrollment, delivery of reports, and other events. In accruing for these activities, we obtain information from various sources and estimate the level of effort or expense allocated to each period. Adjustments to our research and development expenses may be necessary in future periods as our estimates change.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

	Year Ended December 31,		
	2024	2023	
	(in thousands)		Increase (Decrease)
Revenue	$ 302	$ 314	$ (12)
Research and development expenses	238,254	159,765	78,489
General and administrative expenses	61,083	94,999	(33,916)
Other income (expense), net	29,086	16,716	12,370
Net loss	$ (269,949)	$ (237,734)	$ (32,215)

Revenue

Revenue was $0.3 million for the years ended December 31, 2024 and 2023. Revenue for both periods was attributable to our collaboration agreement with Zenas BioPharma.

Research and Development Expenses

	Year Ended December 31,		
	2024	2023	
	(in thousands)		Increase (Decrease)
Direct research and development expenses			
TED portfolio	$ 131,133	$ 71,646	59,487
FcRn inhibitor portfolio	41,941	29,973	11,968
Other nonclinical and research and development costs	3,001	13,540	(10,539)
Unallocated expenses			
Personnel related expense (including share based compensation)	55,237	39,608	15,629
Facility and other operating costs	6,942	4,998	1,944
Total research and development expenses	$ 238,254	$ 159,765	$ 78,489

Direct costs related to the TED portfolio increased by $59.5 million during the year ended December 31, 2024 compared to the year ended December 31, 2023, primarily attributable to:

- $50.5 million increase in clinical trial costs and a $10.9 million increase in chemistry, manufacturing and controls costs to support the veligrotug and VRDN-003 clinical trials.

Direct costs related to the FcRn inhibitor portfolio increased by $12.0 million during the year ended December 31, 2024 compared to the year ended December 31, 2023, primarily attributable to:

- $14.0 million increase in nonclinical research to advance the FcRn inhibitor portfolio; and
- $14.0 million increase in chemistry, manufacturing and controls costs to support IND-enabling activities.

These increases were partially offset by a $16.3 million decrease in milestone, license and option fees as a result expenses incurred during the year ended December 31, 2023, primarily due to a $15.0 million upfront payment related to the development of subcutaneous delivery systems.

Direct costs related to other nonclinical research and development decreased by $10.5 million during the year ended December 31, 2024 compared to the year ended December 31, 2023, primarily attributable to:

- $5.7 million decrease in milestone, license and option fees as a result of an upfront payment for an exclusive license and collaboration agreement during the year ended December 31, 2023;
- $3.9 million decrease in other nonclinical research expenses due to prioritization of the FcRn inhibitor portfolio.

Personnel-related costs increased $15.6 million during the year ended December 31, 2024 compared to the year ended December 31, 2023, primarily attributable to:

- $11.3 million increase in personnel related costs, due primarily to increased headcount to support our ongoing research and development efforts, including share-based compensation and other employee compensation and recruiting costs; and
- $4.3 million increase in severance costs primarily related to separation agreements with former executive officers, including a $3.2 million increase in share-based compensation related to the acceleration of stock option vesting during the year ended December 31, 2024.

Facility and other operating costs increased $1.9 million during the year ended December 31, 2024 compared to the year ended December 31, 2023, primarily attributable to an increase in professional services fees for consultants and contractors, as well as an increase in facility and information technology costs to support our ongoing research and development efforts.

We expect our research and development expenses to continue to increase as we work to progress our clinical and nonclinical programs.

General and Administrative Expenses

General and administrative expenses were $61.1 million during the year ended December 31, 2024, compared to $95.0 million during the year ended December 31, 2023. The $33.9 million decrease in general and administrative expenses is primarily attributable to the following:

- $27.2 million decrease in severance costs, due primarily to separation agreements with former executive officers, including a $22.7 million decrease in share-based compensation related to the modification and acceleration of stock option vesting for former executives. Share-based compensation costs for the year ended December 31, 2024 included $3.4 million in costs related to the modification and acceleration of vesting for former executive officers as compared to $26.1 million for the year ended December 31, 2023; and
- $8.4 million decrease in personnel-related costs, primarily due to a decrease in headcount and a decrease in share-based compensation and other employee compensation and recruiting costs.

These decreases were partially offset by a $2.9 million increase in legal services, market research and other professional and consulting fees to prepare for commercial activities.

Other Income, net

Other income, net was $29.1 million during the year ended December 31, 2024 compared to $16.7 million during the year ended December 31, 2023. Other income, net for the year ended December 31, 2024 is comprised of $31.6 million of interest income earned on short-term investments as well as $0.3 million of sub-lease income, offset by $2.2 million in interest expense related to our Hercules Loan and Security Agreement, and $0.6 million in other losses. Other income, net for the year ended December 31, 2023 is comprised of $18.2 million of interest income earned on short-term investments as well as $0.3 million of sub-lease income, offset by $1.3 million in interest expense related to our Hercules Loan and Security Agreement and $0.5 million in other losses. The increase in interest income is primarily attributable to higher interest rates and higher average short-term investments balances during the year ended December 31, 2024 as compared to the year ended December 31, 2023.

Liquidity and Capital Resources

We have funded our operations to date principally through proceeds received from the sale of our common stock, our Series A Convertible Preferred Stock, our Series B Convertible Preferred Stock and other equity securities, debt financings, license fees, and reimbursements received under collaboration agreements. As of December 31, 2024, we had $717.6 million in cash, cash equivalents, and short-term investments. We expect that our current cash, cash equivalents and short-term investments will be sufficient to fund our planned operations, including our clinical development plan described elsewhere in this Annual Report, into the second half of 2027. In addition, as of December 31, 2024, the Company has access to additional undrawn funds under the Hercules Amended Term Loan, as described below.

We have no products approved for commercial sale and have not generated any revenue from product sales. Since our inception and through December 31, 2024, we have generated an accumulated deficit of $995.9 million. Substantially all of our operating losses resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We will continue to require substantial additional capital to continue the development of our product candidates, and potential commercialization activities, and to fund our ongoing operations, including our clinical development plan described above. The amount and timing of future funding requirements will depend on many factors, including the pace and results of our clinical development efforts, equity financings, securing additional license and collaboration agreements, and issuing debt or other financing vehicles. Our ability to secure capital is dependent upon a number of factors, including success in developing our technology and product candidates. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to develop our product candidates. Changing circumstances, such as changes in the scope and timing of our clinical studies, may cause us to consume capital significantly faster or slower than we currently anticipate. If we are unable to acquire additional capital or resources, we will be required to modify our operational plans to complete future milestones. We have based these estimates on assumptions that may prove to be wrong, and we could exhaust our available financial resources sooner than we currently anticipate. We may be forced to reduce our operating expenses and raise additional funds to meet our working capital needs, principally through the additional sales of our securities or debt financings or entering into strategic collaborations.

Our material cash requirements include obligations as of December 31, 2024, as well as resources required to fulfill our research and development activities and the effects that such obligations and activities are expected to have on our liquidity and cash flows in future periods. We expect that our operating losses will fluctuate significantly from quarter to quarter and year to year due to timing of our development activities and efforts to achieve regulatory approval.

Our commitments primarily consist of obligations under our collaboration, development, and license agreements. Under these agreements, we are required to make milestone payments upon successful completion of certain regulatory and sales milestones. The payment obligations under the license agreements are contingent upon future events such as our achievement of specified development, regulatory and commercial milestones and we will be required to make development milestone payments and royalty payments in connection with the sale of products developed under these agreements. As of December 31, 2024, we were unable to estimate the timing or likelihood of achieving the milestones or making future product sales. For additional information regarding our agreements, see Note 7 and Note 8 to our condensed consolidated financial statements included elsewhere in this report.

Our operating lease obligations primarily consist of lease payments on our office space in Waltham, Massachusetts and our lab and office facilities in Boulder, Colorado. For additional information regarding our lease obligations, see Note 8 to our condensed consolidated financial statements included elsewhere in this report.

Additionally, we have entered into agreements with third-party contract manufacturers for the manufacture and processing of certain of our product candidates for clinical testing purposes, and we have entered and will enter into other contracts in the normal course of business with contract research organizations for clinical trials and other vendors for other services and products for operating purposes. These agreements generally provide for termination or cancellation with appropriate notice, other than for costs already incurred. We expect to enter into additional clinical development, contract research, clinical and commercial manufacturing, supplier and collaborative research agreements in the future, which may require upfront payments and long-term commitments of capital resources.

If we raise additional funds through the issuance of debt, the obligations related to such debt could be senior to rights of holders of our capital stock and could contain covenants that may restrict our operations. Should additional capital not be available to us in the near term, or not be available on acceptable terms, we may be unable to realize value from our assets and discharge our

liabilities in the normal course of business, which may, among other alternatives, cause us to further delay, substantially reduce, or discontinue operational activities to conserve our cash resources.

Loan and Security Agreement with Hercules Capital, Inc.

On April 1, 2022, we entered into the Hercules Loan and Security Agreement among the Company, certain of our subsidiaries from time to time party thereto (together with the Company, collectively, the "Borrower"), Hercules and certain other lenders party thereto (the "Lenders"). Under the Hercules Loan and Security Agreement, the Lenders provided us with access to a term loan with an aggregate principal amount of up to $75.0 million, in four tranches (collectively the "Term Loan"), including an initial tranche of $25.0 million, which was available to us through June 15, 2023. Upon signing, we drew an initial principal amount of $5.0 million.

Per the terms of the Hercules Loan and Security Agreement, we were originally obligated to make interest-only payments through April 1, 2024, which was extended to October 1, 2024 upon the achievement of a development milestone in August 2022. We were required to repay the Term Loan amount in equal monthly installments of the principal amount and interest between the end of the interest-only period and the maturity date of October 1, 2026. In addition, we were required to pay an end-of-term fee equal to 6% of the principal amount of funded Term Loan Advances (as defined in the Hercules Loan and Security Agreement) at maturity, which were being accreted as additional interest expense over the term of the loan.

In August 2023, we executed an amendment to the Hercules Loan and Security Agreement (the "Hercules Amendment"). The Hercules Amendment was determined to substantially alter the Hercules Loan and Security Agreement and therefore was accounted for as a debt extinguishment. We recognized a loss on debt extinguishment of $0.2 million in August 2023 related to unamortized debt discount and debt issuance costs.

Under the Hercules Amendment, the Lenders provided the Company access to an increased term loan with an aggregate principal amount of up to $150 million, in four tranches (collectively the "Amended Term Loan"), consisting of (1) an initial tranche of $50.0 million, $5.0 million of which was drawn at closing of the Hercules Loan and Security Agreement in April 2022, $15.0 million of which was drawn at closing of the Hercules Amendment in August 2023, $5.0 million of which was available through December 15, 2023, and $25.0 million of which was available from July 1, 2024 through December 15, 2024; (2) a second tranche of $20.0 million, subject to achievement of certain regulatory milestones, available through February 15, 2025; (3) a third tranche of $20.0 million, subject to achievement of certain regulatory milestones, available through March 31, 2025; and (4) a fourth tranche of $60.0 million subject to approval by the Lenders' investment committee(s), available through June 15, 2025. As of December 31, 2024, the milestones for the second and third tranches have been achieved. The obligations of the Borrower under the Hercules Amendment agreement are secured by substantially all of the assets of the Borrower, excluding the Borrower's intellectual property. The Amended Term Loan has a maturity date of October 1, 2026.

The Amended Term Loan bears interest at a floating per annum rate equal to the greater of (i) 7.45% and (ii) 4.2% above the Prime Rate (as defined therein), provided that the Term Loan interest rate shall not exceed a per annum rate of 8.95%. Interest is payable monthly in arrears on the first day of each month. The interest rate as of December 31, 2024 was 8.95%.

Per the terms of the Hercules Amendment, we were originally obligated to make interest-only payments through April 1, 2025. Upon achievement of certain development milestones related to our topline results for our phase 3 THRIVE trial in September 2024, the interest-only period was extended to October 1, 2025. Upon achievement of certain development milestones related to topline results for the Company's phase 3 THRIVE-2 trial in December 2024, the interest-only period was further extended to April 1, 2026. The Borrower is required to repay the Amended Term Loan amount in equal monthly installments of the principal amount and interest between the end of the interest-only period and the maturity date of October 1, 2026. In addition, the Borrower is required to pay an end-of-term fee equal to 6% of the principal amount of funded Amended Term Loan advances at maturity, which are being accreted as additional interest expense over the term of the loan.

ATM Agreement

In September 2022, we entered into the September 2022 ATM Agreement with Jefferies pursuant to which we may offer and sell shares of our common stock having an aggregate offering price of up to $175.0 million from time to time at prices and on terms to be determined by market conditions at the time of offering, with Jefferies acting as the sales agent. Jefferies will receive a commission of 3.0% of the gross proceeds of any shares of common stock sold under the September 2022 ATM Agreement. During the year ended December 31, 2022, 964,357 shares were sold under the September 2022 ATM Agreement at a weighted average price of $26.01 per share, for aggregate net proceeds of approximately $24.2 million, including commissions to Jefferies as a sales agent. During the year ended December 31, 2023, the Company sold 684,298 shares under

the September 2022 ATM Agreement with Jefferies at a weighted average price of $22.30 per share, for aggregate net proceeds of approximately $14.8 million, including commissions to Jefferies as a sales agent.

During the year ended December 31, 2024, 3,058,751 shares were sold under the September 2022 ATM Agreement at a weighted average price of $22.86 per share, for aggregate net proceeds of approximately $67.7 million, including commissions to Jefferies as a sales agent. During the quarter ended December 31, 2024, the Company sold 1,497,181 shares under the September 2022 ATM Agreement with Jefferies at a weighted average price of $22.47 per share, for aggregate net proceeds of approximately $32.6 million, including commissions to Jefferies as a sales agent.

Public Offerings

In September 2024, we entered into an underwriting agreement with Jefferies, Goldman Sachs & Co. LLC and Stifel, Nicolaus & Company, Incorporated related to the offer and sale (the "September 2024 Public Offering") of 12,466,600 shares of our common stock, which includes 1,800,000 shares of common stock issued in connection with the exercise in full by the underwriters of their option to purchase additional shares at a public offering price of $18.75 per share, and 20,000 shares of our Series B Convertible Preferred Stock at a price per share of $1,250.0625 per share. The aggregate gross proceeds to us from the September 2024 Public Offering, including the exercise of the option, were approximately $258.8 million, before deducting underwriting discounts and commissions and other offering expenses payable by us.

In January 2024, we entered into an underwriting agreement with Jefferies LLC ("Jefferies") and Leerink Partners LLC relating to the offer and sale (the "January 2024 Public Offering") of 7,142,858 shares of our common stock at a public offering price of $21.00 per share. The aggregate gross proceeds to us from the January 2024 Public Offering were approximately $150.0 million, before deducting underwriting discounts and commissions and other offering expenses payable by us.

Private Placements

In November 2023, we issued and sold in private placement transactions an aggregate of 8,869,797 shares of our common stock at a price per share of $12.38 and 92,312 shares of our Series B Convertible Preferred Stock at a price per share of $825.3746, pursuant to securities purchase agreements with certain institutional and accredited investors. We received aggregate gross proceeds of approximately $186.0 million, before deducting offering expenses payable by us.

Summarized cash flows for the year ended December 31, 2024 and 2023 are as follows:

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (232,319)	$ (184,170)
Investing activities	(228,651)	(94,252)
Financing activities	457,737	225,670
Total	$ (3,233)	$ (52,752)

Operating Activities

Net cash used in operating activities was $232.3 million for the year ended December 31, 2024, and primarily consisted of a net loss of $269.9 million, adjusted for non-cash items of $28.0 million, including share-based compensation of $42.2 million partially offset by accretion and amortization of premiums and discounts on available-for-sale securities of $15.7 million, and working capital adjustments of $9.6 million. The change in working capital was primarily related to an increase of $21.5 million in accounts payable and accrued and other liabilities, partially offset by an increase of $11.8 million in prepaid expenses and other current assets due to the timing of payments and prepayments to vendors for ongoing clinical trial and manufacturing activities.

Net cash used in operating activities was $184.2 million for the year ended December 31, 2023, and primarily consisted of a net loss of $237.7 million, adjusted for non-cash items of $63.0 million, including share-based compensation of $67.2 million and working capital adjustments of $9.4 million. The change in working capital was primarily related to a decrease of $7.0 million

in accounts payable and accrued and other liabilities and an increase of $2.1 million in prepaid expenses and other current assets due to the timing of payments and prepayments to vendors for ongoing clinical trial and manufacturing activities.

Investing Activities

Net cash used in investing activities was $228.7 million during the year ended December 31, 2024. Net cash used in investing activities in 2024 primarily consisted of net purchases of investments of $228.1 million and property and equipment purchases of $0.5 million.

Net cash used in investing activities was $94.3 million during the year ended December 31, 2023. Net cash used in investing activities in 2023 primarily consisted of net purchases of investments of $93.4 million and property and equipment purchases of $0.9 million.

Financing Activities

Net cash provided by financing activities was $457.7 million during the year ended December 31, 2024. Net cash provided by financing activities in 2024 was primarily driven by net proceeds of $451.7 million from the 2024 Public Offerings and the September 2022 ATM Agreement, as well as $5.3 million in proceeds from the exercise of stock options and $0.7 million in proceeds from the issuance of common stock under our employee stock purchase plan.

Net cash provided by financing activities was $225.7 million for the year ended December 31, 2023. Net cash provided by financing activities in 2023 was primarily driven by net proceeds of $189.5 million from the 2023 Private Placement and the September 2022 ATM Agreement, as well as $19.3 million in proceeds from the exercise of stock options, $14.5 million in net proceeds from the Hercules Amendment, $1.9 million in proceeds from the exercise of warrants and $0.6 million in proceeds from the issuance of common stock under our employee stock purchase plan.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Fluctuation Risk

As of December 31, 2024, we had cash, cash equivalents and short-term investments of $717.6 million, consisting of money market accounts, corporate bonds, and U.S. Treasury Securities. The primary objectives of our investment activities are to preserve principal, provide liquidity and maximize income without significantly increasing risk. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our cash equivalents and short-term investments are primarily invested in U.S. Treasury Securities, corporate paper and bonds and money market funds. A change in prevailing interest rates, and/or credit risk, may cause the fair value of the investment to fluctuate. The average duration of all of our available-for-sale investments held as of December 31, 2024, was less than 12 months. Due to the relatively short-term nature of these financial instruments, we believe there is no material exposure to interest rate risk, and/or credit risk, arising from our portfolio of financial instruments.

Inflation Fluctuation Risk

Inflation generally affects us by increasing our cost of labor and the cost of services provided by our vendors. We do not believe that inflation had a material effect on our business, financial condition or consolidated results of operations during the years ended December 31, 2024 and 2023.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements and supplemental data required by this item are set forth on the pages indicated in Part IV, Item 15(a)(1) of this Annual Report.

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 that are designed to ensure that information required to be disclosed in the reports that we file under the Exchange Act, is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Under the supervision and with the participation of our principal executive officer, principal financial officer, and other senior management personnel, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report. Based on this evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Annual Report.

Management's Report on Internal Control Over Financial Reporting

Internal control over financial reporting refers to the process designed by, or under the supervision of, our principal officer and principal financial officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP, and 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 our assets, (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors 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.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of the end of the period covered by this Annual Report. Management used the framework set forth in the report entitled "Internal Control — Integrated Framework (2013 Framework)" published by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of our internal control over financial reporting. Based on its evaluation, management concluded that our internal control over financial reporting was effective at a reasonable level of assurance as of December 31, 2024, the end of our most recent fiscal year.

The effectiveness of our internal control over financial reporting as of December 31, 2024, has been audited by KPMG LLP, an independent registered public accounting firm, as stated in their report which appears in this Annual Report on Form 10-K.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially effect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Rule 10b5-1 Trading Plans

During the three months ended December 31, 2024, none of the Company's directors or officers adopted or terminated any "Rule 10b5-1 trading arrangement" or any "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408 or Regulation S-K.

Amended Executive Employment Agreements

On February 25, 2025, the Company and Stephen Mahoney, the Company's President, Chief Executive Officer and Director, entered into an amendment, effective January 1, 2025, to his employment agreement with the Company, dated as of October 27, 2023 (as amended, the "CEO Executive Employment Agreement"). On February 25, 2025, the Company also entered into amendments to the existing employment agreements (as amended, the "Non-CEO Executive Employment Agreements") with Thomas Beetham, the Company's Chief Operating Officer, Seth Harmon, the Company's Chief Financial Officer, and Jennifer Tousignant, the Company's Chief Legal Officer (each, an "Executive" and, collectively, the "Non-CEO Executives" and the Non-CEO Executives, together with Mr. Mahoney, the "Executives").

The principal terms of the Executives' compensation arrangements, including annual base salary and target bonus opportunity, were not modified pursuant to the amendments. The amendments to the CEO Executive Employment Agreement and the Non-CEO Executive Employment Agreements provide that (a) a change in title, reporting relationships and/or responsibilities of the applicable Executive could constitute a material reduction in such Executive's authority, duties or responsibilities pursuant to which such Executive may terminate his or her employment with the Company by resigning for "good reason," and that the determination of whether a material reduction has occurred shall be made by the Company in good faith other than in connection with a change in control (as defined in the applicable agreement); and (b) in the event of an involuntary termination in connection with a change in control, each Executive shall be entitled to receive (i) continued payment of his or her annual base salary in effect immediately prior to the termination for a period of 24 months, in the case of Mr. Mahoney, or 12 months, in the case of the Non-CEO Executives, payable over the Company's regular payroll schedule; (ii) reimbursement of COBRA coverage for up to 24 months, in the case of Mr. Mahoney, or 12 months, in the case of the Non-CEO Executives (or, if sooner, until he or she receives substantially similar coverage from another employer or ceases to be eligible for COBRA coverage); (iii) the immediate vesting of all of the Executive's outstanding stock options and other equity awards that are subject to time-based vesting requirements; and (iv) payment of his or her Annual Performance Bonus (as defined in the CEO Executive Employment Agreement or the Non-CEO Executive Employment Agreements, as applicable) at either two times the full Target Amount (as defined in the CEO Executive Employment Agreement), with respect to Mr. Mahoney, or the full Target Amount (as defined in the applicable Non-CEO Executive Employment Agreement), with respect to the Non-CEO Executives, in each case within thirty days after the effective date of the involuntary termination.

The foregoing summaries of the CEO Executive Employment Agreement and the Non-CEO Executive Employment Agreements do not purport to be complete and are qualified in their entirety by reference to the full text of the applicable Executive's employment agreement, as amended. Copies of the amendments for each of the CEO Executive Employment Agreement, with respect to Mr. Mahoney, and Non-CEO Executive Employment Agreements, with respect to each of Mr. Beetham, Mr. Harmon and Ms. Tousignant, are filed as exhibits to this Annual Report.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTION

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

The information required by this Item is incorporated by reference to our 2025 Proxy Statement to be filed with the SEC within 120 days after December 31, 2024.

Our board of directors has adopted a written code of business conduct and ethics that applies to our directors, officers, and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A current copy of the code is posted on our website, which is located at *www.viridiantherapeutics.com*. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a Current Report on Form 8-K.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 is incorporated herein by reference to our 2025 Proxy Statement, including under headings "Executive Officer and Director Compensation," "Compensation Discussion and Analysis," and "Directors, Executive Officers and Corporate Governance – Compensation Committee Interlocks and Insider Participation, "Compensation Committee Report" and "Risks Related to Compensation Practices and Polices." The section titled "Pay Versus Performance" in our 2025 Proxy Statement is not incorporated by reference herein.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item 12 is incorporated herein by reference to our 2025 Proxy Statement, including under headings "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance Under Equity Compensation Plans."

