

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2025

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 No. 001-36483

VIRIDIAN THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

221 Crescent Street, Suite 103A

Waltham, MA

(Address of principal executive offices)

47-1187261

(I.R.S. Employer Identification No.)

02453

(Zip Code)

(617) 272-4600

(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report): N/A

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 |

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 | <input checked="" type="checkbox"/> | Accelerated filer | <input type="checkbox"/> |
| Non-accelerated filer | <input type="checkbox"/> | Smaller reporting company | <input type="checkbox"/> |
| | | Emerging growth company | <input type="checkbox"/> |

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

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

As of October 31, 2025, there were 95,442,008 shares of the registrant's common stock outstanding.

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

This Quarterly Report on Form 10-Q (“Quarterly 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 Quarterly 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 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 filing and approval of the biologics license application (“BLA”) by FDA for veligrotug and submission of a Marketing Authorization Application (“MAA”) to the European Medicines Agency (“EMA”) in the first quarter of 2026, as well as our expectation that Breakthrough Therapy Designation may support eligibility for and potential receipt of Priority Review of our BLA, and 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
- our expectations regarding the ability of our existing cash, cash equivalents, potential near-term milestone payments, and anticipated commercial revenues, if both veligrotug and VRDN-003 are approved, to fund our future anticipated operating expenses and capital expenditure requirements.

Any forward-looking statements in this Quarterly 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 II, Item 1A, “Risk Factors” in this Quarterly 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 Quarterly 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 Quarterly 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 Quarterly 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 Quarterly Report that modify or impact any of the forward-looking statements contained in this Quarterly Report will be deemed to modify or supersede such statements in this Quarterly 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 Quarterly 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 Quarterly 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 Quarterly Report and our other filings with the SEC, before making an investment decision regarding our common stock.

- If we are unable to secure 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, and may be delayed due to factors beyond our control, including as a result of a government shutdown. 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. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS
VIRIDIAN THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)
(Unaudited)

| | September 30, 2025 | December 31, 2024 |
|---|-----------------------|----------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 169,647 | \$ 99,594 |
| Short-term investments | 321,254 | 617,990 |
| Unbilled revenue | 70,000 | — |
| Prepaid expenses and other current assets | 11,012 | 20,877 |
| Total current assets | 571,913 | 738,461 |
| Property and equipment, net | 1,125 | 1,236 |
| Operating lease right-of-use asset | 2,582 | 2,205 |
| Other assets | 1,518 | 501 |
| Total assets | <u>\$ 577,138</u> | <u>\$ 742,403</u> |
| Liabilities and Stockholders' Equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 10,063 | \$ 2,143 |
| Accrued liabilities | 40,633 | 45,731 |
| Total current liabilities | 50,696 | 47,874 |
| Long-term debt | 20,890 | 20,582 |
| Other liabilities | 2,582 | 2,308 |
| Total liabilities | 74,168 | 70,764 |
| Commitments and contingencies (Note 7) | | |
| Stockholders' equity: | | |
| Preferred stock, series A non-voting convertible preferred stock, \$0.01 par value; 435,000 shares authorized; 134,864 shares issued and outstanding as of September 30, 2025 and December 31, 2024 | 61,188 | 61,188 |
| Preferred stock, series B non-voting convertible preferred stock, \$0.01 par value; 500,000 shares authorized; 145,160 shares issued and outstanding as of September 30, 2025 and December 31, 2024 | 127,697 | 127,697 |
| Common stock, \$0.01 par value; 200,000,000 shares authorized; 82,229,158 and 80,994,046 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively | 822 | 810 |
| Additional paid-in capital | 1,531,003 | 1,477,811 |
| Accumulated other comprehensive income (loss) | 363 | (10) |
| Accumulated deficit | (1,218,103) | (995,857) |
| Total stockholders' equity | 502,970 | 671,639 |
| Total liabilities and stockholders' equity | <u>\$ 577,138</u> | <u>\$ 742,403</u> |