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by this Item 13 is incorporated herein by reference to our 2025 Proxy Statement, including under headings "Directors, Executive Officers and Corporate Governance" and "Transactions with Related Persons."

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item 14 is incorporated herein by reference to our 2025 Proxy Statement, including under the heading "Ratification of Selection of Independent Registered Accounting Firm."

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements

The financial statements required by this item are submitted in a separate section beginning on page F-1 of this Annual Report.

(a)(2) Financial Statement Schedules

Financial statement schedules have been omitted because they are either not required, not applicable, or the information is otherwise included.

(a)(3) Exhibits

See Exhibit Index, which is incorporated herein by reference.

EXHIBIT INDEX

The exhibits listed in the Exhibit Index are required by Item 601 of Regulation S-K. The SEC file number for all items incorporated by reference herein from reports on Forms 10-K, 10-Q, and 8-K is 001-36483.

		Incorporated by Reference			
Exhibit No.	**Description of Exhibit**	**Form**	**Filing Date**	**Number**	
3.1	Second Restated Certificate of Incorporation of the Registrant, effective as of March 9, 2022.	10-K	03/11/2022	3.1	
3.2	Fourth Amended and Restated Bylaws of the Registrant, effective as of December 15, 2023.	8-K	12/18/2023	3.1	
3.3	Certificate of Designation of Series A Non-Voting Convertible Preferred Stock.	8-K	10/28/2020	3.1	
3.4	Certificate of Designation of Series B Non-Voting Convertible Preferred Stock.	8-K	09/23/2021	3.1	
4.1	Specimen Common Stock Certificate.	S-1	03/19/2014	4.1	
4.2	Warrant to Purchase Stock between Miragen Therapeutics, Inc. and Silicon Valley Bank, dated April 30, 2015.	10-K	03/14/2019	4.2	
4.3	Warrant to Purchase Stock between Miragen Therapeutics, Inc. and Silicon Valley Bank, dated November 14, 2017.	8-K	11/15/2017	10.2	
4.4	Form of Warrant to Purchase Common Stock.	8-K	02/07/2020	4.1	
4.5	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.				x
10.1^	License Agreement, by and between the Registrant and ImmunoGen, dated as of October 12, 2020.	8-K	12/09/2020	10.1	
10.2+	Form of Indemnity Agreement between the Registrant and each of its directors and executive officers.	10-K	02/27/2024	10.2	
10.3+	Stephen Mahoney Employment Agreement, dated October 27, 2023.	10-Q	11/13/2023	10.2	
10.4+	Thomas Beetham Employment Agreement, dated October 27, 2023.	10-Q	11/13/2023	10.3	
10.5+	Thomas Ciulla Employment Agreement, dated January 12, 2023.	10-K	02/27/2024	10.9	
10.6+	Seth Harmon Employment Agreement, dated April 24, 2023.	10-K	02/27/2024	10.10	
10.7+	Amendment to Seth Harmon Employment Agreement, dated September 28, 2023.	10-K	02/27/2024	10.11	
10.8+	Jennifer Tousignant Employment Agreement, dated January 10, 2024.	10-K	02/27/2024	10.12	
10.9+	Form of Inducement Stock Option Agreement.	S-8	03/11/2022	99.3	
10.10+	Form of Inducement Restricted Stock Unit Agreement.	S-8	03/10/2023	99.4	
10.11+	Viridian Therapeutics, Inc. Amended & Restated 2016 Equity Incentive Plan.	8-K	06/20/2024	10.1	

10.12+	Form of Stock Option Grant Notice and Stock Option Agreement under 2016 Equity Incentive Plan.	10-K	2/27/2024	10.16	
10.13+	Form of Restricted Stock Award Agreement under the 2016 Equity Incentive Plan.	10-K	2/27/2024	10.17	
10.14+	2016 Amended and Restated Employee Stock Purchase Plan.	10-K	2/27/2024	10.18	
10.15+	Viridian Therapeutics, Inc. 2020 Stock Incentive Plan.	S-8	11/24/2020	99.1	
10.16+	Form of 2020 Incentive Stock Option Grant Notice under Viridian Therapeutics, Inc. 2020 Stock Incentive Plan.	10-K	03/26/2021	10.23	
10.17+	Form of 2008 Equity Incentive Plan.	S-4	12/02/2016	10.48	
10.18+	Form of Stock Option Grant Notice and Stock Option Agreement under the Registrant 2008 Equity Incentive Plan.	S-4	12/02/2016	10.49	
10.19	Lease by and between Registrant and Crestview, LLC, dated as of December 16, 2010.	S-4	12/02/2016	10.40	
10.20	First Addendum to Lease by and between Registrant and Crestview, LLC, dated as of February 18, 2015.	S-4	12/02/2016	10.40.1	
10.21	Second Addendum to Lease by and between Registrant and Crestview, LLC, dated as of October 23, 2015.	S-4	12/02/2016	10.40.2	
10.22	Third Addendum to Lease by and between Registrant and Crestview, LLC, dated as of January 17, 2020.	10-K	03/13/2020	10.12.3	
10.23	Fourth Addendum to Lease by and between Registrant and Crestview, LLC, dated as of April 7, 2020.	10-Q	05/08/2020	10.2	
10.24	Fifth Addendum to Lease by and between Registrant and Crestview LLC, dated as of March 26, 2021.	10-Q	08/12/2021	10.4	
10.25	Waltham Lease between Registrant and Watch City Ventures MT, LLC dated as of January 13, 2020.	10-Q	11/05/2021	10.1	
10.26	First Amendment to Waltham Lease between Registrant and Watch City Ventures MT, LLC dated as of July 6, 2021.	10-Q	11/05/2021	10.2	
10.27	Second Amendment to Lease by and between the Registrant and Watch City Ventures MT, LLC dated as of April 13, 2022.	10-Q	08/15/2022	10.2	
10.28	Third Amendment to Lease by and between Registrant and Watch City Ventures MT, LLC dated as of July 29, 2022.	10-Q	11/14/2022	10.1	
10.29	Fourth Amendment to Lease by and between Registrant and Watch City Ventures MT, LLC dated as of April 8, 2024.	10-Q	08/08/2024	10.1	
10.30	Fifth Amendment to Lease by and between Registrant and Watch City Ventures MT, LLC dated as of September 19, 2024.	10-Q	11/12/2024	10.1	
10.31^	Securities Purchase Agreement, dated as of October 27, 2020, by and among the Registrant and each purchaser identified on Annex A thereto.	8-K	10/28/2020	10.1	
10.32^	Registration Rights Agreement, dated as of October 30, 2020, by and among the Registrant and certain purchasers.	10-Q	11/12/2020	10.8	
10.33	Open Market Sale Agreement℠, dated as of September 9, 2022 by and between the Registrant and Jefferies LLC.	S-3	09/09/2022	1.2	
10.34^	Loan and Security Agreement, dated as of April 1, 2022, among the Viridian Therapeutics, Inc., certain of its subsidiaries from time to time party thereto, the Lenders from time to time party thereto and Hercules Capital, Inc., as Agent.	8-K	04/05/2022	10.1	
10.35^	First Amendment to Loan and Security Agreement, dated as of August 7, 2023, among the Viridian Therapeutics, Inc., certain of its subsidiaries from time to time party thereto, the Lenders from time to time party thereto and Hercules Capital, Inc., as Agent.	10-Q	11/13/2023	10.1	
10.36	Registration Rights Agreement, dated October 30, 2023, by and between the Company and the Purchasers signatory thereto.	8-K	10/30/2023	10.2	
10.37	Amended and Restated License Agreement by and between Registrant and Paragon Therapeutics, Inc. dated as of September 20, 2024.	10-Q	11/12/2024	10.2	
10.38+	Amendment to Stephen Mahoney Employment Agreement, dated February 25, 2025.				x

10.39+	Amendment to Thomas Beetham Employment Agreement, dated February 25, 2025.				x
10.40+	Amendment to Seth Harmon Employment Agreement, dated February 25, 2025.				x
10.41+	Amendment to Jennifer Tousignant Employment Agreement, dated February 25, 2025.				x
19	Insider Trading Policy.				x
21.1	Subsidiaries of the Registrant.				x
23.1	Consent of Independent Registered Public Accounting Firm.				x
24.1	Power of Attorney (included on signature page hereto).				x
31.1	Certification of Principal Executive Officer pursuant to Rule13a-14(a) and Rule 15d-14(a) of the Securities and Exchange Act, as amended.				x
31.2	Certification of Principal Financial Officer pursuant to Rule13a-14(a) and Rule 15d-14(a) of the Securities and Exchange Act, as amended.				x
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				x
97.1	Viridian Therapeutics, Inc. Incentive Compensation Clawback Policy.	10-K	2/27/2024	97.1	
101.INS	XBRL Instance Document				x
101.SCH	XBRL Taxonomy Extension Schema Document				x
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				x
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				x
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				x
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				x
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)				x

^ Schedules have been omitted from this filing pursuant to Item 601(b)(2) of Regulation S-K. Viridian agrees to furnish supplementally a copy of any omitted schedule to the SEC upon its request; provided, however, that Viridian may request confidential treatment pursuant to Rule 24b-2 of the Exchange Act for any schedule so furnished. Certain portions of the exhibit, identified by the mark, "[***]," may have been omitted because such portions contained information that is both (i) not material and (ii) would likely cause competitive harm if publicly disclosed.

\+ Indicates management contract or compensatory plan.

* This certification is being furnished pursuant to 18 U.S.C. Section 1350 and is not being filed for purposes of Section 18 of the Exchange Act and is not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof.

x Filed/furnished herewith.

ITEM 16. FORM 10-K SUMMARY

None.

VIRIDIAN THERAPEUTICS, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Viridian Therapeutics, Inc.:

Opinions on the Consolidated Financial Statements and Internal Control Over Financial Reporting

We have audited the accompanying consolidated balance sheets of Viridian Therapeutics, Inc. and subsidiaries (the Company) as of December 31, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2024, and the related notes (collectively, the consolidated financial statements).

We also have audited the Company's internal control over financial reporting as of December 31, 2024, 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 consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2024 based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Basis for Opinion

The Company's management is responsible for these consolidated financial statements, 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's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's consolidated financial statements and an opinion on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (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 consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated 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 consolidated financial statements. 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 audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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 its 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 the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matter

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

Accrued outsourced clinical trials and nonclinical studies

As discussed in Notes 2 and 5 to the consolidated financial statements, accrued expenses for clinical trials and nonclinical studies are based on estimates of costs incurred for services provided by clinical research organizations, manufacturing organizations, and other providers. In accruing for these activities, the Company obtains information from various sources and estimates the level of effort or expense allocated to each period. The estimates consider a number of factors such as site initiation, patient screening, enrollment, delivery of reports, and other events. Accrued liabilities for outsourced clinical trials and nonclinical studies were $30.9 million as of December 31, 2024.

The following are the primary procedures we performed to address this critical audit matter. We evaluated the design and tested the operating effectiveness of certain internal controls related to accrued outsourced clinical trials and nonclinical studies. This included controls related to the estimation of costs incurred for services provided by clinical research organizations, manufacturing organizations, and other providers during the period that are included in accrued liabilities and other at the end of each reporting period. For a sample of accrued liabilities for outsourced clinical trials and nonclinical studies, we compared the relevant factors used by management to estimate the accrued expenses to contracts, invoices and third-party confirmations of contractual milestones and project status. We compared the Company's estimate of costs accrued as of year-end to a selection of third-party invoices received after year-end, but prior to the issuance of the Company's financial statements. We assessed the sufficiency of audit evidence obtained related to accrued outsourced clinical trials and nonclinical studies by assessing the cumulative results of the audit procedures.

/s/ KPMG LLP

We have served as the Company's auditor since 2009.

Boston, Massachusetts
March 3, 2025

VIRIDIAN THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	December 31,	
	2024	**2023**
Assets		
Current assets:		
Cash and cash equivalents	$ 99,594	$ 102,827
Short-term investments	617,990	374,543
Prepaid expenses and other current assets (including related party of $800 and $— as of December 31, 2024 and 2023, respectively)	20,877	9,006
Unbilled revenue - related party	—	102
Total current assets	738,461	486,478
Property and equipment, net	1,236	1,672
Operating lease right-of-use asset	2,205	1,670
Other assets	501	604
Total assets	$ 742,403	$ 490,424
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,143	$ 2,239
Accrued liabilities and other (including related party of $0 and $374 as of December 31, 2024 and 2023, respectively)	45,443	24,108
Current portion of deferred revenue - related party	288	288
Total current liabilities	47,874	26,635
Long-term debt, net	20,582	20,205
Deferred revenue - related party	284	573
Other liabilities	2,024	989
Total liabilities	70,764	48,402
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, series A non-voting convertible preferred stock, $0.01 par value; 435,000 shares authorized; 134,864 and 172,435 shares issued and outstanding as of December 31, 2024 and 2023, respectively	61,188	78,235
Preferred stock, series B non-voting convertible preferred stock, $0.01 par value; 500,000 shares authorized; 145,160 and 143,522 shares issued and outstanding as of December 31, 2024 and 2023, respectively	127,697	128,281
Common stock, $0.01 par value; 200,000,000 shares authorized; 80,994,046 and 53,986,112 shares issued and outstanding as of December 31, 2024 and 2023, respectively	810	540
Additional paid-in capital	1,477,811	960,536
Accumulated other comprehensive income (loss)	(10)	338
Accumulated deficit	(995,857)	(725,908)
Total stockholders' equity	671,639	442,022
Total liabilities and stockholders' equity	$ 742,403	$ 490,424

See accompanying notes to these consolidated financial statements.

VIRIDIAN THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)

	Year Ended December 31,		
	2024	2023	2022
Revenue:			
Collaboration revenue - related party	$ 302	$ 314	$ 1,772
Operating expenses:			
Research and development (including related party expenses of $14,191, $12,035, and $5,619 during the years ended December 31, 2024, 2023, and 2022, respectively)	238,254	159,765	100,894
General and administrative	61,083	94,999	35,182
Total operating expenses	299,337	254,764	136,076
Loss from operations	(299,035)	(254,450)	(134,304)
Other income (expense):			
Interest and other income	32,132	18,563	4,916
Interest and other expense	(3,046)	(1,847)	(486)
Other income, net	29,086	16,716	4,430
Net loss	$ (269,949)	$ (237,734)	$ (129,874)
Net loss per share, basic and diluted, common stock	$ (3.07)	$ (3.91)	$ (2.71)
Weighted-average shares common shares outstanding, basic and diluted	67,885,831	44,755,475	32,087,293
Net loss per share, basic and diluted, Series A convertible preferred stock	$ (204.82)	$ (260.70)	$ (181.03)
Weighted-average Series A convertible preferred stock outstanding, basic and diluted	154,856	174,226	203,190
Net loss per share, basic and diluted, Series B convertible preferred stock	$ (204.82)	$ (260.69)	$ (180.85)
Weighted-average Series B convertible preferred stock outstanding, basic and diluted	144,862	66,385	33,436
Comprehensive loss:			
Net loss	$ (269,949)	$ (237,734)	$ (129,874)
Other comprehensive (loss) income:			
Change in unrealized (loss) gain on investments	(348)	728	(233)
Total other comprehensive (loss) income	(348)	728	(233)
Total comprehensive loss	$ (270,297)	$ (237,006)	$ (130,107)

See accompanying notes to these consolidated financial statements.

VIRIDIAN THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(in thousands, except share data)

	Preferred Stock				Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock							
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance as of December 31, 2021	260,437	$118,164	23,126	$ 15,669	23,924,004	$ 239	$ 412,101	$ (157)	$(358,300)	$ 187,716
Issuance of common stock upon the conversion of convertible preferred stock	(72,056)	(32,694)	—	—	4,803,965	48	32,646	—	—	—
Issuance of Series B convertible preferred stock and common stock in the 2022 Public Offering, net of issuance costs of $2,992 and $18,146, respectively	—	—	28,084	41,008	11,352,640	114	248,528	—	—	289,650
Issuance of common stock, 2022 ATM, net of issuance costs of $926	—	—	—	—	964,357	10	24,150	—	—	24,160
Issuance of common stock upon exercises of warrants	—	—	—	—	56,666	1	934	—	—	935
Issuance of common stock for exercises of stock options	—	—	—	—	191,291	2	2,760	—	—	2,762
Issuance of common stock for cash under employee stock purchase plan	—	—	—	—	13,024	—	183	—	—	183
Share-based compensation expense	—	—	—	—	—	—	19,765	—	—	19,765
Change in unrealized loss on investments	—	—	—	—	—	—	—	(233)	—	(233)
Net loss	—	—	—	—	—	—	—	—	(129,874)	(129,874)
Balance as of December 31, 2022	188,381	$ 85,470	51,210	$ 56,677	41,305,947	$ 414	$ 741,067	$ (390)	$(488,174)	$ 395,064
Issuance of common stock upon the conversion of convertible preferred stock	(15,946)	(7,235)	—	—	1,063,118	10	7,225	—	—	—
Issuance of common stock under license agreement	—	—	—	—	243,902	3	5,690	—	—	5,693
Issuance of Series B convertible preferred stock and common stock, 2023 Private Placement, net of issuance costs of $4,588 and $6,805, respectively	—	—	92,312	71,604	8,869,797	89	102,914	—	—	174,607
Issuance of common stock, September 2022 ATM, net of issuance costs of $493	—	—	—	—	684,298	7	14,761	—	—	14,768
Issuance of common stock upon exercises of warrants	—	—	—	—	114,219	1	1,880	—	—	1,881
Issuance of common stock for exercises of stock options	—	—	—	—	1,538,199	15	19,248	—	—	19,263
Issuance of common stock for cash under employee stock purchase plan	—	—	—	—	31,216	—	580	—	—	580
Vesting of restricted stock units	—	—	—	—	135,416	1	(1)	—	—	—
Share-based compensation expense	—	—	—	—	—	—	67,172	—	—	67,172
Change in unrealized gain on investments	—	—	—	—	—	—	—	728	—	728
Net loss	—	—	—	—	—	—	—	—	(237,734)	(237,734)
Balance as of December 31, 2023	172,435	$ 78,235	143,522	$128,281	53,986,112	$ 540	$ 960,536	$ 338	$(725,908)	$ 442,022
Issuance of common stock upon the conversion of convertible preferred stock	(37,571)	(17,047)	(18,362)	(24,085)	3,729,048	37	41,095	—	—	—

	Preferred Stock				Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock							
	Shares	Amount	Shares	Amount	Shares	Amount				
Issuance of common stock, January 2024 Public Offering, net of issuance costs of $9,304	—	—	—	—	7,142,858	71	140,625	—	—	140,696
Issuance of Series B convertible preferred stock and common stock, September 2024 Public Offering, net of issuance costs of $1,500 and $13,954, respectively	—	—	20,000	23,501	12,466,600	125	219,669	—	—	243,295
Issuance of common stock, September 2022 ATM, net of issuance costs of $2,156	—	—	—	—	3,058,751	31	67,724	—	—	67,755
Issuance of common stock for exercises of stock options	—	—	—	—	437,146	4	5,340	—	—	5,344
Issuance of common stock for cash under employee stock purchase plan	—	—	—	—	44,136	1	673	—	—	674
Vesting of restricted stock units	—	—	—	—	129,395	1	(1)	—	—	—
Share-based compensation expense	—	—	—	—	—	—	42,150	—	—	42,150
Change in unrealized gain/loss on investments	—	—	—	—	—	—	—	(348)	—	(348)
Net loss	—	—	—	—	—	—	—	—	(269,949)	(269,949)
Balance as of December 31, 2024	134,864	$ 61,188	145,160	$127,697	80,994,046	$ 810	$1,477,811	$ (10)	$(995,857)	$ 671,639

See accompanying notes to these consolidated financial statements.

VIRIDIAN THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2023	2023	2022
Cash flows from operating activities:			
Net loss	$ (269,949)	$ (237,734)	$ (129,874)
Adjustments to reconcile net loss to net cash used in operating activities:			
Issuance of common stock under license agreement	—	5,693	—
Share-based compensation expense	42,150	67,172	19,765
Non-cash interest expense and amortization of debt issuance costs	377	317	228
Depreciation and amortization	540	522	255
Accretion and amortization of premiums and discounts on available-for-sale securities	(15,655)	(11,490)	(210)
Net loss on extinguishment of debt	—	181	—
Fees paid directly to creditor related to extinguishment of debt	—	514	—
Loss on sale of equipment	449	1	—
Non-cash lease expenses	171	48	36
Other non cash items	—	31	—
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	(11,768)	(2,107)	(3,339)
Accounts payable	(73)	(12,040)	11,524
Accrued and other liabilities	21,625	5,010	7,716
Unbilled revenue	102	—	349
Deferred revenue	(288)	(288)	(288)
Net cash used in operating activities	(232,319)	(184,170)	(93,838)
Cash flows from investing activities:			
Purchases of short-term investments	(695,068)	(407,880)	(223,264)
Proceeds from sales and maturities of short-term investments	466,928	314,526	108,935
Purchases of property and equipment	(511)	(898)	(797)
Net cash used in investing activities	(228,651)	(94,252)	(115,126)
Cash flows from financing activities:			
Proceeds from the issuance of common stock, pursuant to 2023 Private Placement and September 2022 ATM Agreement	—	125,069	—
Proceeds from the issuance of Series B convertible preferred stock, pursuant to the 2023 Private Placement	—	76,192	—
Proceeds from the issuance of common stock, pursuant to Public Offerings and September 2022 ATM Agreement	453,660	—	291,874
Payments of issuance costs associated with the sale of common stock	(25,442)	(7,213)	(19,072)
Proceeds from the issuance of Series B convertible preferred stock, pursuant to Public Offerings	25,001	—	44,000
Payment of issuance costs associated with the sale of convertible preferred stock	(1,500)	(4,588)	(2,992)
Proceeds from the exercise of warrants	—	1,881	935
Proceeds from issuance of long-term debt	—	15,000	5,000
Payment of debt extinguishment costs	—	(514)	—
Payment of debt issuance costs	—	—	(446)
Proceeds from issuance of common stock upon the exercise of stock options	5,344	19,263	2,762
Proceeds from the issuance of common stock for cash under employee stock purchase plan	674	580	183
Net cash provided by financing activities	457,737	225,670	322,244
Net increase (decrease) in cash and cash equivalents	(3,233)	(52,752)	113,280
Cash and cash equivalents at beginning of period	102,827	155,579	42,299
Cash and cash equivalents at end of period	$ 99,594	$ 102,827	$ 155,579

Supplemental disclosure of cash flow information			
Interest paid	$ 1,820	$ 886	$ 293
Supplemental disclosure of non-cash investing and financing activities			
Purchase of property and equipment in accounts payable and accrued liabilities	$ 43	$ —	$ 380
Unpaid common and convertible preferred stock issuance costs included in accrued liabilities	$ 58	$ 41	$ —
Unpaid common and convertible preferred stock issuance costs included in accounts payable	$ —	$ 45	$ —
Right-of-use asset and lease liability recognized for new operating lease	$ 496	$ —	$ —
Remeasurement of operating lease right-of-use assets for lease modifications	$ 837	$ 641	$ 448
Extinguishment of long-term debt	$ —	$ 4,707	$ —
Issuance of long-term debt	$ —	$ 5,000	$ —
Amortization of public offering costs	$ —	$ —	$ 75

See accompanying notes to these consolidated financial statements.

1. DESCRIPTION OF BUSINESS

Viridian Therapeutics, Inc., a Delaware corporation (the "Company" or "Viridian"), is a biopharmaceutical company focused on discovering, developing and commercializing potential best-in-class medicines for serious and rare diseases. The Company's most advanced program, veligrotug (formerly known as VRDN-001), is a differentiated monoclonal antibody targeting insulin-like growth factor-1 receptor ("IGF-1R"), a clinically and commercially validated target for the treatment of thyroid eye disease ("TED"). The Company's second product candidate, VRDN-003, is an extended half-life monoclonal antibody with the same binding domains as veligrotug designed for administration as convenient, low-volume, subcutaneous pen injections. TED is a serious and debilitating rare autoimmune disease that causes inflammation within the orbit of the eye that can cause bulging of the eyes, redness and swelling, double vision, pain, and potential blindness.

In addition to developing therapies for TED, the Company is also developing a portfolio of engineered anti-neonatal Fc receptor ("FcRn") inhibitors, including VRDN-006 and VRDN-008. FcRn inhibitors have the potential to treat a broad array of autoimmune diseases, representing a significant commercial market opportunity.

Liquidity

The accompanying consolidated financial statements have been prepared on a basis that assumes the Company is a going concern and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from any uncertainty related to its ability to continue as a going concern. The Company has funded its operations to date principally through proceeds received from the sale of the Company's common stock, its Series A Convertible Preferred Stock, Series B Convertible Preferred Stock, and other equity securities, debt financings, license fees, and reimbursements received under collaboration agreements. Since its inception and through December 31, 2024, the Company has generated an accumulated deficit of $995.9 million. The Company expects to continue to generate operating losses for the foreseeable future.

The Company has no products approved for commercial sale, has not generated any revenue from product sales, and cannot guarantee when or if it will generate any revenue from product sales. Substantially all of the Company's operating losses resulted from expenses incurred in connection with its research and development programs and from general and administrative costs associated with its operations. The Company expects to incur significant expenses and operating losses for at least the next several years as it continues the development of, and seeks regulatory approval for, its product candidates. It is expected that operating losses will fluctuate significantly from quarter to quarter and year to year due to timing of development programs and efforts to achieve regulatory approval.

As of December 31, 2024, the Company had approximately $717.6 million in cash, cash equivalents, and short-term investments. In addition, the Company also has access to additional undrawn funds under the Hercules Loan and Security Agreement Amended Term Loan, as further described in Note 6. *Debt*. As of the issuance date of these consolidated financial statements, the Company expects that its current resources will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next twelve months from the issuance date of these financial statements.

The Company will require additional capital in order to continue to finance its operations. The amount and timing of future funding requirements will depend on many factors, including the pace and results of the Company's clinical development efforts, timing of market research and other professional and consulting activities to prepare for commercial activities, equity financings, entering into license and collaboration agreements, and issuing debt or other financing vehicles. The Company's ability to secure additional capital is dependent upon a number of factors, some of which are outside of the Company's control, including success in developing its product candidates, operational performance, and market conditions, including those resulting from the current inflationary and broader macroeconomic environment.

Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on the Company's financial condition and its ability to develop its product candidates. Changing circumstances may cause the Company to consume capital significantly faster or slower than currently anticipated. If the Company is unable to acquire additional capital or resources, it will be required to modify its operational plans. The estimates included herein are based on assumptions that may prove to be wrong, and the Company could exhaust its available financial resources sooner than currently anticipated.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Viridian Therapeutics Europe Limited and Viridian Therapeutics S.à.r.l., both of which were formed for the sole purpose of submitting regulatory filings in Europe, and Viridian Securities Corporation, which was formed in July 2021. The Company's subsidiaries have no employees or operations.

The consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") and include all adjustments necessary for the fair presentation of the Company's financial position, results of operations, and cash flows for the periods presented. All significant intercompany balances have been eliminated in consolidation. The Company's management performed an evaluation of its activities through the date of filing of these consolidated financial statements and concluded that there are no subsequent events requiring disclosure, other than as disclosed.

Risks and Uncertainties - Global Economic and Political Considerations

The global macroeconomic environment is uncertain, and could be negatively affected by, among other things, increased U.S. trade tariffs and trade disputes with other countries, instability in the global capital and credit markets, supply chain weaknesses, and instability in the geopolitical environment, including as a result of the Russian invasion of Ukraine, the rising tensions between China and Taiwan, the conflict in Israel and surrounding area and other political tensions. Such challenges have caused, and may continue to cause, recession fears, concerns regarding potential sanctions, high interest rates, foreign exchange volatility and inflationary pressures. At this time, the Company is unable to quantify the potential effects of this economic instability on its future operations.

Going Concern

At each reporting period, the Company evaluates whether there are conditions or events that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. The Company is required to make certain additional disclosures if it concludes substantial doubt exists and it is not alleviated by the Company's plans or when its plans alleviate substantial doubt about the Company's ability to continue as a going concern.

The Company's evaluation entails, among other things, analyzing the results of the Company's clinical development efforts, license and collaboration agreements as well as the entity's current financial condition including conditional and unconditional obligations anticipated within a year, and related liquidity sources at the date the financial statements are issued. This is reflected in the Company's prospective operating budgets and forecasts and compared to the current cash, cash equivalents and short-term investments balance.

Use of Estimates

The Company's consolidated financial statements are prepared in accordance with U.S. GAAP, which requires it to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and contingent liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the accrual for clinical trial costs, including manufacturing activities, and other outsourced research and development expenses, and the valuation of share-based awards. Although these estimates are based on the Company's knowledge of current events and actions it may take in the future, actual results may ultimately differ from these estimates and assumptions.

Revenue Recognition

The Company accounts for revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606").

The Company enters into collaboration agreements and certain other agreements that are within the scope of ASC 606, under which the Company licenses, may license, or grants an option to license rights to certain of the Company's product candidates and performs research and development services in connection with such agreements. The terms of these agreements typically include payment of one or more of the following: non-refundable, up-front fees; reimbursement of research and development costs; developmental, clinical, regulatory, and commercial sales milestone payments; and royalties on net sales of licensed products.

In accordance with ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services.

To determine the appropriate amount of revenue to be recognized, for agreements within the scope of ASC 606, the Company performs the following five steps: (i) identification of the goods or services within the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct within the terms of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the identified performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect consideration it is entitled to in exchange for the goods or services it transfers to the customer.

The promised goods or services in the Company's agreements typically consist of a license, or option to license, rights to the Company's intellectual property or research and development services. Performance obligations are promises in a contract to transfer a distinct good or service to the customer and are considered distinct when (i) the customer can benefit from the good or service on its own or together with other readily available resources and (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct, the Company considers factors such as the stage of development of the underlying intellectual property, the capabilities of the customer to develop the intellectual property on its own or whether the required expertise is readily available, and whether the goods or services are integral or dependent to other goods or services in the contract.

The Company estimates the transaction price based on the amount expected to be received for transferring the promised goods or services in the contract. The consideration may include fixed consideration or variable consideration. At the inception of each agreement that includes variable consideration, the Company evaluates the amount of potential payment and the likelihood that the payments will be received. The Company utilizes either the most likely amount method or expected value method to estimate the amount expected to be received based on which method best predicts the amount expected to be received. The amount of variable consideration that is included in the transaction price may be constrained and is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period.

The Company's contracts often include development and regulatory milestone payments that are assessed under the most likely amount method and constrained if it is probable that a significant revenue reversal would occur. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of such development and clinical milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration and other research and development revenue in the period of adjustment.

For agreements that include sales-based royalties, including milestone payments based on the level of sales, and where the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from any of the Company's collaboration or strategic alliance agreements.

The Company allocates the transaction price based on the estimated standalone selling price. The Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company utilizes key assumptions to determine the stand-alone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction, and the estimated costs. Variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated are consistent with the amounts the Company would expect to receive for the satisfaction of each performance obligation.

The consideration allocated to each performance obligation is recognized as revenue when control is transferred for the related goods or services. For performance obligations which consist of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

The Company receives payments from its customers based on billing schedules established in each contract. Up-front payments and fees are recorded as deferred revenue upon receipt or when due until the Company performs its obligations under these arrangements. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional.

Research and Development

Research and development costs are expensed as incurred in performing research and development activities. The costs include employee-related expense including salaries, benefits, share-based compensation, restructuring charges including severance costs, fees for acquiring and maintaining licenses under third-party license agreements, consulting fees, costs of research and development activities conducted by third parties on the Company's behalf, costs to have clinical trial materials manufactured on the Company's behalf, purchases of laboratory supplies, depreciation, and facilities and overhead costs. The Company records research and development expense in the period in which the Company receives or takes ownership of the applicable goods or when the applicable services are performed. In circumstances where amounts have been paid in excess of costs incurred, the Company records a prepaid expense.

The Company records up-front and milestone payments to acquire and retain contractual rights to licensed technology as research and development expenses when incurred if there is uncertainty in the Company receiving future economic benefit from the acquired contractual rights. The Company considers future economic benefits from acquired contractual rights to licensed technology to be uncertain until such a drug candidate is approved for sale by the U.S. Food and Drug Administration ("FDA") or when other significant risk factors are abated. Such up-front and milestone payments are reflected as cash used in operating activities within the consolidated statement of cash flows.

Clinical Trial and Nonclinical Study Accruals

The Company makes estimates of accrued expenses as of each balance sheet date in its consolidated financial statements based on certain facts and circumstances at that time. The Company's accrued expenses for clinical trials and nonclinical studies are based on estimates of costs incurred for services provided by clinical research organizations, manufacturing organizations, and other providers. Payments under the Company's agreements with external service providers depend on a number of factors, such as site initiation, patient screening, enrollment, delivery of reports, and other events. In accruing for these activities, the Company obtains information from various sources and estimates the level of effort or expense allocated to each period. Adjustments to the Company's research and development expenses may be necessary in future periods as its estimates change.

Share-Based Compensation

The Company issues stock-based awards to employees and non-employees in the form of stock options and restricted stock units ("RSUs"). The Company measures and recognizes share-based compensation expense for its stock-based awards granted to employees and non-employees based on the estimated grant date fair value in accordance with ASC Topic 718, *Compensation - Stock Compensation* and determines the fair value of RSUs based on the fair value of its common stock. The Company uses the Black-Scholes option pricing model to determine the fair value of stock options. The use of the Black-Scholes option-pricing model requires the Company to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected life of the option, risk-free interest rates and expected dividend yields of the common stock. The Company recognizes share-based compensation expense for awards with service-based conditions using the straight-line method over the requisite service period, net of any actual forfeitures.

Cash and Cash Equivalents

All highly-liquid investments that have maturities of 90 days or less at the date of purchase are classified as cash equivalents. Cash equivalents are reported at cost, which approximates fair value due to the short maturities of these instruments.

Investments

The Company's investments consist of highly-rated corporate and U.S. Treasury securities and have been classified as available-for-sale securities. Accordingly, these investments are recorded at their respective fair values, as determined based on quoted market prices. The Company may hold securities with stated maturities greater than one year. All available-for-sale securities are considered available to support current operations, and thus investments with maturities beyond one year are generally classified as current assets.

Unrealized gains and losses are reported as a component of stockholders' equity until their disposition. Realized gains and losses are included as a component of other income (expense), net based on the specific identification method. The securities

are subject to a periodic impairment review. An impairment charge would occur when a decline in the fair value of the investments below the cost basis is judged to be other-than-temporary.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under U.S. GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2 inputs utilize observable inputs other than Level 1 prices, such as quoted prices, for similar assets or liabilities, quoted market 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 related assets or liabilities.
- Level 3 inputs are unobservable data points for the asset or liability and include situations where there is little, if any, market activity for the asset or liability.

Certain of the Company's financial instruments are not measured at fair value on a recurring basis but are recorded at amounts that approximate their fair value due to the short-term nature of their maturities, such as cash and cash equivalents, accounts receivable, accounts payable and accrued expenses.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash equivalents, which include short-term investments that have maturities of less than three months. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts. The Company invests its excess cash primarily in deposits and money market funds held with one financial institution. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Property and Equipment

The Company carries its property and equipment at cost, less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally three to five years. Leasehold improvements are amortized over the shorter of the life of the lease (including any renewal periods that are deemed to be reasonably assured) or the estimated useful life of the assets. Construction in progress is not depreciated until placed in service. Repairs and maintenance costs are expensed as incurred and expenditures for major improvements are capitalized.

Operating Lease Right-of-Use Assets and Liabilities

The Company determines if an arrangement is, or contains, a lease at contract inception and during modifications or renewal of existing leases. Operating lease assets represent the Company's right to use an underlying asset for the lease term and operating lease liabilities represent the Company's obligation to make lease payments arising from the lease. The Company has recorded operating lease assets and liabilities pursuant to the guidance in Accounting Standards Update ("ASU") No. 2016-02*, Leases (Topic 842),* and subsequent amendments to the initial guidance: ASU No. 2017-13, ASU No. 2018-10, and ASU No. 2018-11 (collectively, "ASC 842"). These operating lease assets and liabilities are recognized at the commencement date of the lease based upon the present value of lease payments over the lease term. The Company includes the initial lease term in its assessment of a lease arrangement; options to extend a lease are not included in the assessment unless there is reasonable certainty that the Company will exercise the option to extend. The lease payments used to determine the Company's operating lease assets may include lease incentives, stated rent increases, and escalation clauses and are recognized in the Company's operating lease assets in the Company's consolidated balance sheets. The Company's operating leases are reflected in operating lease right-of-use asset and operating lease liability within accrued and other liabilities in the Company's consolidated balance sheets. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. Short-term leases, defined as leases that have a lease term of 12 months or less at the commencement date, are excluded from this treatment and are recognized on a straight-line basis over the term of the lease. Refer to Note 8. *Commitments and Contingencies - Lease Obligations* for additional information related to the Company's operating leases.

Debt and Debt Issuance Costs

Debt issuance costs and expenses paid by the Company to its lenders are presented on the consolidated balance sheet as a direct deduction from the related debt liability rather than capitalized as an asset in accordance with ASU No. 2015-03, *Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*. Debt issuance costs represent legal and other direct costs incurred in connection with the Company's Term Loan (as defined in Note 6. *Debt*). These costs are amortized as a non-cash component of interest expense using the effective interest method over the term of the loan.

Convertible Preferred Stock

The Company records shares of non-voting convertible preferred stock at their respective fair values on the dates of issuance, net of issuance costs.

Impairment of Long-Lived Assets

The Company assesses the carrying amount of its property and equipment whenever events or changes in circumstances indicate the carrying amount of such assets may not be recoverable. No impairment charges were recorded during the years ended December 31, 2024, 2023 and 2022.

Net Loss per Share

The Company computes net loss per share of common stock, Series A Convertible Preferred Stock, and Series B Convertible Preferred Stock using the two-class method required for multiple classes of common stock and other participating securities. The Company has determined that the Series A Convertible Preferred Stock and Series B Convertible Preferred Stock do not have preferential rights over the Company's common stock and, accordingly, are considered to be a second and third class of common stock for purposes of calculating net loss per share. Basic net loss per share is calculated by dividing the allocated net loss to each share class by the weighted average number of shares outstanding during the period. Since the Company was in a loss position for all periods presented, diluted net loss per share is the same as basic net loss per share for all periods, as the inclusion of all potential common shares outstanding is antidilutive.

Comprehensive Loss

Comprehensive loss is comprised of net loss and adjustments for the change in unrealized gains and losses on investments. Unrealized accumulated comprehensive gains or losses are reflected as a separate component in the consolidated statements of changes in stockholders' equity. The Company had an unrealized loss of $0.3 million, an unrealized gain of $0.7 million and an unrealized loss of $0.2 million during the years ended December 31, 2024, 2023 and 2022, respectively.

Income Taxes

The Company accounts for income taxes by using an asset and liability method of accounting for deferred income taxes. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. A valuation allowance is recorded to the extent it is more likely than not that a deferred tax asset will not be realized. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date.

The Company's significant deferred tax assets are for net operating loss carryforwards, tax credits, accruals and reserves, and capitalized start-up costs. The Company has provided a valuation allowance for its entire net deferred tax assets since inception as, due to its history of operating losses, the Company has concluded that it is more likely than not that its deferred tax assets will not be realized.

The Company has no unrecognized tax benefits. The Company classifies interest and penalties arising from the underpayment of income taxes in the consolidated statements of operations and comprehensive loss as general and administrative expenses. No such expenses have been recognized during the years ended December 31, 2024, 2023 and 2022.

Warrants

Upon the issuance of warrants to purchase shares of common stock, the Company evaluates the terms of the warrant issue to determine the appropriate accounting and classification of the warrant issue pursuant to FASB ASC Topic 480, *Distinguishing Liabilities from Equity*, FASB ASC Topic 505, *Equity*, FASB ASC 815, *Derivatives and Hedging,* and ASC 718, *Compensation - Stock Compensation*, and classifies warrants for common stock as liabilities or equity. Warrants are classified as liabilities when the Company may be required to settle a warrant exercise in cash and classified as equity when the Company settles a warrant exercise in shares of its common stock.

Segment Information

The Company manages its operations as a single segment, focused on discovering, developing and commercializing potential best-in-class medicines for serious and rare diseases. The Company's Chief Operating Decision Maker ("CODM") is its Chief Executive Officer. The CODM reviews and evaluates consolidated net loss for purposes of assessing performance, making operating decisions, allocating resources, and planning and forecasting for future periods.

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): *Improvements to Report Segment Disclosures* ("ASU 2023-07"). ASU 2023-07 requires enhanced disclosures about significant segment expenses, enhanced interim disclosure requirements, clarifies circumstances in which an entity can disclose multiple segment measures of profit or loss, provides new segment disclosure requirements for entities with a single reportable segment, and contains other disclosure requirements. ASU 2023-07 is effective for the Company's annual reporting period beginning after December 15, 2023, and subsequent interim periods, with early adoption permitted. ASU 2023-07 requires retrospective application to all prior periods presented in the financial statements. The Company adopted ASU 2023-07 effective December 31, 2024 and adoption of this ASU did not materially impact the Company's consolidated financial statements. See Note 15, *Segment Information,* for disclosures related to the adoption of ASU 2023-07.

Recent Accounting Pronouncements – To Be Adopted

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that the Company adopts as of the specified effective date. The Company does not believe that the adoption of recently issued standards have or may have a material impact on the Company's consolidated financial statements or disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): *Improvements to Income Tax Disclosures* ("ASU 2023-09"). ASU 2023-09 requires a company's annual financial statements to include consistent categories and greater disaggregation of information in the rate reconciliation, and income taxes paid disaggregated by jurisdiction. ASU 2023-09 is effective for the Company's annual reporting periods beginning after December 15, 2024. Adoption is either with a prospective method or a fully retrospective method of transition. Early adoption is permitted. The Company is currently evaluating the effect that adoption of ASU 2023-09 will have on its consolidated financial statements.

In November 2024, the FASB issued ASU-2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosure*s (Subtopic 220-40): Disaggregation of Income Statement Expenses ("ASU 2024-03"). ASU 2024-03 requires additional disclosures of the nature of the expenses included in the income statement, including disaggregation of the expense captions presented on the face of the income statement into specific categories. ASU 2024-03 is effective for the Company's annual reporting periods beginning after December 15, 2026, and for interim periods beginning after December 15, 2027, with early adoption permitted. The requirements will be applied prospectively with the option for retrospective application. The Company is currently evaluating the effect that adoption of ASU 2024-03 will have on its consolidated financial statements.

3. INVESTMENTS AND FAIR VALUE MEASUREMENTS

Investments

The Company's investments consisted of the following as of December 31, 2024 and 2023:

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2024				
Money market funds	$ 96,058	$ —	$ —	$ 96,058
U.S. treasury securities	286,039	196	(320)	285,915
U.S. corporate paper and bonds	326,966	361	(247)	327,080
International corporate bond holdings	4,995	—	—	4,995
Total	$ 714,058	$ 557	$ (567)	$ 714,048
December 31, 2023				
Money market funds	$ 77,724	$ 7	$ —	$ 77,731
U.S. treasury securities	148,423	255	(5)	148,673
U.S. corporate paper and bonds	227,463	142	(85)	227,520
International corporate bond holdings	9,304	24	—	9,328
Total	$ 462,914	$ 428	$ (90)	$ 463,252

The money market funds above are included in cash and cash equivalents on the Company's consolidated balance sheets.

The Company considers the unrealized losses in its investment portfolio to be temporary in nature and not due to credit losses. The Company has the intent and ability to hold such investments until their recovery at fair value. The Company had no realized gains in its available for sale securities for the years ended December 31, 2024, 2023, or 2022. The contractual maturity dates of the Company's investments are all less than 24 months.

Fair Value Measurements

The following tables summarize the Company's assets and liabilities that are measured at fair value on a recurring basis:

(in thousands)	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
December 31, 2024				
Assets:				
Cash equivalents:				
Money market funds	$ 96,058	$ —	$ —	$ 96,058
Short-term investments:				
U.S. treasury securities	21,692	264,223	—	285,915
U.S. corporate paper and bonds	—	327,080	—	327,080
International corporate bond holdings	—	4,995	—	4,995
Total cash equivalents and short-term investments	$ 117,750	$ 596,298	$ —	$ 714,048
December 31, 2023				
Assets:				
Cash equivalents:				
Money market funds	$ 77,731	$ —	$ —	$ 77,731
U.S. corporate paper and bonds	—	10,978	—	10,978
Short-term investments:				
U.S. treasury securities	—	148,673	—	148,673
U.S. corporate paper and bonds	—	216,542	—	216,542
International corporate bond holdings	—	9,328	—	9,328
Total cash equivalents and short-term investments	$ 77,731	$ 385,521	$ —	$ 463,252

4. PROPERTY AND EQUIPMENT

Property and equipment, net, consisted of the following:

	December 31,	
	2024	2023
	(in thousands)	
Lab equipment	$ 1,141	$ 1,145
Leasehold improvements	254	670
Computer hardware and software	560	489
Furniture and fixtures	547	417
Property and equipment, gross	2,502	2,721
Less: accumulated depreciation and amortization	(1,266)	(1,049)
Property and equipment, net	$ 1,236	$ 1,672

During the years ended December 31, 2024, 2023, and 2022, depreciation and amortization expense was $0.5 million, $0.5 million and $0.3 million, respectively.

5. ACCRUED LIABILITIES

Accrued liabilities consisted of the following:

	December 31,	
	2024	2023
	(in thousands)	
Accrued outsourced clinical trials and nonclinical studies	$ 30,955	$ 10,724
Accrued employee compensation and related taxes	10,638	10,513
Operating lease liability, short-term	513	843
Accrued legal fees and expenses	1,245	399
Accrued other professional service fees	1,078	473
Value of liability-classified stock purchase warrants	100	100
Accrued interest payable	154	154
Other accrued liabilities	760	902
Total accrued liabilities	$ 45,443	$ 24,108

6. DEBT

Loan and Security Agreement with Hercules Capital, Inc.