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

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|-------------------------------------|-------------|------------------------------------|--------------|
| | 2025 | 2024 | 2025 | 2024 |
| Revenue: | | | | |
| License revenue | \$ 70,000 | \$ — | \$ 70,000 | \$ — |
| Collaboration revenue - related party | 570 | 86 | 717 | 230 |
| Total revenue | 70,570 | 86 | 70,717 | 230 |
| Operating expenses: | | | | |
| Research and development | 86,261 | 69,158 | 249,721 | 166,294 |
| General and administrative | 24,322 | 14,408 | 61,642 | 45,499 |
| Total operating expenses | 110,583 | 83,566 | 311,363 | 211,793 |
| Loss from operations | (40,013) | (83,480) | (240,646) | (211,563) |
| Other income (expense): | | | | |
| Interest income | 5,521 | 7,515 | 19,607 | 23,077 |
| Interest expense | (560) | (529) | (1,666) | (1,680) |
| Other income (expense), net | 453 | (195) | 459 | (58) |
| Total other income (expense), net | 5,414 | 6,791 | 18,400 | 21,339 |
| Net loss | \$ (34,599) | \$ (76,689) | \$ (222,246) | \$ (190,224) |
| Net loss per share, basic and diluted, common stock | \$ (0.34) | \$ (0.88) | \$ (2.22) | \$ (2.26) |
| Weighted-average common shares outstanding, basic and diluted | 81,784,499 | 66,420,063 | 81,576,987 | 63,800,798 |
| Net loss per share, basic and diluted, Series A convertible preferred stock | \$ (22.96) | \$ (58.99) | \$ (147.81) | \$ (150.57) |
| Weighted-average Series A convertible preferred shares outstanding, basic and diluted | 134,864 | 156,699 | 134,864 | 161,568 |
| Net loss per share, basic and diluted, Series B convertible preferred stock | \$ (22.96) | \$ (58.98) | \$ (147.81) | \$ (150.58) |
| Weighted-average Series B convertible preferred shares outstanding, basic and diluted | 145,160 | 147,218 | 145,160 | 144,763 |
| Comprehensive loss: | | | | |
| Net loss | \$ (34,599) | \$ (76,689) | \$ (222,246) | \$ (190,224) |
| Other comprehensive income: | | | | |
| Unrealized gain on available-for-sale securities | 294 | 1,475 | 373 | 594 |
| Total other comprehensive income | 294 | 1,475 | 373 | 594 |
| Comprehensive loss | \$ (34,305) | \$ (75,214) | \$ (221,873) | \$ (189,630) |

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

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

| | Convertible Preferred Stock | | | | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Income (Loss) | Accumulated Deficit | Total Stockholders' Equity |
|--|-----------------------------|-----------|----------|-----------|--------------|--------|----------------------------------|--|------------------------|----------------------------------|
| | Series A | | Series B | | Shares | Amount | | | | |
| | Shares | Amount | Shares | Amount | | | | | | |
| 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 |
| Issuance of common stock, September 2022 ATM, net of issuance costs of \$149 | — | — | — | — | 245,388 | 3 | 4,792 | — | — | 4,795 |
| Issuance of common stock upon exercises of warrants | — | — | — | — | 115,146 | 1 | 1,617 | — | — | 1,618 |
| Issuance of common stock upon exercises of stock options | — | — | — | — | 185,426 | 2 | 2,295 | — | — | 2,297 |
| Issuance of common stock under employee stock purchase plan | — | — | — | — | 41,106 | — | 561 | — | — | 561 |
| Issuance of common stock upon vesting of restricted stock units | — | — | — | — | 8,315 | — | — | — | — | — |
| Share-based compensation expense | — | — | — | — | — | — | 10,220 | — | — | 10,220 |
| Unrealized gain on available-for-sale securities | — | — | — | — | — | — | — | 255 | — | 255 |
| Net loss | — | — | — | — | — | — | — | — | (86,912) | (86,912) |
| Balance as of March 31, 2025 | 134,864 | \$ 61,188 | 145,160 | \$127,697 | 81,589,427 | \$ 816 | \$ 1,497,296 | \$ 245 | \$ (1,082,769) | \$ 604,473 |
| Issuance of common stock upon exercises of stock options | — | — | — | — | 61,527 | 1 | 762 | — | — | 763 |
| Issuance of common stock upon vesting of restricted stock units | — | — | — | — | 232 | — | — | — | — | — |
| Share-based compensation expense | — | — | — | — | — | — | 10,844 | — | — | 10,844 |
| Unrealized loss on available-for-sale securities | — | — | — | — | — | — | — | (176) | — | (176) |
| Net loss | — | — | — | — | — | — | — | — | (100,735) | (100,735) |
| Balance as of June 30, 2025 | 134,864 | \$ 61,188 | 145,160 | \$127,697 | 81,651,186 | \$ 817 | \$ 1,508,902 | \$ 69 | \$ (1,183,504) | \$ 515,169 |
| Issuance of common stock, March 2025 ATM, net of issuance costs of \$209 | — | — | — | — | 500,000 | 5 | 9,746 | — | — | 9,751 |
| Issuance of common stock upon exercises of stock options | — | — | — | — | 34,522 | — | 547 | — | — | 547 |
| Issuance of common stock under employee stock purchase plan | — | — | — | — | 43,450 | — | 558 | — | — | 558 |
| Share-based compensation expense | — | — | — | — | — | — | 11,250 | — | — | 11,250 |
| Unrealized gain on available-for-sale securities | — | — | — | — | — | — | — | 294 | — | 294 |
| Net loss | — | — | — | — | — | — | — | — | (34,599) | (34,599) |
| Balance as of September 30, 2025 | 134,864 | \$ 61,188 | 145,160 | \$127,697 | 82,229,158 | \$ 822 | \$ 1,531,003 | \$ 363 | \$ (1,218,103) | \$ 502,970 |