In April 2022, the Company entered into a loan and security agreement (the "Hercules Loan and Security Agreement") among the Company, certain of its subsidiaries from time to time party thereto (together with the Company, collectively, the "Borrower"), Hercules Capital, Inc. ("Hercules") and certain other lenders named therein (the "Lenders"). Under the Hercules Loan and Security Agreement, the Lenders provided the Company with access to a term loan with an aggregate principal amount of up to $75.0 million, in four tranches (collectively the "Term Loan"), including an initial tranche of $25.0 million, available to the Company through June 15, 2023. Upon signing the Hercules Loan and Security Agreement, the Company drew an initial principal amount of $5.0 million (the "initial draw"). The Company incurred debt issuance costs of $0.2 million in connection with the Term Loan and paid to the Lenders a facility fee of $0.1 million, as well as $0.1 million of other expenses incurred by the Lenders and reimbursed by the Company ("Lender Expenses") in connection with the initial draw. The debt issuance costs and the Lender Expenses were being amortized as additional interest expense over the term of the loan.

The Company was originally obligated to make interest-only payments through April 1, 2024, which was extended to October 1, 2024 upon achievement of a development milestone in August 2022. In addition, the Borrower was required to pay an end-of-term fee equal to 6% of the principal amount of funded Term Loan advances at maturity, which were being accreted as additional interest expense over the term of the loan. The obligations of the Borrower under the Hercules Loan and Security Agreement were secured by substantially all of the assets of the Borrower, excluding the Borrower's intellectual property. The Term Loan had a maturity date of October 1, 2026.

In August 2023, the Company executed an amendment to the Hercules Loan and Security Agreement (the "Hercules Amendment") to modify certain terms of the agreement and increase the aggregate principal amount of up to $150.0 million. Upon execution of the Hercules Amendment, the Company drew a principal amount of $15.0 million. The Hercules Amendment was determined to substantially alter the Hercules Loan and Security Agreement and therefore was accounted for as a debt extinguishment. The Company recognized a loss on debt extinguishment of $0.2 million in August 2023 related to unamortized debt discount and debt issuance costs.

Under the Hercules Amendment, the Lenders provided the Company access to an increased term loan with an aggregate principal amount of up to $150.0 million, in four tranches (collectively the "Amended Term Loan"), consisting of (1) an initial tranche of $50.0 million, $5.0 million of which was drawn at closing of the Hercules Loan and Security Agreement in April 2022, $15.0 million of which was drawn at closing of the Hercules Amendment in August 2023, $5.0 million of which was available through December 15, 2023, and $25.0 million of which was available from July 1, 2024 through December 15, 2024; (2) a second tranche of $20.0 million, subject to achievement of certain regulatory milestones, available through February 15, 2025; (3) a third tranche of $20.0 million, subject to achievement of certain regulatory milestones, available through March 31, 2025; and (4) a fourth tranche of $60.0 million subject to approval by the Lenders' investment committee(s), available through June 15, 2025. As of December 31, 2024, the milestones for the second and third tranches have been achieved. The obligations

of the Borrower under the Hercules Amendment agreement are secured by substantially all of the assets of the Borrower, excluding the Borrower's intellectual property. The Amended Term Loan has a maturity date of October 1, 2026.

The Amended Term Loan bears interest at a floating per annum rate equal to the greater of (i) 7.45% and (ii) 4.2% above the Prime Rate (as defined therein), provided that the Term Loan interest rate shall not exceed a per annum rate of 8.95%. Interest is payable monthly in arrears on the first day of each month. The interest rate as of December 31, 2024 was 8.95%.

Per the terms of the Hercules Amendment, the Company was originally obligated to make interest-only payments through April 1, 2025. Upon achievement of certain development milestones related to topline results for the Company's phase 3 THRIVE trial in September 2024, the interest-only period was extended to October 1, 2025. Upon achievement of additional development milestones related to topline results for the Company's phase 3 THRIVE-2 trial in December 2024, the interest-only period was further extended to April 1, 2026. The Borrower is required to repay the Amended Term Loan amount in equal monthly installments of the principal amount and interest between the end of the interest-only period and the maturity date of October 1, 2026. In addition, the Borrower is required to pay an end-of-term fee equal to 6% of the principal amount of funded Amended Term Loan advances at maturity, which are being accreted as additional interest expense over the term of the loan.

The total cost of all items (cash interest, the amortization/accretion of the debt issuance costs and the end-of-term fee) is being recognized as interest expense using an effective interest rate of approximately 9.3%. The Company recorded interest expense of $2.2 million, $1.3 million and $0.5 million during the years ended December 31, 2024, 2023, and 2022, respectively.

The following table summarizes the impact of the Term Loan, on the Company's consolidated balance sheet at December 31, 2024 and 2023:

	December 31,	
	2024	2023
	(in thousands)	
Gross proceeds	20,000	20,000
Accrued end-of-term fee	582	205
Carrying value	20,582	20,205

The carrying value of the Amended Term Loan approximates its fair value. Future principal payments, which exclude the end-of-term fee, in connection with the Hercules Loan and Security Agreement as of December 31, 2024 are as follows (in thousands):

Fiscal Year	
2025	—
2026	20,000
Total	$ 20,000

7. COLLABORATION AGREEMENTS

License Agreement with Zenas BioPharma

In October 2020, the Company became party to a license agreement with Zenas BioPharma (Cayman) Limited (now Zenas BioPharma, Inc., their successor in interest, "Zenas BioPharma") to license technology comprising certain materials, patent rights, and know-how to Zenas BioPharma. Since February 2021, the Company has entered into several letter agreements with Zenas BioPharma pursuant to which the Company agreed to provide assistance to Zenas BioPharma with certain development activities, including manufacturing. In May 2022, the Company entered into a Manufacturing Development and Supply Agreement with Zenas BioPharma to manufacture and supply, or to have manufactured and supplied, clinical drug product for developmental purposes. The license agreement and subsequent letter agreements and supply agreement (collectively, the "Zenas Agreements") were negotiated with a single commercial objective and are treated as a combined contract for accounting purposes. Under the terms of the Zenas Agreements, the Company granted Zenas BioPharma an exclusive license to develop, manufacture, and commercialize certain IGF-1R directed antibody products for non-oncology indications in the greater area of China. In January 2025, Zenas BioPharma sublicensed their rights under the license agreement to Zai Lab (Hong Kong)

Limited (“Zai Lab”) and assigned the Manufacturing Development and Supply Agreement to Zai Lab in connection with the sublicense transaction.

As consideration for the Zenas Agreements, the transaction price included upfront non-cash consideration and variable consideration in the form of payment for the Company’s goods and services and milestone payments due upon the achievement of specified events. Under the Zenas Agreements, the Company can receive non-refundable milestone payments upon achieving specific milestone events during the contract term. Additionally, the Company may receive royalty payments based on a percentage of the annual net sales of any licensed products sold on a country-by-country basis in the greater area of China. The royalty percentage may vary based on different tiers of annual net sales of the licensed products made. Zenas BioPharma is obligated to make royalty payments to the Company for the royalty term in the Zenas Agreements.

The Zenas Agreements would qualify as a collaborative arrangement under the scope of ASC, Topic 808, *Collaborative Arrangements* (“ASC 808”). While this arrangement is in the scope of ASC 808, the Company applied ASC 606 to account for certain aspects of this arrangement. The Company applied ASC 606 for certain activities within the arrangement associated with the Company’s transfer of a good or service (i.e., a unit of account) that is part of the Company’s ongoing major or central operations. The Company allocated the transaction price based on the relative estimated standalone selling prices of each performance obligation or, in the case of certain variable consideration, to one or more performance obligations. Research and development activities are priced generally at cost. The Company’s license of goods and services to Zenas BioPharma during the contract term was determined to be a single performance obligation satisfied over time. The Company will recognize the transaction price from the license agreement over the Company’s estimated period to complete its activities.

At the inception of the arrangement, the Company evaluated whether the milestones were considered probable of being reached and estimated the amount to be included in the transaction price using the most likely amount method. As it was not probable that a significant revenue reversal would not occur, none of the associated milestone payments were included in the transaction price at contract inception. For the sales-based royalties included in the arrangement, the license was deemed to be the predominant item to which the royalties relate. The Company will recognize royalty revenues at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). During the years ended December 31, 2024, 2023 and 2022, the Company recognized $0.3 million, $0.3 million and $1.8 million, respectively, of collaboration revenue related to the Zenas Agreements.

In January 2024, the Company entered into a letter agreement with Zenas BioPharma (the “Zenas Letter Agreement”) pursuant to which Zenas BioPharma agreed to support the Company’s THRIVE-2 and STRIVE trials by initiating and managing the studies in China. Under the Zenas Letter Agreement, the Company agreed to reimburse costs incurred by Zenas BioPharma, including a full-time equivalent rate for services rendered. In connection with the execution of the Zenas Letter Agreement, the Company made an initial payment of $1.5 million, which was recorded as research and development expense during the year ended December 31, 2024 as services were performed.

In January 2025, the Company entered into the third amendment to license agreement (the “Third Amendment”) to modify certain provisions of the Zenas Agreements, including provisions related to future milestones.

As of December 31, 2024 and 2023, the Zenas Agreements are considered related party transactions because Fairmount Funds Management LLC (“Fairmount”) beneficially owns more than 5% of the Company’s common stock and is also a 5% or greater stockholder of Zenas BioPharma and has a seat on Zenas BioPharma’s board of directors.

Antibody and Discovery Option Agreement with Paragon Therapeutics, Inc.

In January 2022, the Company and Paragon Therapeutics, Inc. (“Paragon”) entered into an antibody and discovery option agreement (the “Paragon Research Agreement”) under which the Company and Paragon will cooperate to develop one or more proteins or antibodies. Under the terms of the Paragon Research Agreement, Paragon will perform certain development activities in accordance with an agreed upon research plan, and the Company will pay Paragon agreed upon development fees in exchange for Paragon’s commitment of the necessary personnel and resources to perform these activities. The Paragon Research Agreement stipulates a final deliverable to the Company comprising of a report summarizing the experiments and processes performed under the research plan (the “Final Deliverable”).

Additionally, Paragon agreed to grant the Company an option for an exclusive license to all of Paragon’s right, title and interest in and to certain antibody technology and the Final Deliverable, and a non-exclusive license to certain background intellectual property owned by Paragon solely to research, develop, make, use, sell, offer for sale and import of the licensed intellectual property and resulting products worldwide (each, an “Option” and together, the “Options”). Paragon also granted to the Company a limited, exclusive, royalty-free license, without the right to sublicense, to certain antibody technology and the Final

Deliverable, and a non-exclusive, royalty-free license without the right to sublicense, under certain background intellectual property owned by Paragon, solely to evaluate the antibody technology and Option and for the purpose of allowing the Company to determine whether to exercise the Option with respect to certain programs. The Company may, at its sole discretion, exercise the Option with respect to specified programs ("Programs") at any time until the date that is 90 days after the Company's receipt of the Final Deliverable the applicable program, or such longer period as agreed upon by the parties ("Option Period") by delivering written notice of such exercise to Paragon. If the Company fails to exercise an Option prior to expiration of the applicable Option Period, such Option for such Programs will terminate. In consideration for Paragon's grant of the Options to the Company, the Company paid to Paragon a non-refundable, non-creditable one-time fee of $2.5 million, which was recorded as research and development expense during the three months ended March 31, 2022. In December 2022, the Company and Paragon entered into a first amendment to the Paragon Research Agreement, under which the Company obtained an additional limited license for the purpose of conducting certain activities. In consideration for the rights and licenses obtained under the first amendment, Viridian paid Paragon a non-refundable fee of $2.3 million (the "First Amendment Payment"), which was recorded as research and development expense during the three months ended December 31, 2022. The non-refundable upfront fee and the First Amendment Payment are separate from any development costs or cost advance paid or owing with respect to the specified program.

In October 2023, the Company entered into a License Agreement with Paragon (the "Paragon License Agreement") as a result of exercising its Option under the Paragon Research Agreement to obtain exclusive licenses to develop, manufacture and commercialize certain antibodies, proteins and associated products. In connection with the execution of the Paragon License Agreement, the Company made an initial payment of $5.3 million, which was recorded as research and development expense during the three months ended December 31, 2023. As further described below, the Paragon License Agreement was amended and restated by the Amended and Restated License Agreement with Paragon in September 2024.

In January 2024, the Company entered into a letter agreement with Paragon pursuant to which Paragon agreed to continue to perform development activities under the existing Paragon Research Agreement and Paragon License Agreement, which the Company renewed in July 2024. In consideration for the development activities to be conducted by Paragon, the Company will reimburse Paragon for actual development costs incurred and agreed upon development fees in exchange for Paragon's commitment of the necessary personnel and resources to perform these activities. In September 2024, the Company entered into a second amendment to the Paragon Research Agreement to include additional development activities to be performed by Paragon. Under the amended Paragon Research Agreement, the Company will be obligated to make a one-time non-refundable payment of $3.5 million to Paragon following the achievement of certain research and development objectives. The Company achieved such objectives in February 2025 and the $3.5 million payment was recorded as research and development expense during the three months ended March 31, 2025.

In September 2024, the Company entered into the Amended and Restated License Agreement with Paragon (the "Amended Paragon License Agreement") which amended and restated the Paragon License Agreement. In connection with the execution of the Amended Paragon License Agreement, the Company paid Paragon a non-refundable fee of $4.0 million in September 2024, which was recorded as research and development expense during the three months ended September 30, 2024. In consideration for rights granted by Paragon, the Company is obligated to make certain future milestone payments of up to $16.0 million on a program-by-program basis upon the achievement of specified clinical and regulatory milestones, with total milestone payments under all programs not to exceed $40.0 million. Additionally, if the Company develops a product utilizing certain intellectual property rights granted to it under the Amended Paragon License Agreement, the Company is obligated to pay Paragon potential additional future development milestone payments of up to $3.1 million and commercial milestone payments of up to $17.0 million with respect to such product. If the Company successfully commercializes any product candidate subject to the Amended Paragon License Agreement, it is responsible for royalty payments equal to a percentage in the mid-single digits of such product's net sales. During the years ended December 31, 2024, 2023 and 2022, the Company recorded $14.2 million, $12.0 million and $5.6 million, respectively, in research and development costs related to the Paragon Research Agreement and Amended Paragon License Agreement (collectively, the "Paragon Agreements").

As of December 31, 2024 and 2023, the Paragon Agreements are considered a related party transaction because Fairmount beneficially owns more than 5% of the Company's capital stock and has two seats on the Company's board of directors, and beneficially owns more than 5% of Paragon, which is a joint venture between Fairmount and FairJourney Biologics, and has appointed the sole director on Paragon's board of directors and has the contractual right to approve the appointment of any executive officers.

8. COMMITMENTS AND CONTINGENCIES

License Agreement with ImmunoGen, Inc.

In October 2020, the Company became party to a license agreement (the "ImmunoGen License Agreement") with Immunogen, Inc. ("ImmunoGen"), under which the Company obtained an exclusive, sublicensable, worldwide license to certain patents and other intellectual property rights to develop, manufacture, and commercialize certain products for non-oncology and non-radiopharmaceutical indications. In consideration for rights granted by ImmunoGen, the Company is obligated to make certain future development milestone payments of up to $48.0 million upon the achievement of specified clinical and regulatory milestones. In December 2021, the Company paid a $2.5 million milestone payment to ImmunoGen upon the submission of an investigational new drug ("IND") application for veligrotug with the FDA. In May 2022, the Company paid a $3.0 million milestone payment to ImmunoGen related to the first patient dosed in the clinical trial for veligrotug. In December 2022, the Company recorded $10.0 million as research and development expense related to a milestone owed to ImmunoGen related to the first patient dosed in a pivotal clinical trial for veligrotug, amount which was paid in January 2023. Additionally, if the Company successfully commercializes any product candidate subject to the ImmunoGen License Agreement, it is responsible for royalty payments equal to a percentage in the mid-single digits of net sales and commercial milestone payments of up to $95.0 million. The Company is obligated to make any such royalty payments on a product-by-product and country-by-country basis from the first commercial sale of a specified product in each country until the later of (i) the expiration of the last patent claim subject to the ImmunoGen License Agreement in such country, (ii) the expiration of any applicable regulatory exclusivity obtained for each product in such country, or (iii) the 12th anniversary of the date of the first commercial sale of such product in such country. On February 12, 2024, AbbVie Inc. acquired ImmunoGen. The terms of the ImmunoGen License Agreement did not change as a result of this acquisition.

Development and License Agreement with Enable Injections

In January 2023, the Company entered into a Development and License Agreement (the "Enable License Agreement") with Enable Injections, Inc. ("Enable"), under which Enable granted the Company an exclusive, royalty-bearing, sublicensable, non-transferrable license to (i) develop, commercialize, seek marketing approval for and otherwise use and exploit certain products, and (ii) make and have made such product solely for such permitted uses. Pursuant to the terms of the Enable License Agreement, the Company granted Enable a non-exclusive, royalty-free, non-sublicensable, non-transferable license. In consideration for the rights granted by Enable the Company paid Enable an initial, non-creditable, non-refundable license fee of $15.0 million in January 2023. This amount is included in research and development expense for the year ended December 31, 2023 in the accompanying consolidated statement operations. This amount is reflected as a cash outflow from operating activities in the statement of cash flows during the year ended December 31, 2023.

The Company is obligated to make certain future milestone payments of up to $45.0 million upon the achievement of specified development, clinical and regulatory milestones. Additionally, if the Company is successful in commercializing any product candidate subject to the Enable License Agreement, the Company is obligated to make certain commercial milestone payments of up to $150.0 million and royalty payments equal to a percentage in the mid-single digits.

Contingent Value Rights Agreement

In accordance with the merger agreement with miRagen Therapeutics, Inc. ("miRagen"), on November 4, 2020, the Company entered into a contingent value rights agreement (the "CVR Agreement"), pursuant to which each holder of the Company's common stock as of November 6, 2020, other than former stockholders of the private entity Viridian Therapeutics, Inc. (which merged with miRagen), received one contingent value right (a "CVR") for each share of Company common stock held by such holder on that date. Under the CVR Agreement, holders of CVRs would have been entitled to receive a portion of the net proceeds for any dispositions of certain legacy miRagen assets consummated through December 31, 2021. As of December 31, 2021, the disposition period had expired. There were no dispositions of any such legacy assets prior to that time and, accordingly, there will be no payments made under the CVR Agreement. The CVR Agreement expires on November 4, 2025.

Exclusive License and Collaboration Agreement

In May 2023, the Company and a third-party collaborator entered into an Exclusive License and Collaboration Agreement to collaborate and conduct certain IND-enabling activities with respect to the licensed compound and licensed product. Under the terms of the agreement, the Company was granted an exclusive, royalty-bearing, worldwide license to develop, manufacture, and commercialize certain licensed compounds and licensed products in the field (the "License"). In consideration for the rights granted by the License, the Company initially issued 204,843 shares of its common stock to certain stockholders of the third-party. The shares were valued at $5.0 million and recorded as research and development expense during the three months ended

June 30, 2023. On July 24, 2023, the Company issued 39,059 additional shares of its common stock to certain stockholders of the third-party and recorded the related $0.7 million expense as research and development expenses during three months ended September 30, 2023. Additionally, upon the date when the Company decides to pursue certain studies for the licensed compound under the agreement, the Company was obligated to issue the third-party collaborator the equivalent of $10.0 million in shares of its common stock. The Company was also obligated to make certain future milestones of up to $45.0 million upon the achievement of certain development milestones. Remaining development milestone payments would have been payable in cash. If the Company was successful in commercializing products related to the licensed compound, the Company was also obligated to pay up to $60.0 million upon the achievement of certain sales milestones as well as royalty payments equal to a percentage in the mid-single to double digits. This agreement was terminated on December 30, 2024 and no further financial obligations exist under the Exclusive License and Collaboration Agreement.

Lease Obligations

Colorado-based Office and Lab Space

The Company is party to a multi-year, non-cancelable lease agreement for its Colorado-based office and lab space (the "Colorado Lease"). The Colorado Lease includes rent escalation clauses through the lease term and a Company option to extend the lease term for up to three terms of three years each. Minimum base lease payments under the Colorado Lease, including the impact of tenant improvement allowances, are recognized on a straight-line basis over the full term of the lease. The lease term was amended in March 2021 to extend the lease maturity date to December 31, 2024. Upon adoption of ASC 842 and upon subsequent modification of the lease in 2020 and in March 2021, the Company recognized a right-of-use asset and corresponding lease liability for the Colorado Lease of approximately $1.6 million by calculating the present value of lease payments, discounted at 6%, the Company's estimated incremental borrowing rate, over the 12 months expected remaining term.

In September 2024, the Company entered into a new, multi-year lease agreement for its Colorado-based office and lab space (the "New Colorado Lease"). Under ASC 842, the New Colorado Lease was treated as a lease modification representing an extension of the lease term for a reduced portion of the space currently in use under the existing Colorado Lease. As of the effective date, the Company recorded a $0.3 million increase in the right-of-use asset and corresponding lease liability for the extension of the lease term. The remaining space under the Colorado Lease terminated at the original maturity date of December 31, 2024. The New Colorado Lease provides for annual base rent of approximately $0.1 million during the lease term. The Company is also obligated to pay the landlord certain costs, taxes, and operating expenses. The New Colorado Lease is set to expire in December 2026. The Company has the option to extend the lease term for an additional period of five years upon notice to the landlord. The option to extend is not included in the lease term assessment as it is not reasonably certain the Company will exercise the option.

Massachusetts-based Office Space

The Company is party to a multi-year, non-cancelable lease agreement for its Massachusetts-based office space (as subsequently amended in July 2021, April 2022, July 2022, April 2024, and September 2024, the "Massachusetts Lease"). The Massachusetts Lease includes rent escalation clauses throughout the lease term. Minimum base lease payments under the Massachusetts Lease are recognized on a straight-line basis over the full term of the Massachusetts Lease. Upon initial assumption of the Massachusetts Lease in October 2020, the Company recognized a right-of-use asset and corresponding lease liability of $0.1 million by calculating the present value of lease payments, discounted at 6%, the Company's estimated incremental borrowing rate, over the expected remaining term.

In April 2024, the Company entered into a Fourth Amendment of the Massachusetts Lease (the "Fourth Amendment"). The Fourth Amendment makes certain modifications to the Massachusetts Lease, including (i) securing 10,427 square feet of office space in a new building suite (the "New Premises"), (ii) the termination of the 10,956 square feet of leased space under the existing Massachusetts Lease (the "Original Premises"), and (iii) the extension of the expiration date of the leased space to five years from the delivery of the New Premises. The Massachusetts Lease provides for annual base rent of approximately $0.5 million during the lease term. The Company is also obligated to pay the landlord certain costs, taxes and operating expenses. Under the Fourth Amendment, the Massachusetts Lease will expire in July 2029. The Company has the option to extend the lease term for an additional period of three years upon notice to the landlord. The option to extend is not included in the lease term assessment as it is not reasonably certain the Company will exercise the option.

The Company recorded a new right-of-use asset of $1.6 million and corresponding lease liability of $1.9 million for the New Premises and simultaneously derecognized the right-of-use asset of $1.1 million and corresponding lease liability of $1.2 million for the Original Premises on the lease commencement date in April 2024.

In September 2024, the Company entered into a Fifth Amendment of the Massachusetts Lease (the "Fifth Amendment") to lease an additional 2,788 square feet of office space in the same building. The Fifth Amendment provides for additional annual base rent of approximately $0.1 million for the additional office space and includes annual base rent escalation clauses during the lease term. The Fifth Amendment was treated as a lease modification accounted for as a separate contract and the Company recorded a new right-of-use asset and corresponding lease liability of approximately $0.5 million related to the Fifth Amendment on the lease commencement date.

Future lease payments under noncancellable leases as of December 31, 2024 are as follows:

	(in thousands)
2025	723
2026	747
2027	613
2028	627
2029	370
Total future minimum lease payments	3,080
Less: imputed interest	(543)
Total	$ 2,537

As of December 31, 2024, the Company's operating lease obligations were reflected as short-term operating lease liabilities of $0.5 million within accrued liabilities and $2.0 million of long-term lease obligations as other liabilities in the Company's consolidated balance sheets.

Amortization of the operating lease right-of-use assets, and corresponding reduction of operating lease obligations, amounted to $0.7 million, $0.8 million and $0.5 million for the years ended December 31, 2024, 2023 and 2022, respectively, which was included in operating expense in the consolidated statements of operations and comprehensive loss.

The Company is also required to pay for operating expenses related to the leased space, which were $0.4 million, $0.4 million and $0.3 million for the years ended December 31, 2024, 2023 and 2022, respectively. The operating expenses are incurred separately and were not included in the present value of lease payments.

9. CAPITAL STOCK

Common Stock

Under the Company's second restated certificate of incorporation, the Company is authorized to issue 205,000,000 shares of its stock, of which 200,000,000 shares have been designated as common stock and 5,000,000 shares have been designated as convertible preferred stock, both with a par value of $0.01 per share. The number of authorized shares of common stock may be increased or decreased by the affirmative vote of the holders of a majority of the Company's stock who are entitled to vote. Each share of common stock is entitled to one vote. The holders of common stock are entitled to receive dividends when and as declared or paid by its board of directors.

Public Offerings

In September 2024, the Company entered into an underwriting agreement with Jefferies, Goldman Sachs & Co. LLC and Stifel, Nicolaus & Company, Incorporated related to the offer and sale (the "September 2024 Public Offering") of 12,466,600 shares of the Company's common stock, which included 1,800,000 shares of common stock issued in connection with the exercise in full by the underwriters of their option to purchase additional shares at a public offering price of $18.75 per share, and 20,000 shares of the Company's Series B Convertible Preferred Stock at a price per share of $1,250.0625 per share. The aggregate gross proceeds to the Company from the September 2024 Public Offering, including the exercise of the option, were approximately $258.8 million, before deducting underwriting discounts and commissions and other offering expenses payable by the Company.

In January 2024, the Company entered into an underwriting agreement with Jefferies and Leerink Partners LLC relating to the offer and sale (the "January 2024 Public Offering") of 7,142,858 shares of the Company's common stock at a public offering

price of $21.00 per share. The aggregate gross proceeds to the Company from the January 2024 Public Offering were approximately $150.0 million, before deducting underwriting discounts and commissions and other offering expenses payable by the Company.

In August 2022, the Company entered into an underwriting agreement with Jefferies LLC ("Jefferies"), SVB Securities LLC (now known as Leerink Partners LLC ("Leerink Partners")) and Evercore Group L.L.C. ("Evercore") relating to the offer and sale of 11,352,640 shares of the Company's common stock, which includes 1,725,000 shares of common stock issued in connection with the exercise in full by the underwriters of their option to purchase additional shares at a public offering price of $23.50 per share, and 28,084 shares of Series B Non-Voting Convertible Preferred Stock, par value $0.01 per share, at a public offering price of $1,566.745 per share (collectively the "2022 Public Offering"). The aggregate gross proceeds to the Company from the 2022 Public Offering, including the exercise of the option were approximately $311.0 million, before deducting underwriting discounts and commissions and other offering expenses payable by the Company.

Private Placements

In November 2023, the Company issued and sold in private placement transactions an aggregate of 8,869,797 shares of the Company's common stock at a price per share of $12.38 and 92,312 shares of the Company's Series B non-voting convertible preferred stock at a price per share of $825.3746, pursuant to securities purchase agreements with certain institutional and accredited investors. The Company received aggregate gross proceeds of approximately $186.0 million, before deducting offering expenses payable by the Company.

Common Stock Sales Agreements - Jefferies LLC

In September 2022, the Company entered into an Open Market Sale Agreement[SM] (the "September 2022 ATM Agreement") with Jefferies, pursuant to which the Company may offer and sell shares of its common stock having an aggregate offering price of up to $175.0 million from time to time at prices and on terms to be determined by market conditions at the time of offering, with Jefferies acting as its sales agent. Jefferies will receive a commission of 3.0% of the gross proceeds of any shares of common stock sold under the September 2022 ATM Agreement. During the year ended December 31, 2024, the Company sold 3,058,751 shares under the September 2022 ATM Agreement with Jefferies at a weighted average price of $22.86 per share, for aggregate net proceeds of approximately $67.7 million, including commissions to Jefferies as a sales agent. During the year ended December 31, 2023, the Company sold 684,298 shares under the September 2022 ATM Agreement with Jefferies at a weighted average price of $22.30 per share, for aggregate net proceeds of approximately $14.8 million, including commissions to Jefferies as a sales agent. During the year ended December 31, 2022, 964,357 shares were sold under the September 2022 ATM Agreement at a weighted average price of $26.01 per share, for aggregate net proceeds of approximately $24.2 million, including commissions to Jefferies as a sales agent.

Under the Company's second restated certificate of incorporation, the Company's board of directors has the authority to designate and issue up to 5,000,000 shares of convertible preferred stock, at its discretion, in one or more classes or series and to fix the powers, preferences and rights, and the qualifications, limitations, or restrictions thereof, including dividend rights, conversion rights, voting rights, terms of redemption, and liquidation preferences, without further vote or action by the Company's stockholders.

Series A Convertible Preferred Stock

Holders of Series A Convertible Preferred Stock are entitled to receive dividends on shares of Series A Convertible Preferred Stock equal, on an as-if-converted-to-Common-Stock basis, and in the same form as dividends actually paid on shares of the common stock. Except as otherwise required by law, the Series A Convertible Preferred Stock does not have voting rights. However, as long as any shares of Series A Convertible Preferred Stock are outstanding, the Company will not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series A Convertible Preferred Stock, (i) alter or change adversely the powers, preferences or rights given to the Series A Convertible Preferred Stock, (ii) alter or amend the Certificate of Designation, (iii) amend its certificate of incorporation or other charter documents in any manner that adversely affects any rights of the holders of Series A Convertible Preferred Stock, (iv) increase the number of authorized shares of Series A Convertible Preferred Stock, (v) at any time while at least 30% of the originally issued Series A Convertible Preferred Stock remains issued and outstanding, consummate a Fundamental Transaction (as defined in the Certificate of Designation) or (vi) enter into any agreement with respect to any of the foregoing. The Series A Convertible Preferred Stock does not have a preference upon any liquidation, dissolution, or winding-up of the Company. Each share of Series A Convertible Preferred Stock is convertible into 66.67 shares of common stock at any time at the option of the holder thereof, subject to certain limitations, including that a holder of Series A Convertible Preferred Stock is prohibited from converting shares of Series A Convertible Preferred Stock into shares of common stock if, as a result of such conversion, such holder, together with its

affiliates, would beneficially own more than a specified percentage (to be established by the holder between 4.99% and 19.99%) of the total number of shares of common stock issued and outstanding immediately after giving effect to such conversion.

As of December 31, 2024 and 2023, there were 134,864 and 172,435 shares of Series A Convertible Preferred Stock outstanding, respectively.

Series B Convertible Preferred Stock

Each share of Series B Convertible Preferred Stock is convertible into 66.67 shares of common stock, subject to certain limitations, including that a holder of Series B Convertible Preferred Stock is prohibited from converting shares of Series B Convertible Preferred Stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than a specified percentage (to be established by the holder between 4.99% and 19.99%) of the total number of shares of common stock issued and outstanding immediately after giving effect to such conversion. The powers, preferences, rights, qualifications, limitations, and restrictions applicable to the Series B Convertible Preferred Stock are set forth in the Certificate of Designation filed in September 2021.

Holders of Series B Convertible Preferred Stock are entitled to receive dividends on shares of Series B Convertible Preferred Stock equal, on an as-if-converted-to-Common-Stock basis, and in the same form as dividends actually paid on shares of the common stock. Except as otherwise required by law, the Series B Convertible Preferred Stock does not have voting rights. However, as long as any shares of Series B Convertible Preferred Stock are outstanding, the Company will not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series B Convertible Preferred Stock, (i) alter or change adversely the powers, preferences or rights given to the Series B Convertible Preferred Stock, (ii) alter or amend the Certificate of Designation, or (iii) amend its certificate of incorporation or other charter documents in any manner that adversely affects any rights of the holders of Series B Convertible Preferred Stock. The Series B Convertible Preferred Stock does not have a preference upon any liquidation, dissolution, or winding-up of the Company.

As of December 31, 2024 and 2023, there were 145,160 and 143,522 shares of Series B Convertible Preferred Stock outstanding, respectively.

10. WARRANTS

The following table presents information about the Company's outstanding warrants:

	Number of Underlying Shares (1) December 31,		Weighted-Average Exercise Price at December 31, 2024	Remaining Contractual Life at December 31, 2024 (No. Years)
	2024	2023		
Liability-classified warrants				
Issued April 2017	781	781	$127.95	0.33
Equity-classified warrants				
Acquired October 2020	29,446	29,446	$0.02	5.73
Issued February 2020 (2)	218,050	218,050	$14.54	0.11
Issued November 2017	—	1,606	$—	
Subtotal	247,496	249,102	$14.55	
Total warrants	248,277	249,883	$14.91	

(1) If the Company subdivides (by any stock split, stock dividend, recapitalization, or otherwise) its outstanding shares of its common stock into a smaller number of shares, the warrant exercise price is proportionately reduced and the number of shares under outstanding warrants is proportionately increased. Additionally, if the Company combines (by combination, reverse stock split, or otherwise) its outstanding shares of common stock into a smaller number of shares, the warrant exercise price is proportionately increased and the number of shares under outstanding warrants is proportionately decreased.

(2) Subject to specified conditions, the Company may voluntarily reduce the warrant exercise price of the warrants issued in February 2020.

A summary of the Company's warrant activity during the year ended December 31, 2024 is as follows:

	Common Stock Warrants	
	Number	Weighted-Average Exercise Price
Outstanding at December 31, 2023	249,883	$15.51
Exercised	—	$—
Expired	(1,606)	$0.69
Outstanding at December 31, 2024	248,277	$14.91

11. SHARE-BASED COMPENSATION

Equity Incentive Plans

The Company has grants outstanding under its 2008 Equity Incentive Plan (the "2008 Plan"), its amended and restated 2016 Equity Incentive Plan (the "2016 Plan"), and the Viridian 2020 Equity Incentive Plan (the "2020 Plan" and collectively with the 2008 Plan and the 2016 Plan, the "Equity Incentive Plans"). Additionally, beginning in July 2021, the Company granted stock options and RSUs outside of its Equity Incentive Plans to certain employees to induce them to accept employment with the Company (the "Inducement Awards"). The terms and conditions of the Inducement Awards are substantially similar to those awards granted under the Company's Equity Incentive Plans.

In June 2022, the Company's stockholders approved the amendment and restatement of the 2016 Plan to, among other things, transfer the then remaining number of shares available for issuance under the 2020 Plan into the 2016 Plan so that the Company operates from a single equity plan going forward. In June 2023, the Company's stockholders approved a further amendment and restatement of the 2016 Plan to, among other things, increase the number of shares reserved for issuance thereunder by 2,000,000 shares. In June 2024, the Company's stockholders approved a further amendment and restatement of the 2016 Plan to, among other things, increase the number of shares reserved for issuance thereunder by 2,000,000 shares. The 2016 Plan will terminate on April 19, 2034.

As of December 31, 2024, the Company had the following balances by plan:

	Restricted Stock Units Outstanding	Stock Options Outstanding	Shares Available for Issuance
Inducement Awards	—	6,237,328	—
2020 Plan	—	95,684	—
2016 Plan	314,075	5,015,483	5,120,218
2008 Plan	—	24	—
Total	314,075	11,348,519	5,120,218

Restricted Stock Units

RSUs granted under the Equity Incentive Plans and the Inducement Awards generally vest annually over a 4-year period and are settled in shares of the Company's common stock.

A summary of RSU activity is as follows:

	RSUs	Weighted-Average Grant Date Fair Value

Nonvested, December 31, 2023	804,947	15.82
Granted	8,628	20.62
Vested	(129,395)	16.96
Forfeited	(370,105)	15.79
Nonvested, December 31, 2024	314,075	15.51

Stock Options

Options granted under the Equity Incentive Plans and the Inducement Awards have an exercise price equal to the market value of the common stock at the date of grant and expire 10 years from the date of grant. Options generally vest 25% on the first anniversary of the vesting commencement date and 75% ratably in equal monthly installments over the remaining 36 months or in equal monthly or quarterly amounts over periods of up to 48 months.

A summary of common stock option activity is as follows:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2023	11,533,484	$ 19.68	8.50	$ 54,772
Granted	3,739,256	16.45		
Exercised	(437,146)	12.23		
Forfeited or expired	(3,487,075)	22.26		
Outstanding as of December 31, 2024	11,348,519	18.11	7.85	$ 37,138
Vested or expected to vest as of December 31, 2024	11,348,519	$ 18.11	7.85	$ 37,138
Exercisable as of December 31, 2024	3,948,483	$ 20.48	5.60	$ 8,632
Vested as of December 31, 2024	3,948,483	$ 20.48	5.60	$ 8,632

Fair Value Assumptions

The Company uses the Black-Scholes option pricing model to estimate the fair value of stock options granted under its equity compensation plans. The Black-Scholes model requires inputs for risk-free interest rate, dividend yield, volatility, and expected terms of the options. Because the Company has a limited history of stock purchase and sale activity, expected volatility is based on a blend of historical data from public companies that are similar to the Company in size and nature of operations, as well as the Company's own volatility. The Company will continue to use similar entity volatility information until its historical volatility is relevant to measure expected volatility for option grants. The Company accounts for forfeitures as they occur. The risk-free rate for periods within the contractual life of each option is based on the U.S. Treasury yield curve in effect at the time of the grant for a period commensurate with the expected term of the grant. The expected term (without regard to forfeitures) for options granted represents the period of time that options granted are expected to be outstanding and is derived from the contractual terms of the options granted, and actual and expected option-exercise behaviors. The fair value of the underlying common stock is based on the closing price of the common stock on The Nasdaq Capital Market at the date of grant.

The weighted-average grant-date fair value of options granted to the Company's employees and members of its board of directors during the years ended December 31, 2024 and 2023 was $11.75 and $16.12, respectively. The fair value was determined by the Black-Scholes option pricing model using the following weighted-average assumptions:

	Year Ended December 31,	
	2024	2023
Expected term, in years	5.11	5.57
Expected volatility	88.3 %	90.0 %
Risk-free interest rate	4.3 %	4.3 %
Expected dividend yield	— %	— %
Weighted average exercise price	$ 16.45	$ 21.61

Employee Stock Purchase Plan

The 2016 Employee Stock Purchase Plan ("ESPP") allows qualified employees to purchase shares of common stock at a price equal to 85% of the lower of: (i) the closing price at the beginning of the offering period or (ii) the closing price at the end of the offering period. As of December 31, 2024, the Company had 68,503 shares available for issuance, and 102,426 cumulative shares had been issued under the ESPP.

Share-Based Compensation Expense

Share-based compensation related to all equity awards issued pursuant to the Equity Incentive Plans, the Inducement Awards and for estimated shares to be issued under the ESPP for the purchase periods active during each respective period is included in the consolidated statements of operations and comprehensive loss as follows:

	Year Ended December 31,		
	2024	2023	2022
		(in thousands)	
Research and development	$ 22,345	$ 16,220	$ 7,298
General and administrative	19,805	50,952	12,467
Total share-based compensation expense	$ 42,150	$ 67,172	$ 19,765

During the year ended December 31, 2024, the Company recorded an additional $4.6 million in share-based compensation related to the acceleration of vesting for former executive officers, an amount which includes $0.3 million related to the modification of the terms of options outstanding at the time of termination for one executive which would have otherwise forfeited. The Company also recorded $2.0 million in share-based compensation related to the accounting for a modification of the equity awards to extend the post-termination exercise period of certain vested stock options for a former executive.

During the year ended December 31, 2023, the Company recorded an additional $26.1 million in share-based compensation related to the acceleration of vesting for former executive officers, an amount which includes $1.6 million related to the modification of the terms of options outstanding at the time of termination which would have otherwise forfeited.

As of December 31, 2024, the Company had $83.5 million of total unrecognized share-based compensation costs related to stock options, which the Company expects to recognize over a weighted-average remaining period of 2.90 years. As of December 31, 2024, the Company had $4.4 million of total unrecognized share-based compensation costs related to unvested RSUs, which the Company expects to recognize over a weighted-average remaining period of 2.75 years.

12. RETIREMENT BENEFIT PLAN

The Company has established a 401(k) retirement plan that allows participating employees in the U.S. to contribute as defined by the plan and is subject to limitations under Section 401(k) of the Internal Revenue Code of 1986, as amended. The Company matches 100% of the first 4% (subject to annual compensation and contribution limits) of employee contributions. During the years ended December 31, 2024, 2023 and 2022, the Company paid a matching contribution of $1.1 million, $0.7 million and $0.4 million, respectively.

13. NET LOSS PER SHARE

During the current fiscal year, management identified an immaterial error related to the calculation and presentation of loss per share in prior periods. The Company had previously incorrectly concluded that the Series A Convertible Preferred Stock and Series B Convertible Preferred Stock had preferences over the Company's Common Stock and were therefore excluded from the calculation of basic and dilutive net loss per share pursuant to the two-class method. Net loss per share attributable to common stockholders for the years ended December 31, 2023 and 2022 as previously presented was $5.31 and $4.05, respectively, and as corrected is $3.91 and $2.71, respectively. Net loss per share attributable to holders of Series A Convertible Preferred Stock and Series B Convertible Preferred Stock was not previously presented. All related amounts have been updated to reflect the effects of the correction in the consolidated statement of operations and comprehensive loss and related notes, as applicable. The correction of this error had no impact on the previously reported net loss or cash flows.

The Company computes net loss per share of Common Stock, Series A Convertible Preferred Stock, and Series B Convertible Preferred Stock using the two-class method required for multiple classes of common stock and other participating securities. The two-class method is an earnings (loss) allocation method under which earnings (loss) per share is calculated for each class of common stock. The Company has determined that the Series A Convertible Preferred Stock and Series B Convertible Preferred Stock do not have preferential rights when compared to the Company's Common Stock and therefore it must allocate losses to these other classes of stock, as illustrated in the table below.

Basic and diluted net loss per share is computed by dividing the allocated net loss to each share class by the weighted-average number of shares outstanding during the period. For periods in which the Company generated a net loss, the Company does not include potential shares of common stock in diluted net loss per share when the impact of these items is anti-dilutive. The Company has generated a net loss for all periods presented, therefore diluted net loss per share is the same as basic net loss per share since the inclusion of potential shares of common stock would be anti-dilutive.

The following table sets forth the computation of basic and diluted net loss per share of Common Stock, Series A Convertible Preferred Stock, and Series B Convertible Preferred Stock (in thousands, except share and per share amounts):

	Year Ended December 31, 2024		
	Series A Convertible Preferred Stock	Series B Convertible Preferred Stock	Common Stock
Net loss per share, basic and diluted:			
Numerator			
Allocation of losses	$ (31,718)	$ (29,671)	$ (208,560)
Denominator			
Weighted-average shares outstanding	154,856	144,862	67,885,831
Net loss per share, basic and diluted	$ (204.82)	$ (204.82)	$ (3.07)

	Year Ended December 31, 2023		
	Series A Convertible Preferred Stock	Series B Convertible Preferred Stock	Common Stock
Net loss per share, basic and diluted:			
Numerator			
Allocation of losses	$ (45,421)	$ (17,306)	$ (175,007)
Denominator			
Weighted-average shares outstanding	174,226	66,385	44,755,475
Net loss per share, basic and diluted	$ (260.70)	$ (260.69)	$ (3.91)

	Year Ended December 31, 2022		
	Series A Convertible Preferred Stock	Series B Convertible Preferred Stock	Common Stock
Net loss per share, basic and diluted:			
Numerator			
Allocation of losses	$ (36,784)	$ (6,047)	$ (87,043)
Denominator			
Weighted-average shares outstanding	203,190	33,436	32,087,293
Net loss per share, basic and diluted	$ (181.03)	$ (180.85)	$ (2.71)

There are no potentially dilutive securities to Series A Convertible Preferred Stock or Series B Convertible Preferred Stock. Potentially dilutive securities to the Common Stock include the following:

	December 31,		
	2024	2023	2022
Series A Convertible Preferred Stock, as converted to shares of common stock	8,991,383	11,495,724	12,558,796
Series B Convertible Preferred Stock, as converted to shares of common stock	9,677,817	9,568,181	3,414,017
Options to purchase common stock	11,348,519	11,533,484	5,722,449
Warrants to purchase common stock	248,277	249,883	363,963
Restricted stock units	314,075	804,947	—
Total	30,580,071	33,652,219	22,059,225

Quarterly Financial Information (Unaudited)

The immaterial error related to calculation and presentation of loss per share also impacted previously reported quarterly financial information. Net loss per share attributable to common stockholders for the three months ended March 31, 2024 as previously presented was $0.79 and as corrected is $0.59. Net loss per share attributable to common stockholders for the three and six months ended June 30, 2024 as previously presented was $1.02 and $1.82, respectively, and as corrected is $0.77 and $1.37, respectively. Net loss per share attributable to common stockholders for the three and nine months ended September 30, 2024 as previously presented was $1.15 and $2.98, respectively, and as corrected is $0.88 and $2.26, respectively. Net loss per share attributable to holders of Series A Convertible Preferred Stock and Series B Convertible Preferred Stock was not previously presented. The corrected unaudited interim financial information for the three months ended March 31, 2024, the three and six months ended June 30, 2024, and the three and nine months ended September 30, 2024, are included in the tables that follow.

	Three Months Ended March 31, 2024		
	Series A Convertible Preferred Stock	Series B Convertible Preferred Stock	Common Stock
Net loss per share, basic and diluted:			
Numerator			
Allocation of losses	$ (6,731)	$ (5,661)	$ (36,150)
Denominator			
Weighted-average shares outstanding	$ 170,621	$ 143,522	$ 61,099,038
Net loss per share, basic and diluted	$ (39.45)	$ (39.44)	$ (0.59)

	Three Months Ended June 30, 2024			Six Months Ended June 30, 2024		
	Series A Convertible Preferred Stock	Series B Convertible Preferred Stock	Common Stock	Series A Convertible Preferred Stock	Series B Convertible Preferred Stock	Common Stock
Net loss per share, basic and diluted:						
Numerator						
Allocation of losses	$ (8,129)	$ (7,411)	$ (49,453)	$ (14,962)	$ (13,092)	$ (85,481)
Denominator						
Weighted-average shares outstanding	$ 157,435	$ 143,522	$ 63,854,514	$ 164,029	$ 143,522	$ 62,476,777
Net loss per share, basic and diluted	$ (51.63)	$ (51.64)	$ (0.77)	$ (91.22)	$ (91.22)	$ (1.37)

	Three Months Ended September 30, 2024			Nine Months Ended September 30, 2024		
	Series A Convertible Preferred Stock	Series B Convertible Preferred Stock	Common Stock	Series A Convertible Preferred Stock	Series B Convertible Preferred Stock	Common Stock
Net loss per share, basic and diluted:						
Numerator						
Allocation of losses	$ (9,243)	$ (8,683)	$ (58,763)	$ (24,328)	$ (21,798)	$ (144,097)
Denominator						
Weighted-average shares outstanding	$ 156,699	$ 147,218	$ 66,420,063	$ 161,568	$ 144,763	$ 63,800,798
Net loss per share, basic and diluted	$ (58.99)	$ (58.98)	$ (0.88)	$ (150.57)	$ (150.58)	$ (2.26)

14. INCOME TAXES

Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to reverse.