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

| | Convertible Preferred Stock | | | | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Income (Loss) | Accumulated Deficit | Total Stockholders' Equity |
|--|-----------------------------|-----------|----------|-----------|--------------|--------|----------------------------------|--|------------------------|----------------------------------|
| | Series A | | Series B | | Shares | Amount | | | | |
| | Shares | Amount | Shares | Amount | | | | | | |
| 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 | (15,000) | (6,806) | — | — | 1,000,048 | 10 | 6,796 | — | — | — |
| 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 common stock, September 2022 ATM, net of issuance costs of \$1,088 | — | — | — | — | 1,561,570 | 15 | 35,162 | — | — | 35,177 |
| Issuance of common stock for exercises of stock options | — | — | — | — | 66,191 | 1 | 837 | — | — | 838 |

| | | | | | | | | | | |
|--|----------------|------------------|----------------|------------------|-------------------|---------------|---------------------|-----------------|--------------------|-------------------|
| Issuance of common stock for cash under employee stock purchase plan | — | — | — | — | 22,642 | — | 356 | — | — | 356 |
| Vesting of restricted stock units | — | — | — | — | 19,115 | 1 | (1) | — | — | — |
| Share-based compensation expense | — | — | — | — | — | — | 12,688 | — | — | 12,688 |
| Change in unrealized loss on investments | — | — | — | — | — | — | — | (705) | — | (705) |
| Net loss | — | — | — | — | — | — | — | — | (48,542) | (48,542) |
| Balance as of March 31, 2024 | <u>157,435</u> | <u>\$ 71,429</u> | <u>143,522</u> | <u>\$128,281</u> | <u>63,798,536</u> | <u>\$ 638</u> | <u>\$ 1,156,999</u> | <u>\$ (367)</u> | <u>\$(774,450)</u> | <u>\$ 582,530</u> |
| Issuance of common stock for exercises of stock options | — | — | — | — | 81,139 | 1 | 209 | — | — | 210 |
| Share-based compensation expense | — | — | — | — | — | — | 11,767 | — | — | 11,767 |
| Change in unrealized loss on investments | — | — | — | — | — | — | — | (176) | — | (176) |
| Net loss | — | — | — | — | — | — | — | — | (64,993) | (64,993) |
| Balance as of June 30, 2024 | <u>157,435</u> | <u>\$ 71,429</u> | <u>143,522</u> | <u>\$128,281</u> | <u>63,879,675</u> | <u>\$ 639</u> | <u>\$ 1,168,975</u> | <u>\$ (543)</u> | <u>\$(839,443)</u> | <u>\$ 529,338</u> |
| Issuance of common stock upon the conversion of convertible preferred stock | (22,571) | (10,241) | (18,362) | (24,085) | 2,729,000 | 27 | 34,299 | — | — | — |
| Issuance of Series B preferred stock and common stock, September 2024 Public Offering, net of issuance costs of \$15,524 | — | — | 20,000 | 23,501 | 12,466,600 | 125 | 219,600 | — | — | 243,226 |
| Issuance of common stock for exercises of stock options | — | — | — | — | 84,676 | 1 | 1,108 | — | — | 1,109 |
| Issuance of common stock for cash under employee stock purchase plan | — | — | — | — | 21,494 | — | 317 | — | — | 317 |
| Share-based compensation expense | — | — | — | — | — | — | 8,720 | — | — | 8,720 |
| Change in unrealized gain on investments | — | — | — | — | — | — | — | 1,475 | — | 1,475 |
| Net loss | — | — | — | — | — | — | — | — | (76,689) | (76,689) |
| Balance as of September 30, 2024 | <u>134,864</u> | <u>\$ 61,188</u> | <u>145,160</u> | <u>\$127,697</u> | <u>79,181,445</u> | <u>\$ 792</u> | <u>\$ 1,433,019</u> | <u>\$ 932</u> | <u>\$(916,132)</u> | <u>\$ 707,496</u> |

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

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

| | Nine Months Ended September 30, | |
|--|---------------------------------|-------------------|
| | 2025 | 2024 |
| Cash flows from operating activities: | | |
| Net loss | \$ (222,246) | \$ (190,224) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Share-based compensation expense | 32,314 | 33,175 |
| Non-cash interest expense | 308 | 318 |
| Depreciation and amortization | 340 | 417 |
| Accretion and amortization of available-for-sale securities | (5,005) | (12,448) |
| Non-cash lease expense | (30) | 188 |
| Net loss on disposal of equipment | — | 449 |
| Changes in operating assets and liabilities: | | |
| Unbilled revenue | (70,000) | — |
| Prepaid expenses and other assets | 8,849 | (5,256) |
| Accounts payable | 7,942 | 3,850 |
| Accrued and other liabilities | (5,109) | 10,544 |
| Net cash used in operating activities | <u>(252,637)</u> | <u>(158,987)</u> |
| Cash flows from investing activities: | | |
| Purchases of short-term investments | (141,084) | (513,289) |
| Maturities of short-term investments | 443,196 | 347,950 |
| Purchase of property and equipment | (255) | (397) |
| Net cash provided by (used in) investing activities | <u>301,857</u> | <u>(165,736)</u> |
| Cash flows from financing activities: | | |
| Proceeds from sale of common stock in public offering | — | 383,749 |
| Proceeds from sale of common stock in at-the-market offerings | 14,904 | 36,265 |
| Payments of issuance costs associated with sale of common stock | (416) | (24,132) |
| Proceeds from the issuance of Series B preferred stock, pursuant to September 2024 Public Offering | — | 25,001 |
| Payment of issuance costs associated with the sale of preferred stock | — | (1,500) |
| Proceeds from issuance of common stock upon exercises of warrants | 1,618 | — |
| Proceeds from issuance of common stock upon exercises of stock options | 3,607 | 2,157 |
| Proceeds from issuance of common stock under employee stock purchase plan | 1,120 | 673 |
| Net cash provided by financing activities | <u>20,833</u> | <u>422,213</u> |
| Net increase in cash and cash equivalents | 70,053 | 97,490 |
| Cash and cash equivalents at beginning of period | 99,594 | 102,827 |
| Cash and cash equivalents at end of period | <u>\$ 169,647</u> | <u>\$ 200,317</u> |
| Supplemental disclosure of cash flow information | | |
| Cash paid for interest | \$ 1,362 | \$ 1,367 |
| Supplemental disclosure of non-cash investing and financing activities | | |
| Issuance of common stock upon the conversion of convertible preferred stock | \$ — | \$ 41,132 |
| Deferred issuance costs included in accounts payable and accrued liabilities | \$ 528 | \$ 370 |
| Purchase of property and equipment included in accounts payable and accrued liabilities | \$ 17 | \$ 88 |
| Right-of-use asset obtained in exchange for new lease liability | \$ 729 | \$ — |

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

VIRIDIAN THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. DESCRIPTION OF THE 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, 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 auto-injector 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 and Capital Resources

The Company’s unaudited condensed consolidated financial statements have been prepared on the basis of the Company continuing as 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 expects that its cash, cash equivalents and short-term investments as of September 30, 2025 of \$490.9 million will enable the Company to fund its planned operations for at least twelve months from the date of issuance of these unaudited condensed consolidated financial statements.

The Company has funded its operations to date principally through proceeds received from the sale of the Company’s common stock, Series A convertible preferred stock, Series B convertible preferred stock, and other equity securities, debt financings, and license fees and reimbursements received under collaboration agreements. The Company has incurred recurring losses and negative cash flows from operations since inception. As of September 30, 2025, the Company had an accumulated deficit of \$1,218.1 million. 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. In addition, the Company may continue to incur additional operating losses as a result of planned expenditures for research and development activities, its drug development programs, including clinical trial and manufacturing costs, and the continued build-out of clinical, manufacturing, commercial and compliance capabilities.