Since its inception, the Company has incurred net taxable losses, and accordingly, no current provision for income taxes has been recorded. This amount differs from the amount computed by applying the U.S. federal income tax rate of 21% to pretax loss due to the provision of a valuation allowance to the extent of the Company's net deferred tax asset, as well as to state income taxes and nondeductible expenses.

The effective income tax rate of the provision for income taxes differs from the federal statutory rate as follows:

	Year Ended December 31,		
	2024	2023	2022
Federal statutory income tax rate	21.0 %	21.0 %	21.0 %
Federal and state tax credits	2.2	2.3	1.6
State income taxes, net of federal benefit	5.0	5.4	4.2
Change in valuation allowance	(19.5)	(27.6)	(24.5)
Other permanent items	(3.0)	(0.7)	(0.8)
Stock-based compensation	(5.7)	(0.4)	(1.5)
Effective income tax rate	— %	— %	— %

The tax effects of temporary differences that give rise to significant portions of the deferred income tax assets and liabilities are presented below:

	Year Ended December 31,		
	2024	2023	2022
	(in thousands)		
Deferred tax assets:			
Net operating loss carryforwards	$ 77,430	$ 67,755	$ 46,000
Tax credits	15,056	9,231	3,803
Accruals and reserves	9,069	4,891	4,986
Stock-based expense	7,706	15,013	4,161
Start-up costs and amortized costs	12,142	12,750	9,460
IRC § 174 capitalized costs	86,847	45,979	18,252
Unrealized gains/losses	176	71	—
Operating lease right-of-use asset, net	85	44	22
Total deferred tax assets	208,511	155,734	86,684
Valuation allowance	(208,511)	(155,734)	(86,602)
Net deferred tax assets	—	—	82
Deferred tax liabilities:			
Unrealized gains/losses	—	—	$ (82)
Operating lease right-of-use asset, net	—	—	—
Total deferred tax liabilities	—	—	(82)
Total deferred tax assets, net	$ —	$ —	$ —

At December 31, 2024, the Company had approximately $298.3 million and $15.0 million of federal net operating loss and research and experimentation tax carryforwards, respectively, which will begin to expire in 2029 and 2040, respectively. At December 31, 2024, the Company had approximately $322.6 million of state net operating loss carryforwards which will begin to expire in 2029. In addition, the realization of net operating losses to offset potential future taxable income and related income taxes that would otherwise be due is subject to annual limitations under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), and similar state provisions, which may result in the expiration of additional net operating losses before future utilization as a result of ownership changes. As a result of these ownership change provisions during 2020, the Company estimated an aggregate limitation on the utilization of net operating loss carryforwards of $59.0 million. In addition to the limitation of net operating losses of $59.0 million, approximately $15.3 million of research and development tax credits were derecognized with the inability of the Company to ever realize a benefit from those credits in the future. The Company determines on an annual basis whether net operating loss carryforwards will be limited. An IRC 382 analysis has been completed through December 31, 2024 and determined that there was an ownership changes during 2024 with no material effect on the Company's tax attributes. The Company will continue to evaluate changes in ownership and the related limitations on a go forward basis.

As of December 31, 2024 and 2023, the Company's net deferred tax assets before valuation allowance was $208.5 million and $155.7 million, respectively. In assessing the realizability of its deferred tax assets, the Company considers whether it is more likely than not that some portion or all of its deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. The Company considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. As the Company does not have any historical taxable income or projections of future taxable income over the periods in which the deferred tax assets are deductible, and after consideration of its history of operating losses, the Company does not believe it is more likely than not that it will realize the benefits of its net deferred tax assets, and accordingly, has established a valuation allowance equal to 100% of its net deferred tax assets at December 31, 2024 and 2023. The change in valuation allowance was an increase of $52.8 million in 2024, an increase of $69.1 million in 2023 and an increase of $33.2 million in 2022.

The Company concluded that there were no significant uncertain tax positions relevant to the jurisdictions where it is required to file income tax returns requiring recognition in the consolidated financial statements for the years ended 2024 and 2023. As of December 31, 2024 and 2023, the Company had no accrued interest related to uncertain tax positions.

The Company's federal and state returns for 2020 through 2024 remain open to examination by tax authorities.

15. SEGMENT INFORMATION

The Company manages its operations as a single segment, focused on discovering, developing and commercializing potential best-in-class medicines for serious and rare diseases. The Company's Chief Operating Decision Maker ("CODM") is its Chief Executive Officer. The CODM reviews and evaluates consolidated net loss for purposes of assessing performance, making operating decisions, allocating resources, and planning and forecasting for future periods. Operating expenses are used to monitor budget versus actual results. As the Company's operations comprise of a single reporting segment, the segment assets are reflected on the accompanying consolidated balance sheet as "total assets". All equipment, leasehold improvements, and other fixed assets are physically located within the United States and all agreements with the Company's partners are denominated in U.S. dollars, except where noted. Segment asset information is not used by the CODM to allocate resources.

Significant segment expenses, as provided to the CODM, are presented below:

	Year Ended December 31,		
	2024	2023	2022
	(in thousands)		
Segment research and development expense (a)	$ 215,909	$ 143,545	$ 93,597
Segment general and administrative expense (a)	41,278	44,047	22,714
Share-based compensation expense (see Note 11)	42,150	67,172	19,765
Total operating expenses	299,337	254,764	136,076
Other items (b)	(29,388)	(17,030)	(6,202)
Consolidated net loss	$ 269,949	$ 237,734	$ 129,874

(a) Share-based payment expense of $22,345, $16,220, and $7,298 related to research and development and $19,805, $50,952, and $12,467 related to general and administrative have been excluded for the years ended December 31, 2024, 2023, and 2022, respectively, and included within share-based compensation expense.

(b) Other items consist primarily of collaboration revenue, interest income and interest expense.

16. SUBSEQUENT EVENT

Common Stock Sales Agreements - Jefferies LLC

In January 2025, the Company sold 245,388 shares of common stock under the September 2022 ATM Agreement with Jefferies at a weighted average price of $20.14 per share, for aggregate gross proceeds of approximately $4.9 million, before deducting commissions to Jefferies as a sales agent payable by the Company.

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.

VIRIDIAN THERAPEUTICS, INC.

Date: March 3, 2025

By: /s/ Stephen Mahoney
Stephen Mahoney
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: March 3, 2025

By: /s/ Seth Harmon
Seth Harmon
Chief Financial Officer
(Principal Financial Officer; Principal Accounting Officer)

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Stephen Mahoney and Seth Harmon, and each of them, as his or her attorneys-in-fact, with the power of substitution, for him or her in any and all capacities, to sign any 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, hereby ratifying and confirming all that said attorneys-in-fact, and each of them, or his substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of l934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Stephen Mahoney Stephen Mahoney	President, Chief Executive Officer and Director *(Principal Executive Officer)*	March 3, 2025
/s/ Seth Harmon Seth Harmon	Chief Financial Officer *(Principal Financial Officer; Principal Accounting Officer)*	March 3, 2025
/s/ Tomas Kiselak Tomas Kiselak	Chairman of the Board	March 3, 2025
/s/ Sarah Gheuens Sarah Gheuens, M.D., Ph.D.	Director	March 3, 2025
/s/ Peter Harwin Peter Harwin	Director	March 3, 2025
/s/ Arlene Morris Arlene Morris	Director	March 3, 2025
/s/ Jennifer Moses Jennifer Moses	Director	March 3, 2025

Exhibit 4.5

DESCRIPTION OF REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

General

The following is a summary of the material terms of our capital stock, as well as material terms of our second restated certificate of incorporation ("certificate of incorporation"), fourth amended and restated bylaws ("bylaws") and certain provisions of Delaware law. This summary does not purport to be complete and is qualified in its entirety by the provisions of our certificate of incorporation and bylaws, copies of which are filed as exhibits to our Annual Report on Form 10-K, to which this exhibit is also appended.

Our certificate of incorporation, authorizes us to issue up to 200,000,000 shares of common stock, $0.01 par value per share ("Common Stock"), and 5,000,000 shares of preferred stock, $0.01 par value per share, ("Preferred Stock"), of which 435,000 shares are designated as Series A Non-Voting Convertible Preferred Stock, $0.01 par value per share, and 500,000 shares are designated as Series B Non-Voting Convertible Preferred Stock, $0.01 par value per share.

Common Stock

Voting Rights

Each holder of our Common Stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, except on matters relating solely to terms of Preferred Stock. Under our certificate of incorporation and bylaws, our stockholders do not have cumulative voting rights.

Dividends

Subject to preferences that may be applicable to any then-outstanding Preferred Stock, holders of our Common Stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our Common Stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then-outstanding shares of Preferred Stock.

Rights and Preferences

Holders of our Common Stock do not have any preemptive, conversion or subscription rights and there are no redemption or sinking fund provisions applicable to the Common Stock. The rights, preferences and privileges of the holders of Common Stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of Preferred Stock that we may designate in the future.

Fully Paid and Nonassessable

All of our outstanding shares of Common Stock are fully paid and nonassessable.

Preferred Stock

Pursuant to our certificate of incorporation, our board of directors has the authority, without further action by the stockholders (unless such stockholder action is required by applicable law or stock exchange listing rules), to

designate and issue up to 5,000,000 shares of Preferred Stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the designations, powers, preferences, privileges and relative participating, optional or special rights and the qualifications, limitations or restrictions thereof, including dividend rights, conversion rights, voting rights, terms of redemption and liquidation preferences, any or all of which may be greater than the rights of the Common Stock, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors, without stockholder approval, can issue Preferred Stock with voting, conversion or other rights that could adversely affect the voting power and other rights of the holders of Common Stock. Preferred Stock could be issued quickly with terms designed to delay or prevent a change in control of our company or make removal of management more difficult. Additionally, the issuance of Preferred Stock may have the effect of decreasing the market price of the Common Stock and may adversely affect the voting power of holders of Common Stock and reduce the likelihood that holders of our Common Stock will receive dividend payments and payments upon liquidation.

We will fix the designations, voting powers, preferences and rights of the Preferred Stock of each series we issue, as well as the qualifications, limitations or restrictions thereof, in the certificate of designation relating to that series. We will describe the terms of the series of Preferred Stock being offered, including, to the extent applicable:

- the title and stated value;
- the number of shares we are offering;
- the liquidation preference per share;
- the purchase price;
- the dividend rate, period and payment date and method of calculation for dividends;
- whether dividends will be cumulative or non-cumulative and, if cumulative, the date from which dividends will accumulate;
- the procedures for any auction and remarketing;
- the provisions for a sinking fund;
- the provisions for redemption or repurchase and any restrictions on our ability to exercise those redemption and repurchase rights;
- any listing of the Preferred Stock on any securities exchange or market;
- whether the Preferred Stock will be convertible into our Common Stock, and the conversion rate or conversion price, or how they will be calculated, and the conversion period;
- whether the Preferred Stock will be exchangeable into debt securities, and the exchange rate or exchange price, or how they will be calculated, and the exchange period;
- voting rights of the Preferred Stock;
- preemptive rights;

- restrictions on transfer, sale or other assignment;
- whether interests in the Preferred Stock will be represented by depositary shares;
- a discussion of material or special U.S. federal income tax considerations applicable to the Preferred Stock;
- the relative ranking and preferences of the Preferred Stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs;
- any limitations on the issuance of any class or series of Preferred Stock ranking senior to or on a parity with the series of Preferred Stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs; and
- any other specific terms, preferences, rights or limitations of, or restrictions on, the Preferred Stock.

If we issue shares of Preferred Stock, the shares will be fully paid and nonassessable.

The issuance of Preferred Stock could adversely affect the voting power of holders of Common Stock and reduce the likelihood that the holders of our Common Stock will receive dividend payments and payments upon liquidation. The issuance could have the effect of decreasing the market price of the Common Stock. The issuance of Preferred Stock also could have the effect of delaying, deterring or preventing a change in control of us.

Registration Rights

Certain of the holders of our Common Stock are entitled to rights with respect to the registration of such securities as set forth below under the Securities Act of 1933, as amended (the "Securities Act"). These rights are provided under the terms of certain Registration Rights Agreements between us and certain holders of our Common Stock. Under the terms of the Registration Rights Agreements, we have filed a registration statement on Form S-3 to sell registrable securities. We are required to use commercially reasonable efforts to effect a registration of such shares. The Registration Rights Agreements do not include demand registration rights or piggyback registration rights. All fees, costs and expenses of underwritten registrations under these agreements will be borne by us and all selling expenses, including underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

Indemnification

The Registration Rights Agreements contain customary cross-indemnification provisions, under which we are obligated to indemnify holders of registrable securities in the event of material misstatements or omissions in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions attributable to them.

Expenses of Registration

We are generally required to bear all registration and selling expenses incurred in connection with the registration described above, other than underwriting discounts and selling commissions.

Anti-Takeover Provisions

We are subject to Section 203 of the Delaware General Corporation Law, or Section 203. Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder"

for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding upon consummation of the transaction, excluding for purposes of determining the number of shares outstanding (i) shares owned by persons who are directors and also officers and (ii) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or subsequent to the consummation of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 ⅔% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a "business combination" to include:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;

- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and

- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

Certificate of Incorporation and Bylaws

Our certificate of incorporation and bylaws provide that:

- the authorized number of directors can be changed only by resolution of our board of directors;

- our bylaws may be amended or repealed by our board of directors or stockholders;

- our stockholders may not call special meetings of the stockholders or fill vacancies on our board of directors;

- our stockholders may remove our directors only for cause;

- all vacancies, including newly created directorships, may, except as otherwise required by law or subject to the rights of holders of Preferred Stock as designated from time to time, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;

- our board of directors will be authorized to issue, without stockholder approval, Preferred Stock, the rights of which will be determined at the discretion of our board of directors and that, if issued, could operate as a "poison pill" to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that ours board of directors does not approve;

- our stockholders do not have cumulative voting rights, and therefore our stockholders holding a majority of the shares of Common Stock outstanding will be able to elect all of our directors;

- our stockholders must comply with advance notice provisions to bring business before or nominate directors for election at a stockholder meeting; and

- (a) the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have, or declines to accept, jurisdiction, another state court or a federal court located within 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 of our directors, officers or other employee to us or our stockholders, (3) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or bylaws or (4) any action asserting a claim governed by the internal affairs doctrine and (b) the federal district courts of the U.S. will be the sole and exclusive forum for any compliant asserting a cause of action arising under the Securities Act, to the fullest extent permitted by law. Notwithstanding the foregoing, these choice of forum provisions do not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage certain types of transactions that may involve an actual or threatened acquisition of us. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal. The provisions also are intended to discourage certain tactics that may be used in proxy fights. However, these provisions could have the effect of discouraging others from making tender offers for our shares and, as a consequence, they may also reduce fluctuations in the market price of our shares that could result from actual or rumored takeover attempts.

Potential Effects of Authorized but Unissued Stock

Our shares of Common Stock and Preferred Stock are available for future issuance without stockholder approval. We may utilize these additional shares for a variety of corporate purposes, including future public offerings to raise additional capital, to facilitate corporate acquisitions or payment as a dividend on the capital stock.

The existence of unissued and unreserved Common Stock and Preferred Stock may enable our board of directors to issue shares to persons friendly to current management or to issue Preferred Stock with terms that could render more difficult or discourage a third-party attempt to obtain control by means of a merger, tender offer, proxy contest or otherwise, thereby protecting the continuity of our management. In addition, our board of directors has the discretion to determine designations, rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences of each series of Preferred Stock, all to

the fullest extent permissible under the Delaware General Corporation Law and subject to any limitations set forth in our certificate of incorporation. The purpose of authorizing the board of directors to issue Preferred Stock and to determine the rights and preferences applicable to such Preferred Stock is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of Preferred Stock, while providing desirable flexibility in connection with possible financings, acquisitions and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from acquiring, a majority of our outstanding voting stock.

Amendments to Governing Documents

Generally, the amendment of our certificate of incorporation requires approval by our board of directors and a majority vote of stockholders. Any amendment to our bylaws requires the approval of either a majority of our board of directors or approval of at least a majority of the votes entitled to be cast by the holders of our outstanding capital stock in elections of our board of directors.

Listing

Our Common Stock is listed on The Nasdaq Capital Market under the symbol "VRDN."

Transfer Agent and Registrar

The transfer agent and registrar for our Common Stock, our Series A Preferred Stock and our Series B Preferred Stock is Computershare Trust Company, N.A.. The transfer agent and registrar's address is 150 Royall Street, Canton, MA 02021.

Exhibit 10.38

VIRIDIAN THERAPEUTICS, INC. AMENDMENT TO EMPLOYMENT AGREEMENT

Effective January 1, 2025 (the "**Effective Date**"), Viridian Therapeutics, Inc. (the "**Company**") and Steve Mahoney ("**Executive**") enter into this A**MENDMENT** (the "**Amendment**") to the **EMPLOYMENT AGREEMENT** between them dated October 27, 2023 (the "**Agreement**"). Capitalized terms used herein but not otherwise defined shall have the respective meanings given to them in the Agreement.

1. Section 7(b) of the Agreement shall be replaced in its entirety with the following:

(b) Disability. For purposes of this Agreement, "**Disability**" means the inability of Executive to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or that has lasted or can be expected to last for a continuous period of not less than twelve (12) months, as provided in Sections 22(e)(3) and 409A(a)(2)(c)(i) of the Code, and will be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances. A termination of Executive's employment for Disability shall be communicated to Executive by written notice, and shall be effective on the 10th day after sending such notice to Executive (the "**Disability Effective Date**"), unless Executive returns to performance of Executive's duties before the Disability Effective Date

2. Section 7(e) of the Agreement shall be replaced in its entirety with the following:

(e) Termination by Executive for Good Reason. Executive may terminate Executive's employment with the Company by resigning from employment with the Company for Good Reason. The term "**Good Reason**" shall mean the occurrence, without Executive's consent, of any one or more of the following: (i) a material reduction in Executive's base salary of ten percent (10%) or more (unless such reduction is pursuant to a salary reduction program applicable generally to the Company's similarly situated executives); (ii) a material reduction in Executive's authority, duties or responsibilities; provided, however, that (a) the acquisition of the Company and subsequent conversion of the Company to a subsidiary, division or unit of the acquiring company will not by itself result in a reduction of Executive's position and (b) a change in title, reporting relationships and/or responsibilities of the Executive could, but do not necessarily in and of themselves, individually or in the aggregate, constitute a material reduction for purposes of this Section 7(e), and in all instances, the determination of whether a material reduction has occurred shall be made by the Company in good faith (except that this Section (e)(ii)(b) does not apply in connection with a Change in Control); (iii) a relocation of Executive's principal place of employment with the Company (or its successor, if applicable) to a place that increases Executive's one-way commute by more than twenty five (25) miles as compared to

Executive's then-current principal place of employment immediately prior to such relocation, except for required travel by Executive on the Company's business to an extent substantially consistent with Executive's business travel obligations prior to such relocation; or (iv) material breach by the Company of any material provision of this Agreement.

No resignation for Good Reason shall be effective unless (1) Executive provides written notice, within thirty (30) days after the first occurrence of the event giving rise to Good Reason, to the Chairman of the Board setting forth in reasonable detail the material facts constituting Good Reason and the reasonable steps Executive believes necessary to cure, (2) the Company has had thirty (30) business days from the date of such notice to cure any such occurrence otherwise constituting Good Reason, and (3) if such event is not reasonably cured within such period, Executive must resign from all positions Executive then holds with the Company (including any position as a member of the Board) effective not later than fifteen (15) days after the expiration of the cure period. Further, no resignation for Good Reason shall be effective if prior to Executive's written notice of resignation for Good Reason the Company first provided Executive notice of its intent to terminate Executive's employment for any reason.

3. Section 8(c) of the Agreement shall be replaced in its entirety with the following:

(c) Involuntary Termination in Connection with a Change in Control. In the event that Executive's Involuntary Termination occurs during the one (1) month period prior to, on or within the twelve (12) months following the consummation of a Change in Control (as defined below) and subject in all events to Executive's compliance with Section 8(d) below, then Executive: (i) shall be entitled to the benefits provided above in Sections 8(b)(i) and (iii), except that the Severance Period shall be twenty-four (24) months after the date of such termination instead of eighteen (18) months, (ii) the vesting of all of Executive's outstanding stock options and other equity awards that are subject to time-based vesting requirements shall accelerate in full such that all such equity awards shall be deemed fully vested as of the date of Executive's Involuntary Termination; and (iii) Executive shall receive two (2) times his Annual Performance Bonus at the full Target Amount (at the target percentage then in effect for Executive) within thirty (30) days after the effective date of Executive's Involuntary Termination. For the avoidance of doubt, in no event shall Executive be entitled to benefits under both Section 8(b) and this Section 8(c). If Executive is eligible for benefits under both Section 8(b) and this Section 8(c), Executive shall receive the benefits set forth in this Section 8(c) and such benefits will be reduced by any benefits previously provided to Executive under Section 8(b).

4. Section 10 of the Agreement shall be replaced in its entirety with the following:

Governing Law; Venue; Jurisdiction; Jury Waiver. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, without regard to the conflicts of laws principles thereof. In addition, Executive acknowledges that because Executive will have regular interaction with Company representatives based in Massachusetts, any dispute concerning this Agreement shall be heard only and exclusively by a court of competent jurisdiction within Massachusetts. Executive acknowledges that Executive is subject, and hereby consents, to the personal jurisdiction and venue of the Massachusetts courts in any county where the Company has operations. Both parties further agree that any such dispute shall be tried by a judge alone, and both parties hereby waive and forever renounce the right to a trial before a civil jury in any such dispute. Notwithstanding the foregoing, if Executive lives in California, then the jury waiver shall not apply, and this Agreement shall be governed by the laws of the State of California and any dispute shall be adjudicated in the state or federal courts within California.

5. Section 13(a) of the Agreement shall be replaced in its entirety with the following:

(a) Reserved.

6. All other terms and conditions of the Agreement shall remain in full force and effect.

7. In consideration for the severance and other benefits provided in this Amendment, which Executive acknowledges is mutually agreed upon, Executive agrees to promptly execute and abide by the *Invention Assignment, Non-Disclosure, Non-Competition and Non-Solicitation Agreement* attached as **Exhibit A** (the "**Restrictive Covenants Agreement**"), which shall replace in its entirety Exhibit A of the Agreement and which is and shall be construed as a separate and independent agreement.

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment as of the 25th day of February, 2025.

Viridian Therapeutics, Inc.

By: /s/ Seth Harmon
Seth Harmon
Chief Financial Officer

Executive:

/s/ Steve Mahoney

Steve Mahoney

Attachment

Exhibit A - Invention Assignment, Non-Disclosure, Non-Competition and Non-Solicitation Agreement

4

Exhibit 10.39

VIRIDIAN THERAPEUTICS, INC. AMENDMENT TO EMPLOYMENT AGREEMENT

Effective January 1, 2025 (the "**Effective Date**"), Viridian Therapeutics, Inc. (the "**Company**") and Thomas Beetham ("**Executive**") enter into this **AMENDMENT** (the "**Amendment**") to the **EMPLOYMENT AGREEMENT** between them dated October 27, 2023 (the "**Agreement**"). Capitalized terms used herein but not otherwise defined shall have the respective meanings given to them in the Agreement.