The future viability of the Company is dependent on its ability to generate cash from operating activities or to raise additional capital to finance its operations. There can be no assurance that the Company will ever earn revenues from product sales or achieve profitability, or if achieved, that the revenues or profitability will be sustained on a continuing basis. In addition, the Company’s preclinical and clinical development activities, manufacturing activities, and commercialization activities for the Company’s product candidates, if approved, may require significant additional capital. 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 and Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles (“U.S. GAAP”), for interim financial reporting and as required by Regulation S-X,

Rule 10-01. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification (“ASC”), and Accounting Standards Updates (“ASU”), or the Financial Accounting Standards Board (“FASB”).

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. The Company’s subsidiaries have no employees or operations. All intercompany balances and transactions have been eliminated in consolidation. Management has determined that the Company operates in one segment, which is the business of developing and commercializing novel therapeutics. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with the Company’s consolidated financial statements and the accompanying notes included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2024, filed with the U.S. Securities and Exchange Commission on March 3, 2025. The Company’s management performed an evaluation of its activities through the date of filing of these unaudited condensed consolidated financial statements and concluded that there are no subsequent events requiring disclosure, other than as disclosed.

Unaudited Interim Condensed Consolidated Financial Information

In the opinion of management, all adjustments, consisting of normal recurring accruals and revisions of estimates, considered necessary for a fair presentation of the unaudited condensed consolidated financial statements have been included. Interim results for the nine months ended September 30, 2025, are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2025, or any other future period.

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 unaudited condensed 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 unaudited condensed consolidated financial statements include, but are not limited to, estimates related to revenue recognition, fair value of investments, accrued research and development expenses, income taxes and share-based compensation. 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 license and 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 or other 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 license and 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 license, collaboration or other 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 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"). Such up-front and milestone payments are reflected as cash used in operating activities within the unaudited condensed consolidated statement of cash flows.

Clinical Trial and Nonclinical Study Accruals

The Company makes estimates of accrued liabilities as of each balance sheet date in its unaudited condensed consolidated financial statements based on certain facts and circumstances at that time. The Company's accrued liabilities 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 share-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 share-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*. The Company uses the fair value of its common stock to determine the fair value of RSUs and the Black-Scholes option pricing model to determine the fair value of stock options. The use of the Black-Scholes option-pricing model takes into account the fair value of its common stock, the exercise price, the expected life of the option, the expected volatility of its common stock, the expected dividends on its common stock, and the risk-free interest rate over the expected life of the option. The Company recognizes share-based compensation expense for awards with service-based conditions using the straight-line method over the requisite service period. The Company accounts for forfeitures as they occur.

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 are classified as current assets.

Available-for-sale debt securities with unrealized gains and losses are reported as a component of accumulated other comprehensive income (loss) in 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 determined 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, unbilled revenue, prepaid expenses, accounts payable and accrued liabilities.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents, and short-term investments. 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 in accordance with ASC Topic 842, *Leases* ("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 a 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 condensed 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 condensed 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 7. *Commitments and Contingencies - Lease Obligations* for additional information related to the Company's operating leases.

Convertible Preferred Stock

The Company records shares of non-voting convertible preferred stock classified in equity 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 long-lived assets whenever events or changes in circumstances indicate the carrying amount of such assets may not be recoverable. No impairment charges were recorded during the nine months ended September 30, 2025 and 2024.

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 would be antidilutive.

Comprehensive Loss

Comprehensive loss is comprised of net loss and adjustments for the unrealized gains and losses on available-for-sale securities. Accumulated other comprehensive income (loss) are reflected as a separate component in the unaudited condensed consolidated statements of stockholders' equity.

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, capitalized research and development costs, 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 unaudited condensed consolidated statements of operations and comprehensive loss as general and administrative expenses. No such expenses have been recognized during the nine months ended September 30, 2025 and 2024.

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 ASC Topic 480, *Distinguishing*

Liabilities from Equity, ASC Topic 505, *Equity*, ASC 815, *Derivatives and Hedging*, and ASC 718, *Compensation - Stock Compensation*. Warrants for common stock are classified as liabilities when the Company may be required to settle the warrants in cash and classified as equity when the Company will settle the warrants in shares of its common stock.