1. Section 7(b) of the Agreement shall be replaced in its entirety with the following:

> (b) Disability. For purposes of this Agreement, "**Disability**" means the inability of Executive to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or that has lasted or can be expected to last for a continuous period of not less than twelve (12) months, as provided in Sections 22(e)(3) and 409A(a)(2)(c)(i) of the Code, and will be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances. A termination of Executive's employment for Disability shall be communicated to Executive by written notice, and shall be effective on the 10th day after sending such notice to Executive (the "**Disability Effective Date**"), unless Executive returns to performance of Executive's duties before the Disability Effective Date

2. Section 7(e) of the Agreement shall be replaced in its entirety with the following:

> (e) Termination by Executive for Good Reason. Executive may terminate Executive's employment with the Company by resigning from employment with the Company for Good Reason. The term "Good Reason" shall mean the occurrence, without Executive's consent, of any one or more of the following: (i) a material reduction in Executive's base salary of ten percent (10%) or more (unless such reduction is pursuant to a salary reduction program applicable generally to the Company's similarly situated executives); (ii) a material reduction in Executive's authority, duties or responsibilities; provided, however, that (a) the acquisition of the Company and subsequent conversion of the Company to a subsidiary, division or unit of the acquiring company will not by itself result in a reduction of Executive's position and (b) a change in title, reporting relationships and/or responsibilities of the Executive could, but do not necessarily in and of themselves, individually or in the aggregate, constitute a material reduction for purposes of this Section 7(e), and in all instances, the determination of whether a material reduction has occurred shall be made by the Company in good faith (except that this Section (e)(ii)(b) does not apply in connection with a Change in Control); (iii) a relocation of Executive's principal place of employment with the Company (or its successor, if applicable) to a place that increases Executive's one-way commute by more than twenty five (25) miles as compared to

Executive's then-current principal place of employment immediately prior to such relocation, except for required travel by Executive on the Company's business to an extent substantially consistent with Executive's business travel obligations prior to such relocation; or (iv) material breach by the Company of any material provision of this Agreement.

No resignation for Good Reason shall be effective unless (1) Executive provides written notice, within thirty (30) days after the first occurrence of the event giving rise to Good Reason, to the Chairman of the Board setting forth in reasonable detail the material facts constituting Good Reason and the reasonable steps Executive believes necessary to cure, (2) the Company has had thirty (30) business days from the date of such notice to cure any such occurrence otherwise constituting Good Reason, and (3) if such event is not reasonably cured within such period, Executive must resign from all positions Executive then holds with the Company (including any position as a member of the Board) effective not later than fifteen (15) days after the expiration of the cure period. Further, no resignation for Good Reason shall be effective if prior to Executive's written notice of resignation for Good Reason the Company first provided Executive notice of its intent to terminate Executive's employment for any reason.

3. Section 8(c) of the Agreement shall be replaced in its entirety with the following:

(c) Involuntary Termination in Connection with a Change in Control. In the event that Executive's Involuntary Termination occurs during the one (1) month period prior to, on or within the twelve (12) months following the consummation of a Change in Control (as defined below) and subject in all events to Executive's compliance with Section 8(d) below, then Executive: (i) shall be entitled to the benefits provided above in Sections 8(b)(i) and (iii); (ii) the vesting of all of Executive's outstanding stock options and other equity awards that are subject to time-based vesting requirements shall accelerate in full such that all such equity awards shall be deemed fully vested as of the date of Executive's Involuntary Termination; and (iii) Executive shall receive their Annual Performance Bonus at the full Target Amount (at the target percentage then in effect for Executive) within thirty (30) days after the effective date of Executive's Involuntary Termination. For the avoidance of doubt, in no event shall Executive be entitled to benefits under both Section 8(b) and this Section 8(c). If Executive is eligible for benefits under both Section 8(b) and this Section 8(c), Executive shall receive the benefits set forth in this Section 8(c) and such benefits will be reduced by any benefits previously provided to Executive under Section 8(b).

4. Section 10 of the Agreement shall be replaced in its entirety with the following:

Governing Law; Venue; Jurisdiction; Jury Waiver. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts,

without regard to the conflicts of laws principles thereof. In addition, Executive acknowledges that because Executive will have regular interaction with Company representatives based in Massachusetts, any dispute concerning this Agreement shall be heard only and exclusively by a court of competent jurisdiction within Massachusetts. Executive acknowledges that Executive is subject, and hereby consents, to the personal jurisdiction and venue of the Massachusetts courts in any county where the Company has operations. Both parties further agree that any such dispute shall be tried by a judge alone, and both parties hereby waive and forever renounce the right to a trial before a civil jury in any such dispute. Notwithstanding the foregoing, if Executive lives in California, then the jury waiver shall not apply, and this Agreement shall be governed by the laws of the State of California and any dispute shall be adjudicated in the state or federal courts within California.

5. Section 13(a) of the Agreement shall be replaced in its entirety with the following:

   (a) Reserved.

6. All other terms and conditions of the Agreement shall remain in full force and effect.

7. In consideration for the severance and other benefits provided in this Amendment, which Executive acknowledges is mutually agreed upon, Executive agrees to promptly execute and abide by the *Invention Assignment, Non-Disclosure, Non-Competition and Non-Solicitation Agreement* attached as **Exhibit A** (the "**Restrictive Covenants Agreement**"), which shall replace in its entirety Exhibit A of the Agreement and which is and shall be construed as a separate and independent agreement.

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment as of the 25th day of February, 2025.

Viridian Therapeutics, Inc.

By: /s/ Stephen Mahoney
Stephen Mahoney
President and CEO

Executive:

/s/ Thomas Beetham

Thomas Beetham

Attachment

Exhibit A - Invention Assignment, Non-Disclosure, Non-Competition and Non-Solicitation Agreement

Exhibit 10.40

VIRIDIAN THERAPEUTICS, INC. AMENDMENT TO EMPLOYMENT AGREEMENT

Effective January 1, 2025 (the "**Effective Date**"), Viridian Therapeutics, Inc. (the "**Company**") and Seth Harmon ("**Executive**") enter into this **AMENDMENT** (the "**Amendment**") to the **EMPLOYMENT AGREEMENT** between them dated April 24, 2023, as amended on September 28, 2023 (the "**Agreement**"). Capitalized terms used herein but not otherwise defined shall have the respective meanings given to them in the Agreement.

1. The phrase "SVP, Finance & Accounting" in Section 2 of the Agreement is hereby replaced with "Chief Financial Officer."

2. Section 7(b) of the Agreement shall be replaced in its entirety with the following:

(b) Disability. For purposes of this Agreement, "**Disability**" means the inability of Executive to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or that has lasted or can be expected to last for a continuous period of not less than twelve (12) months, as provided in Sections 22(e)(3) and 409A(a)(2)(c)(i) of the Code, and will be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances. A termination of Executive's employment for Disability shall be communicated to Executive by written notice, and shall be effective on the 10th day after sending such notice to Executive (the "**Disability Effective Date**"), unless Executive returns to performance of Executive's duties before the Disability Effective Date.

3. The phrase "Continuous Service" in the last sentence of Section 7(c) of the Agreement is hereby replaced with the word "employment."

4. Section 7(e) of the Agreement shall be replaced in its entirety with the following:

(e) Termination by Executive for Good Reason. Executive may terminate Executive's employment with the Company by resigning from employment with the Company for Good Reason. The term "**Good Reason**" shall mean the occurrence, without Executive's consent, of any one or more of the following: (i) a material reduction in Executive's base salary of ten percent (10%) or more (unless such reduction is pursuant to a salary reduction program applicable generally to the Company's similarly situated executives); (ii) a material reduction in Executive's authority, duties or responsibilities; provided, however, that (a) the acquisition of the Company and subsequent conversion of the Company to a subsidiary, division or unit of the acquiring company will not by itself result in a reduction of Executive's position

and (b) a change in title, reporting relationships and/or responsibilities of the Executive could, but do not necessarily in and of themselves, individually or in the aggregate, constitute a material reduction for purposes of this Section 7(e), and in all instances, the determination of whether a material reduction has occurred shall be made by the Company in good faith (except that this Section (e)(ii)(b) does not apply in connection with a Change in Control); (iii) a relocation of Executive's principal place of employment with the Company (or its successor, if applicable) to a place that increases Executive's one-way commute by more than twenty five (25) miles as compared to Executive's then-current principal place of employment immediately prior to such relocation, except for required travel by Executive on the Company's business to an extent substantially consistent with Executive's business travel obligations prior to such relocation; or (iv) material breach by the Company of any material provision of this Agreement.

No resignation for Good Reason shall be effective unless (1) Executive provides written notice, within thirty (30) days after the first occurrence of the event giving rise to Good Reason, to the Chairman of the Board setting forth in reasonable detail the material facts constituting Good Reason and the reasonable steps Executive believes necessary to cure, (2) the Company has had thirty (30) business days from the date of such notice to cure any such occurrence otherwise constituting Good Reason, and (3) if such event is not reasonably cured within such period, Executive must resign from all positions Executive then holds with the Company (including any position as a member of the Board) effective not later than fifteen (15) days after the expiration of the cure period. Further, no resignation for Good Reason shall be effective if prior to Executive's written notice of resignation for Good Reason the Company first provided Executive notice of its intent to terminate Executive's employment for any reason.

5. Section 8(c) of the Agreement shall be replaced in its entirety with the following:

(c) Involuntary Termination in Connection with a Change in Control. In the event that Executive's Involuntary Termination occurs during the one (1) month period prior to, on or within the twelve (12) months following the consummation of a Change in Control (as defined below) and subject in all events to Executive's compliance with Section 8(d) below, then Executive: (i) shall be entitled to the benefits provided above in Sections 8(b)(i) and (iii); (ii) the vesting of all of Executive's outstanding stock options and other equity awards that are subject to time-based vesting requirements shall accelerate in full such that all such equity awards shall be deemed fully vested as of the date of Executive's Involuntary Termination; and (iii) Executive shall receive their Annual Performance Bonus at the full Target Amount (at the target percentage then in effect for Executive) within thirty (30) days after the effective date of Executive's Involuntary Termination. For the avoidance of doubt, in no event shall Executive be entitled to benefits under both Section 8(b) and this Section 8(c). If Executive is eligible for benefits under both Section 8(b) and this Section 8(c), Executive shall receive the benefits set forth in this Section 8(c) and such benefits will be reduced by any benefits previously provided to Executive under Section 8(b).

6. Section 10 of the Agreement shall be replaced in its entirety with the following:

   Governing Law; Venue; Jurisdiction; Jury Waiver. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, without regard to the conflicts of laws principles thereof. In addition, Executive acknowledges that because Executive will have regular interaction with Company representatives based in Massachusetts, any dispute concerning this Agreement shall be heard only and exclusively by a court of competent jurisdiction within Massachusetts. Executive acknowledges that Executive is subject, and hereby consents, to the personal jurisdiction and venue of the Massachusetts courts in any county where the Company has operations. Both parties further agree that any such dispute shall be tried by a judge alone, and both parties hereby waive and forever renounce the right to a trial before a civil jury in any such dispute. Notwithstanding the foregoing, if Executive lives in California, then the jury waiver shall not apply, and this Agreement shall be governed by the laws of the State of California and any dispute shall be adjudicated in the state or federal courts within California.

7. Section 13(a) of the Agreement shall be replaced in its entirety with the following:

   (a) Reserved.

8. All other terms and conditions of the Agreement shall remain in full force and effect.

9. In consideration for the severance and other benefits provided in this Amendment, which Executive acknowledges is mutually agreed upon, Executive agrees to promptly execute and abide by the *Invention Assignment, Non-Disclosure, Non-Competition and Non-Solicitation Agreement* attached as **Exhibit A** (the "**Restrictive Covenants Agreement**"), which shall replace in its entirety Exhibit A of the Agreement and which is and shall be construed as a separate and independent agreement.

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment as of the 25th day of February, 2025.

Viridian Therapeutics, Inc.

By: /s/ Stephen Mahoney
Stephen Mahoney
President and CEO

Executive:

/s/ Seth Harmon

Seth Harmon

Attachment
Exhibit A - Invention Assignment, Non-Disclosure, Non-Competition and Non-Solicitation Agreement

Exhibit 10.41

VIRIDIAN THERAPEUTICS, INC. AMENDMENT TO EMPLOYMENT AGREEMENT

Effective January 1, 2025 (the "**Effective Date**"), Viridian Therapeutics, Inc. (the "**Company**") and Jennifer Tousignant ("**Executive**") enter into this **AMENDMENT** (the "**Amendment**") to the **EMPLOYMENT AGREEMENT** between them dated January 10, 2024 (the "**Agreement**"). Capitalized terms used herein but not otherwise defined shall have the respective meanings given to them in the Agreement.

1. Section 7(b) of the Agreement shall be replaced in its entirety with the following:

   (b) Disability. For purposes of this Agreement, "**Disability**" means the inability of Executive to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or that has lasted or can be expected to last for a continuous period of not less than twelve (12) months, as provided in Sections 22(e)(3) and 409A(a)(2)(c)(i) of the Code, and will be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances. A termination of Executive's employment for Disability shall be communicated to Executive by written notice, and shall be effective on the 10th day after sending such notice to Executive (the "**Disability Effective Date**"), unless Executive returns to performance of Executive's duties before the Disability Effective Date.

2. The phrase "Continuous Service" in the last sentence of Section 7(c) of the Agreement is hereby replaced with the word "employment."

3. Section 7(e) of the Agreement shall be replaced in its entirety with the following:

   (e) Termination by Executive for Good Reason. Executive may terminate Executive's employment with the Company by resigning from employment with the Company for Good Reason. The term "**Good Reason**" shall mean the occurrence, without Executive's consent, of any one or more of the following: (i) a material reduction in Executive's base salary of ten percent (10%) or more (unless such reduction is pursuant to a salary reduction program applicable generally to the Company's similarly situated executives); (ii) a material reduction in Executive's authority, duties or responsibilities; provided, however, that (a) the acquisition of the Company and subsequent conversion of the Company to a subsidiary, division or unit of the acquiring company will not by itself result in a reduction of Executive's position and (b) a change in title, reporting relationships and/or responsibilities of the Executive could, but do not necessarily in and of themselves, individually or in the aggregate, constitute a material reduction for purposes of this Section 7(e), and in all instances, the determination of whether a material reduction has occurred shall be made by the

Company in good faith (except that this Section (e)(ii)(b) does not apply in connection with a Change in Control); (iii) a relocation of Executive's principal place of employment with the Company (or its successor, if applicable) to a place that increases Executive's one-way commute by more than twenty five (25) miles as compared to Executive's then-current principal place of employment immediately prior to such relocation, except for required travel by Executive on the Company's business to an extent substantially consistent with Executive's business travel obligations prior to such relocation; or (iv) material breach by the Company of any material provision of this Agreement.

No resignation for Good Reason shall be effective unless (1) Executive provides written notice, within thirty (30) days after the first occurrence of the event giving rise to Good Reason, to the Chairman of the Board setting forth in reasonable detail the material facts constituting Good Reason and the reasonable steps Executive believes necessary to cure, (2) the Company has had thirty (30) business days from the date of such notice to cure any such occurrence otherwise constituting Good Reason, and (3) if such event is not reasonably cured within such period, Executive must resign from all positions Executive then holds with the Company (including any position as a member of the Board) effective not later than fifteen (15) days after the expiration of the cure period. Further, no resignation for Good Reason shall be effective if prior to Executive's written notice of resignation for Good Reason the Company first provided Executive notice of its intent to terminate Executive's employment for any reason.

4. Section 8(c) of the Agreement shall be replaced in its entirety with the following:

(c) Involuntary Termination in Connection with a Change in Control. In the event that Executive's Involuntary Termination occurs during the one (1) month period prior to, on or within the twelve (12) months following the consummation of a Change in Control (as defined below) and subject in all events to Executive's compliance with Section 8(d) below, then Executive: (i) shall be entitled to the benefits provided above in Sections 8(b)(i) and (iii); (ii) the vesting of all of Executive's outstanding stock options and other equity awards that are subject to time-based vesting requirements shall accelerate in full such that all such equity awards shall be deemed fully vested as of the date of Executive's Involuntary Termination; and (iii) Executive shall receive their Annual Performance Bonus at the full Target Amount (at the target percentage then in effect for Executive) within thirty (30) days after the effective date of Executive's Involuntary Termination. For the avoidance of doubt, in no event shall Executive be entitled to benefits under both Section 8(b) and this Section 8(c). If Executive is eligible for benefits under both Section 8(b) and this Section 8(c), Executive shall receive the benefits set forth in this Section 8(c) and such benefits will be reduced by any benefits previously provided to Executive under Section 8(b).

5. Section 10 of the Agreement shall be replaced in its entirety with the following:

Governing Law; Venue; Jurisdiction; Jury Waiver. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, without regard to the conflicts of laws principles thereof. In addition, Executive acknowledges that because Executive will have regular interaction with Company representatives based in Massachusetts, any dispute concerning this Agreement shall be heard only and exclusively by a court of competent jurisdiction within Massachusetts. Executive acknowledges that Executive is subject, and hereby consents, to the personal jurisdiction and venue of the Massachusetts courts in any county where the Company has operations. Both parties further agree that any such dispute shall be tried by a judge alone, and both parties hereby waive and forever renounce the right to a trial before a civil jury in any such dispute. Notwithstanding the foregoing, if Executive lives in California, then the jury waiver shall not apply, and this Agreement shall be governed by the laws of the State of California and any dispute shall be adjudicated in the state or federal courts within California.

6. Section 13(a) of the Agreement shall be replaced in its entirety with the following:

   (a) Reserved.

7. All other terms and conditions of the Agreement shall remain in full force and effect.

8. In consideration for the severance and other benefits provided in this Amendment, which Executive acknowledges is mutually agreed upon, Executive agrees to promptly execute and abide by the *Invention Assignment, Non-Disclosure, Non-Competition and Non-Solicitation Agreement* attached as **Exhibit A** (the "**Restrictive Covenants Agreement**"), which shall replace in its entirety Exhibit A of the Agreement and which is and shall be construed as a separate and independent agreement.

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment as of the 25th day of February, 2025.

Viridian Therapeutics, Inc.

By: /s/ Stephen Mahoney
Stephen Mahoney
President and CEO

Executive:

/s/ Jennifer Tousignant

Jennifer Tousignant

Attachment

Exhibit A - Invention Assignment, Non-Disclosure, Non-Competition and Non-Solicitation Agreement

Exhibit 19

INSIDER TRADING POLICY
(Approved February 12, 2025)

I. INTRODUCTION

Federal and state laws prohibit buying, selling or making other transfers of securities by persons who have material information that is not generally known or available to the public. These laws also prohibit persons with such Material Nonpublic Information from disclosing this information to others who trade. Trading while in possession of Material Nonpublic Information is often referred to as "insider trading."

Who Is Subject to this Policy. Viridian Therapeutics, Inc. (the "Company") has adopted the following policy (this "Policy") regarding trading in securities by directors, officers, employees, and consultants (together, "Company Personnel") as well as their family members who reside with them, anyone else who lives in their household, and any family members who do not live in their household but whose transactions in Company securities (as defined below) are directed by them or are subject to their influence or control (collectively, "Family Members"), and corporations or other business entities controlled, influenced, or managed by them or their Family Members, and trusts for which such persons are a trustee or in which they have a beneficial or pecuniary interest (collectively, "Controlled Entities," and together with "Company Personnel" and "Family Members," "Insiders"). Unless otherwise indicated, all references to "you" in this Policy should be read to include all of your Family Members and Controlled Entities.

Which Securities Are Subject to this Policy. This Policy applies to transactions, whether direct or indirect, in the Company's securities, including its common stock, options to purchase common stock, restricted stock or restricted stock units, or any other type of securities that the Company may issue from time to time, including but not limited to preferred stock and convertible debentures, as well as derivative securities relating to the Company but that are not issued by the Company, such as exchange-traded put or call options or swaps relating to the Company's securities. Similarly, this Policy applies to all securities issued by a Related Company (as defined below), as well as any derivative securities, such as puts, calls, or swaps relating to a Related Company's securities. When this Policy refers to another entity's "securities," it refers to its common stock, options to purchase common stock, or any other type of securities that the entity may issue, as well as derivative securities relating to that entity but that are not issued by that entity.

No Exceptions. The securities laws do not recognize any mitigating circumstances, and, in any event, even the appearance of an improper transaction must be avoided to preserve the Company's reputation for adhering to high standards of conduct.

Individual Responsibility. You are responsible for ensuring that you (as well as your Family Members and Controlled Entities) do not violate federal or state securities laws or this Policy. We designed this Policy to promote compliance with the federal securities laws and to protect the Company and you from the serious liabilities and penalties that can result from violations of these laws.

Consequences for Violating Insider Trading Laws. If you violate the insider trading laws, you may have to pay civil fines for up to three times the profit gained or loss avoided by such trading, as well as criminal fines of up to $5 million. You also may have to serve a jail sentence of up to 20 years. In addition, the Company may face civil penalties up to the greater of $1 million, or three times the profit gained or loss avoided as a result of your insider trading violations, as well as criminal fines of up to $25 million.

Both the Securities and Exchange Commission ("SEC") and The Nasdaq Stock Market ("Nasdaq") are very effective at detecting and pursuing insider trading cases. The SEC has successfully prosecuted cases against employees trading through foreign accounts, trading by family members and friends, and trading involving only a small number of shares. Therefore, it is important that you understand the breadth of activities that constitute illegal insider trading. This Policy sets out the Company's policy in the area of insider trading and should be read carefully and complied with fully.

Administrative Provisions. All Company Personnel will be required to certify their understanding of and intent to comply with this Policy by signing the Acknowledgment attached hereto periodically. This Policy will be reviewed, evaluated, and revised by the Company from time to time in light of regulatory changes, developments in the Company's business, and other factors.

II. POLICIES AND PROCEDURES

A. Trading Policy

1. *General Prohibition.* You may not buy, sell or gift the Company's securities when you have Material Nonpublic Information about the Company. This Policy against "insider trading" applies to trading in any form of the Company's securities, as well as to trading in the securities of other companies with whom the Company has a business relationship, such as the Company's customers, distributors and suppliers, licensing, collaboration or joint-venture counterparties, contract research organizations, contract manufacturing organizations, or a firm with which the Company is negotiating a major transaction (a "Related Company").

2. *No Tipping.* You may not convey Material Nonpublic Information about the Company or a Related Company to others. You also may not suggest that anyone purchase or sell the securities of the Company or a Related Company while you are aware of Material Nonpublic Information about the Company or a Related Company, respectively. These practices, known as "tipping," also violate the U.S. securities laws and can result in the same civil and criminal penalties that apply if you engage in insider trading directly, even if you do not receive any money or derive any benefit from trades made by persons to whom you passed Material Nonpublic Information. This Policy against "tipping" applies to information about the Company and its securities, as well as to information about Related Companies and their respective securities. Persons with whom you have a history, pattern, or practice of sharing confidences—such as family members, close friends, and financial and personal counselors—may be presumed to act on the basis of information known to you; therefore, special care should be taken so that Material Nonpublic Information is not disclosed to such persons. This Policy does not restrict legitimate business communications on a "need to know" basis. Material Nonpublic Information, however,

should not be disclosed to persons outside the Company unless you are specifically authorized to disclose such information and such disclosure is made in accordance with the Company's policies regarding the protection or authorized external disclosure of information regarding the Company.

3. *No Short-Term or Speculative Trading.* Our directors and executive offices subject to Section 16 of the Securities and Exchange Act of 1934, as amended ("Section 16 officers") may not engage in short-term or speculative transactions in the securities of the Company or any Related Company. As such, our directors and Section 16 officers may not engage in: (a) short-term trading (generally defined as selling Company securities within six months following a purchase); (b) short sales (selling Company securities you do not own); (c) transactions involving publicly traded options or other derivatives, such as trading in puts or calls with respect to Company securities; and (d) hedging transactions (such as "cashless" collars, forward sales, equity swaps, and other similar arrangements).

4. *Pledging.* Because securities held in a margin account or pledged as collateral may be sold without your consent, if you fail to meet a margin call or if you default on a loan, a margin or foreclosure sale may result in unlawful insider trading. The Company's directors and Section 16 officers are prohibited from holding the Company's securities in a margin account or pledging the Company's securities as collateral for a loan. An exception may be granted where an individual wishes to pledge Company securities as collateral for a loan (not including margin debt) and clearly demonstrates the financial capacity to repay the loan without resort to the pledged securities. If an individual wishes to pledge Company securities as collateral for a loan, she or he must submit a request for approval to the Company's Chief Legal Officer at least two weeks prior to the proposed execution of documents evidencing the proposed pledge.

5. *No Standing or Limit Orders.* Standing and limit orders (except standing and limit orders under Rule 10b5-1 Trading Plans, as described herein) create heightened risks for insider trading violations similar to the use of margin accounts. There is no control over the timing of purchases or sales that result from standing instructions to a broker, and as a result the broker could execute a transaction when a director, officer, or other employee is in possession of Material Nonpublic Information. The Company therefore discourages placing standing or limit orders on Company securities other than pursuant to Rule 10b5-1 Trading Plans. If a person subject to this Policy determines that they must use a standing order or limit order (other than pursuant to an approved Rule 10b5-1 Trading Plan), that person must contact the Chief Legal Officer for clearance to place the order.

6. *Applying the Policy.* As stated above, these restrictions also apply to your Family Members and Controlled Entities. The SEC and federal prosecutors may presume that trading by Family Members or Controlled Entities is based on information you supplied and may treat any such transactions as if you had traded yourself. There is no exception for small transactions or transactions that may seem necessary or justifiable for independent reasons, such as the need to raise money for an emergency expenditure.

For purposes of this Policy, references to "trading" and "transactions" include, among other things:

- purchases and sales of Company securities in public markets;

- sales of Company securities obtained through the exercise of employee stock options granted by the Company;
- making gifts of Company securities; and
- using Company securities to secure a loan.

Company Personnel should consult the Chief Legal Officer if they have any questions.

7. *Company Transactions.* From time to time, the Company may engage in transactions in its own securities. It is the Company's policy to comply with all applicable securities and state laws (including appropriate approvals by the Board of Directors or appropriate committee, if required) when engaging in transactions in Company securities. The Company strives to avoid engaging in transactions in respect of Company securities, or adopting any securities repurchase plans, when it is in possession of Material Non-public Information concerning itself, other than in compliance with applicable law.

B. What is "Material Nonpublic Information"? When is Information "Public"?

1. *Material Information*

Material information generally means information for which there is a substantial likelihood that a reasonable investor would consider important in making an investment decision to buy, hold, or sell securities. Either positive or negative information may be material. There is no bright-line standard for assessing materiality; rather, materiality is based on an assessment of all the facts and circumstances. With respect to contingent or speculative events, a materiality assessment requires balancing the probability that the event will occur and the anticipated magnitude of the event. Depending on the circumstances, common examples of information that may be material include:

- significant new product developments, innovations, or discoveries;
- pending U.S. Food and Drug Administration, European Medicines Agency or other regulatory action;
- clinical data or significant interactions, approval, or rulings by a regulatory agency relating to the Company or a Company product;
- status of pre-clinical or clinical studies;
- earnings, revenue, or similar financial information;
- unexpected financial results;
- unpublished financial reports or projections;
- extraordinary borrowing or liquidity problems;

- changes in control or sale of all or part of the Company's business;
- changes in directors, senior management, or auditors;
- information about current, proposed, or contemplated transactions, business plans, financial restructurings, acquisition targets, or significant expansions or contractions of operations;
- changes in dividend policies, the declaration of a stock split or the proposed or contemplated issuance, redemption, or repurchase of securities;
- negotiations regarding an important license, distribution agreement, joint venture, or collaboration agreement;
- material defaults under agreements or actions by creditors, clients, or suppliers relating to the Company's credit rating;
- information about major contracts;
- gain or loss of a significant customer or supplier;
- significant cybersecurity incidents, events, or risks that affect the Company or third- party providers that support the Company's business operations, including computer system or network compromises, viruses or other destructive software, and data breach incidents that may disclose personal, business, or other confidential information;
- product recalls;
- impending financial problems;
- the interruption of production or other aspects of the Company's business as a result of an accident, fire, natural disaster, public health emergency, or breakdown of labor negotiations;
- major environmental incidents;
- institution of, or developments in, major litigation, investigations, or regulatory actions or proceedings;
- information about Company affiliates and Related Companies; and
- the imposition of a trading "blackout" by the Company on transactions in Company securities or the securities of a Related Company.

Federal and Nasdaq investigators will scrutinize a questionable trade after the fact with the benefit of hindsight, so you should always err on the side of deciding that the information is material and not trade. The mere fact that a person is aware of Material Nonpublic Information is a

bar to trading. It is no excuse that such person's reasons for trading were not based on the Material Nonpublic Information. If you have questions regarding specific transactions, please contact the Chief Legal Officer.

2. *Nonpublic Information*

Nonpublic information is information that is not generally known by or available to the public. We consider information to be available to the public only when:

- it has been released to the public by the Company through appropriate channels (e.g., by means of a press release, a filing with the SEC, or a widely disseminated statement from a senior officer); and
- enough time has elapsed to permit the investment market to absorb and evaluate the information. As a general rule, you should consider information to be nonpublic until two full trading days have lapsed following the time of public disclosure. For example, if the Company issues a press release before the market opens on a Tuesday, the information would be considered public when the market opens on Thursday. If, however, the Company issues a press release after trading begins Tuesday, the information would not be considered public until the market opens on Friday.

The fact that rumors, speculation, or statements attributed to unidentified sources are public is insufficient to be considered "generally available to the public" even when the information is accurate.

C. Unauthorized Disclosure; Prohibition on Certain Paid Public Speaking

All Company Personnel must maintain the confidentiality of Company information for competitive, security, and other business reasons, as well as to comply with securities laws. All information you learn about the Company, or its business plans is potentially nonpublic information until it is publicly disclosed. You should treat this information as confidential and proprietary to the Company. You may not disclose it to others, such as Family Members, other relatives, or business or social acquaintances.

In addition, you are prohibited from participating as an "expert," consultant, advisor, and/or in any capacity for an "expert network" and/or any other outside firm which compensates individuals for speaking with investors and other investment professionals. This prohibition is designed to protect the Company, its stockholders, and you. Indeed, United States criminal authorities and the SEC have prosecuted numerous public company employees who received monetary compensation by expert networks to speak with investors and disclose confidential company information which investors then used for trading purposes.

Legal rules govern the timing and nature of our disclosure of material information to outsiders or the public. Violation of these rules could result in substantial liability for you, the Company, and its management. For this reason, we permit only specifically designated representatives of the Company to discuss the Company with the news media, securities analysts, and investors and only in accordance with the Company's Corporate Disclosure Policy. If you

receive inquiries of this nature, refer them to the Chief Financial Officer ("CFO") or the Chief Legal Officer.

D. When and How to Trade Company Stock

1. *Special Blackout Periods*

From time to time due to certain developments relating to Material Nonpublic Information, the Company may implement special blackout periods during which the Company may notify particular individuals that they should not engage in any transactions involving the purchase, sale, gift, or other transaction in Company securities or the securities of a Related Company, as applicable (subject to the exceptions set forth in Section II.D.3 or pursuant to an approved Rule 10b5-1 Trading Plan pursuant to Section II.E). If you are subject to a special blackout period, you should not trade in the applicable company's securities during such time and you should not disclose to others the fact that you are prohibited from trading, as the existence of a special blackout period may, itself, be deemed Material Nonpublic Information. These special blackout periods will vary in length, be determined by the Chief Legal Officer, and typically be communicated to the appropriate personnel via e-mail. Termination of a special blackout period will also typically be communicated to the appropriate personnel via e-mail.

However, it is not the Company's policy to impose special blackout periods every time that Material Nonpublic Information exists or every time that Insiders may be in the possession of Material Nonpublic Information. Thus, the absence of a special blackout period should not be interpreted as permission to trade. In addition, if you are subject to the Company's pre-clearance policy (described below), you must pre-clear transactions even if you initiate them while a special blackout period is not in place.

Generally, all pending purchase and sale orders regarding Company securities that could be executed while a special blackout period is not in place must be cancelled before a special blackout period is implemented so as to avoid any purchases and sales during such period.

In light of these restrictions, if you expect a need to sell Company stock at a specific time in the future, including executing sales to satisfy tax withholding obligations in connection with the exercise of stock options, vesting of restricted stock, or settlement of restricted stock units in the future, you may wish to consider entering into a prearranged Rule 10b5-1 Trading Plan, as discussed below.

2. *Pre-clearance*

The Company requires its directors, officers, as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended ("Section 16 Persons") and certain other employees and consultants who are so designated from time to time (such officers and designated employees and consultants, "Restricted Employees") to contact the Chief Legal Officer in advance of effecting any purchase, sale, gift, or other trading of Company securities and to obtain prior approval of the transaction. All requests must be submitted to the Chief Legal Officer at least two business days in

advance of the proposed transaction.[I] **The pre-clearance policy applies to directors and Restricted Employees, including their Family Members and Controlled Entities, even if they are initiating a transaction while a special blackout period is not in place.**

If a transaction is approved under the pre-clearance policy, the transaction must be executed by the end of the second full trading day after the approval is obtained, but regardless may not be executed if you acquire Material Nonpublic Information concerning the Company during that time. If a transaction is not completed within the period described above, the director or Restricted Employee may make a new trading request.

If a proposed transaction is not approved under the pre-clearance policy, you may not transact in Company securities, and you should not inform anyone within or outside of the Company of the restriction. For the avoidance of doubt, there should be no presumption that the Chief Legal Officer will grant any or all pre-clearance requests and there shall be no obligation to inform directors or Restricted Employees of the reasons for any request approval or denial. Any transaction under a Rule 10b5-1 Trading Plan (discussed below) will not require pre-clearance at the time of the transaction, but the adoption, amendment, modification, or termination of any such Rule 10b5-1 Trading Plan is subject to pre-clearance.

3. *Exceptions*

The restrictions contained in this Policy shall not apply to:

- the exercise of Company stock options if (a) no shares are to be sold to third parties or (b) there is only a "net exercise" (defined as the Company withholding shares to satisfy your tax obligations or to cover the exercise price or equivalent), this Policy does, however, apply to any sale of shares as part of a broker-assisted cashless exercise of an option, or any other market sale for the purpose of generating the cash needed to pay the exercise price of or taxes associated with an option;

- the vesting of Company stock options, restricted stock, restricted stock units, or other equity incentive awards according to their terms;

- the withholding of shares to satisfy the exercise price or a tax withholding obligation upon the grant, vesting, or settlement of equity awards pursuant to the Company's equity incentive plans and agreements, for example, from the vesting or settlement of restricted stock units under such plans;

- purchases of Company securities under the Company's Employee Stock Purchase Plan resulting from periodic contributions of money to the plan pursuant to the elections made at the time of enrollment in the plan. This Policy also does not apply to purchases of Company securities resulting from lump sum contributions to the plan, provided that the participant elected to participate by lump-sum payment at the beginning of the applicable enrollment period. This Policy does apply, however, to a participant's election to

[I] Transactions by the Chief Legal Officer (or the Chief Legal Officer's Family Members and Controlled Entities) are required to be approved in advance by the CFO and/or the CEO.

participate in or increase his or her participation in the plan, and to a participant's sales of Company securities purchased pursuant to the plan;

- transferring shares to an entity that does not involve a change in the beneficial ownership of the shares (for example, transferring shares from one brokerage account to another brokerage that you control);
- sales of Company securities as a selling stockholder in a registered public offering, including a "synthetic secondary" offering, in accordance with applicable securities laws; or
- any other purchase of Company securities from the Company or sale of Company securities to the Company in accordance with applicable securities and state laws.

To the extent applicable and such elections are permitted, your elections regarding participation in "net exercise," or "sell to cover" transactions, including changes from any defaults established by the Company, may only be made when you are not subject to a blackout period and are not in possession of Material Nonpublic Information.

E. Rule 10b5-1 Trading Plans

Rule 10b5-1 provides an affirmative defense from insider trading liability if trades occur pursuant to a pre-arranged trading plan that meets certain conditions specified in the rule (a "10b5-1 Trading Plan"). It is possible to pre-arrange trades in Company securities by entering into a 10b5-1 Trading Plan. A 10b5-1 Trading Plan must either specify the number of securities to be bought or sold, along with the price and the date, or provide a written formula for determining this information. Alternatively, a 10b5-1 Trading Plan can delegate investment discretion to a third party, such as a broker, who then makes trading decisions without further input from the person implementing the 10b5-1 Trading Plan. A 10b5-1 Trading Plan must be established at a time when you are not aware of any Material Nonpublic Information and must not permit you to exercise any subsequent control or influence over how, when or whether the purchases or sales are made. Because the SEC rules on 10b5-1 Trading Plans are complex, you should consult with your broker and be sure you fully understand the limitations and conditions of the rules before you establish a trading plan.

All 10b5-1 Trading Plans must be reviewed and approved in advance by the Chief Legal Officer and must comply with the Company's "Guidelines for Rule 10b5-1 Trading Plans" set forth in Appendix A.

F. Noncompliance

Anyone subject to this Policy who fails to comply with this Policy will be subject to appropriate disciplinary action, up to and including termination of employment.

G. Post-Termination Transactions

This Policy will continue to apply to your transactions in Company securities after your employment or service with the Company has terminated until such time as you are no longer

aware of Material Nonpublic Information or until that information has been publicly disclosed or is no longer material.

Questions about this Policy should be directed to the Chief Legal Officer at legal@viridiantherapeutics.com

VIRIDIAN THERAPEUTICS, INC.

INSIDER TRADING POLICY
ACKNOWLEDGMENT

The undersigned acknowledges receipt of the foregoing Insider Trading Policy; has read and understands such Policy; agrees that he or she is bound by the above Policy as a condition of continued employment or service and will comply with the terms of the Policy; and certifies that he or she will communicate with all members of his or her household to inform them of the obligations in this Policy that apply to them. The undersigned understands that violation of this Policy may subject him or her to discipline by Viridian Therapeutics, Inc. up to and including termination for cause.

_____

Signature

_____

Print Name

_____

Date

APPENDIX A

VIRIDIAN THERAPEUTICS, INC. GUIDELINES FOR RULE 10B5-1 TRADING PLANS

As discussed above, Rule 10b5-1 provides an affirmative defense from insider trading liability. In order to be eligible to rely on this affirmative defense, you must enter into a Rule 10b5- 1 Trading Plan for transactions in Company securities that meets certain conditions specified in Rule 10b5-1. Capitalized terms used in these guidelines without definition have the meaning set forth in the Policy.

These guidelines are in addition to, and not in lieu of, the requirements and conditions of Rule 10b5-1. The Chief Legal Officer will interpret and administer these guidelines for compliance with Rule 10b5-1 and the Policy. No personal legal or financial advice is being provided by the Chief Legal Officer or other members of the Company regarding any Rule 10b5-1 Trading Plan or proposed trades. You remain ultimately responsible for ensuring that your Rule 10b5-1 Trading Plan and contemplated transactions fully comply with applicable securities laws. It is recommended that you consult with your own attorney or other advisor about any contemplated Rule 10b5-1 Trading Plan.

Note that for any director or Section 16 Persons, the Company is required to disclose the material terms of his or her Rule 10b5-1 Trading Plan (and may be required to disclose the material terms of Rule 10b5-1 Trading Plans of Family Members and Controlled Entities of such persons), other than with respect to price, in its periodic report for the quarter in which the Rule 10b5-1 Trading Plan is adopted, terminated, or modified (as described below). Therefore, directors and Section 16 Persons must provide the Chief Legal Officer with (i) the final executed copy of any 10b5-1 Trading Plan, (ii) any other trading plan for Company securities and (iii) any amendment to any such Rule 10b5-1 Trading Plan or other trading plan, in each case within two business days of the adoption thereof.

1. **Pre-Clearance Requirement.** The Rule 10b5-1 Trading Plan must be reviewed and approved in advance by the Chief Legal Officer (or, in the case of the Chief Legal Officer, by the CFO or CEO) at least five trading days prior to the entry into the plan in accordance with the procedures set forth in the Policy and these guidelines. The Company may require that you use a standardized form of Rule 10b5-1 Trading Plan.

2. **Time of Adoption.** Subject to pre-clearance requirements described above, the Rule 10b5-1 Trading Plan must be adopted in good faith and at a time when:
    - you are not aware of any Material Nonpublic Information; and
    - you are not subject to a special blackout period.
3. **Plan Instructions.** Any Rule 10b5-1 Trading Plan must be in writing, signed, and either:
    - specify the amount, price, and date of the sales (or purchases) of Company securities to be effected;

- provide a formula, algorithm, or computer program for determining when to sell (or purchase) the Company's securities, the quantity to sell (or purchase), and the price; or
- delegate decision-making authority with regard to these transactions to a broker or other agent without any Material Nonpublic Information about the Company or its securities.

For the avoidance of doubt, you may not subsequently influence how, when, or whether to effect purchases or sales with respect to the securities subject to an approved and adopted Rule 10b5-1 Trading Plan.

4. **No Hedging.** You may not have entered into or alter a corresponding or hedging transaction or position with respect to the securities subject to the Rule 10b5-1 Trading Plan and must agree not to enter into any such transaction while the Rule 10b5-1 Trading Plan is in effect.

5. **Good Faith Requirements.** You must enter into the Rule 10b5-1 Trading Plan in good faith and not as part of a plan or scheme to evade the prohibitions of Rules 10b-5 and 10b5-1. You must act in good faith with respect to the Rule 10b5-1 Trading Plan for the entirety of its duration.

6. **Certifications for Section 16 Persons.** Section 16 Persons and their Family Members and Controlled Entities that enter into Rule 10b5-1 Trading Plans must certify that they are: (1) not aware of any Material Nonpublic Information about the Company or Company securities; and (2) adopting the Rule 10b5-1 Trading Plan in good faith and not as part of a plan or scheme to evade the prohibitions of Rules 10b-5 and 10b5-1 under the Securities Exchange Act of 1934, as amended.

7. **Cooling Off Periods.** The first trade under the Rule 10b5-1 Trading Plan may not occur until the expiration of a cooling-off period as follows:
   - For Section 16 Persons (as well as their Family Members and Controlled Entities), the later of (1) two business days following the filing of the Company's Form 10- Q or Form 10-K for the completed fiscal quarter in which the Rule 10b5-1 Trading Plan was adopted and (2) 90 calendar days after adoption of the Rule 10b5-1 Trading Plan; provided, however, that the required cooling-off period shall in no event exceed 120 days.
   - For others, 30 days after adoption of the Rule 10b5-1 Trading Plan.

8. **No Overlapping Rule 10b5-1 Trading Plans.** You may not enter into overlapping Rule 10b5-1 Trading Plans, except as permitted by Rule 10b5-1. Please consult with the Chief Legal Officer for any questions regarding overlapping Rule 10b5-1 Trading Plans.

9. **Single Transaction Plans.** You may not enter into more than one Rule 10b5-1 Trading Plan designed to effect the open-market purchase or sale of the total amount of securities as a single transaction during any rolling 12-month period (subject to certain exceptions). A single-transaction plan is "designed to effect" the purchase or sale of securities as a

single transaction when the terms of the plan would, for practical purposes, directly or indirectly require execution in a single transaction.

10. Modifications and Terminations. Modifications/amendments and terminations of an existing Rule 10b5-1 Trading Plan are strongly discouraged due to legal risks, and can affect the validity of trades that have taken place under the plan prior to such modification/amendment or termination. Under Rule 10b5-1 and these guidelines, any modification/amendment to the amount, price, or timing of the purchase or sale of the securities underlying the Rule 10b5-1 Trading Plan (a "Material Modification") will be deemed to be a termination of the current Rule 10b5-1 Trading Plan and creation of a new Rule 10b5-1 Trading Plan. As such, the modification/amendment of an existing Rule 10b5- 1 Trading Plan must be reviewed and approved in advance by the Chief Legal Officer in accordance with the pre-clearance procedures set forth in the Policy and these guidelines, and any Material Modification will be subject to all the other requirements set forth in these guidelines regarding the adoption of a new Rule 10b5-1 Trading Plan.

The termination (other than through an amendment or modification) of an existing Rule 10b5-1 Trading Plan must be reviewed and approved in advance by the Chief Legal Officer in accordance with the pre-clearance procedures set forth in the Policy and these guidelines.

The Chief Legal Officer will not approve the modification/amendment or termination of a Rule 10b5-1 Trading Plan unless:

- you are not aware of any Material Nonpublic Information; and
- you are not subject to a blackout period.

Exhibit 21.1

Subsidiaries of the Registrant

Name of Subsidiary	**Jurisdiction of Incorporation**
Viridian Therapeutics Europe Limited	England and Wales
Viridian Therapeutics S.á.r.l.	Luxembourg
Viridian Securities Corporation	Massachusetts

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements (Nos. 333-237413, 333-251367, 333-260859, 333-267351, 333-273390 and 333-275805) on Form S-3 and (Nos. 333-216112, 333-223672, 333-230271, 333-237165, 333-250906, 333-254771, 333-263490, 333-266895, 333-270475 and 333-273813) on Form S-8 of our report dated March 3, 2025 with respect to the consolidated financial statements of Viridian Therapeutics, Inc. and the effectiveness of internal control over financial reporting.

/s/ KPMG LLP

Boulder, Colorado
March 3, 2025

Exhibit 31.1

CERTIFICATION

I, Stephen Mahoney, certify that:

1. I have reviewed this Annual Report on Form 10-K, or this report, of Viridian Therapeutics, Inc., a Delaware corporation;

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

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

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

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

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

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

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

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

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

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

Date: March 3, 2025

By: /s/ Stephen Mahoney
Stephen Mahoney
President, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Seth Harmon, certify that:

1. I have reviewed this Annual Report on Form 10-K, or this report, of Viridian Therapeutics, Inc., a Delaware corporation;

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

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

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

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

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

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

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

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

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

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

Date: March 3, 2025

By: /s/ Seth Harmon

Seth Harmon
Chief Financial Officer
(Principal Financial Officer; Principal Accounting Officer)

Exhibit 32.1

SECTION 1350 CERTIFICATION

Each of the undersigned, Stephen Mahoney, Chief Executive Officer of Viridian Therapeutics, Inc., a Delaware corporation (the "Company"), and Seth Harmon, Chief Financial Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge (1) the Annual Report on Form 10-K of the Company for the annual period ended December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Stephen Mahoney

Stephen Mahoney
President, Chief Executive Officer and Director
(Principal Executive Officer)
Date: March 3, 2025

/s/ Seth Harmon

Seth Harmon
Chief Financial Officer
(Principal Financial Officer; Principal Accounting Officer)
Date: March 3, 2025

This certification accompanies and is being "furnished" with this Report, shall not be deemed "filed" by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability under that Section and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Report, irrespective of any general incorporation language contained in such filing. A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.