Segment Information

The Company manages its operations as a single operating 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 Issued Accounting Standard Updates

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-09"). The guidance in ASU 2023-09 improves the transparency of income tax disclosures by greater disaggregation of information in the rate reconciliation and income taxes paid disaggregated by jurisdiction. The standard is effective for public companies for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2023-09 may have on its consolidated financial statements.

In November 2024, the FASB issued ASU-2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures* (Subtopic 220-40): *Disaggregation of Income Statement Expenses* ("ASU 2024-03"). The guidance in ASU 2024-03 is intended to require more detailed disclosures about specified categories of expenses (including employee compensation, depreciation, and amortization) included in certain expense captions presented on the face of the income statement. ASU 2024-03 is effective for annual periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The amendments may be applied either prospectively to financial statements issued for reporting periods after the effective date of this ASU or retrospectively to all prior periods presented in the financial statements. The Company is in the process of evaluating the impact of this new guidance on its consolidated financial statements.

Other recent accounting pronouncements issued, but not yet effective, are not expected to be applicable to the Company or have a material effect on the consolidated financial statements upon future adoption.

3. INVESTMENTS AND FAIR VALUE MEASUREMENTS

Investments

The Company's investments consisted of the following as of September 30, 2025 and December 31, 2024:

| (in thousands) | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---------------------------------------|-------------------|------------------------|-------------------------|-------------------|
| September 30, 2025 | | | | |
| Money market funds | \$ 149,190 | \$ — | \$ — | \$ 149,190 |
| U.S. treasury securities | 174,357 | 195 | (20) | 174,532 |
| U.S. corporate paper and bonds | 157,524 | 195 | (7) | 157,712 |
| Total | \$ 481,071 | \$ 390 | \$ (27) | \$ 481,434 |
| 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 |

The money market funds above are included in cash and cash equivalents on the Company's unaudited condensed consolidated balance sheets. As of September 30, 2025, \$11.0 million of U.S. corporate paper and bonds are included in cash and cash equivalents on the unaudited condensed consolidated balance sheets.

As of September 30, 2025, 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 did not have any realized gains or losses in its available for sale securities during the three and nine months ended September 30, 2025 and 2024. The Company did not have any sales of short-term investments during the three and nine months ended September 30, 2025 and 2024. The contractual maturity dates of the Company's investments are all less than 24 months.

Fair Value Measurements

The following table summarizes 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 |
|---|---|---|---|-------------------|
| September 30, 2025 | | | | |
| Cash equivalents: | | | | |
| Money market funds | \$ 149,190 | \$ — | \$ — | \$ 149,190 |
| Short-term investments: | | | | |
| U.S. treasury securities | 4,999 | 169,533 | — | 174,532 |
| U.S. corporate paper and bonds | — | 157,712 | — | 157,712 |
| Total cash equivalents and short-term investments | <u>\$ 154,189</u> | <u>\$ 327,245</u> | <u>\$ —</u> | <u>\$ 481,434</u> |
| December 31, 2024 | | | | |
| 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 | <u>\$ 117,750</u> | <u>\$ 596,298</u> | <u>\$ —</u> | <u>\$ 714,048</u> |

4. ACCRUED LIABILITIES

Accrued liabilities consisted of the following:

| | September 30, 2025 | December 31, 2024 |
|---|-----------------------|----------------------|
| | (in thousands) | |
| Accrued outsourced manufacturing | \$ 11,815 | \$ 19,370 |
| Accrued outsourced clinical and nonclinical studies | 10,838 | 11,585 |
| Accrued compensation and related benefits | 10,714 | 10,638 |
| Operating lease liabilities, short-term | 730 | 513 |
| Accrued professional fees | 4,176 | 2,323 |
| Deferred revenue - related party, current | 372 | 288 |
| Accrued interest payable | 149 | 154 |
| Other accrued liabilities | 1,839 | 860 |
| Total accrued liabilities | <u>\$ 40,633</u> | <u>\$ 45,731</u> |

5. 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, which was 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 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 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.

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, which was available through February 15, 2025; (3) a third tranche of \$20.0 million, subject to achievement of certain regulatory milestones, which was available through March 31, 2025; and (4) a fourth tranche of \$60.0 million subject to approval by the Lenders’ investment committee(s), which was available through June 15, 2025. 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 Amended 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 September 30, 2025 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 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 \$0.6 million and \$1.7 million during the three and nine months ended September 30, 2025, respectively, and \$0.5 million and \$1.7 million during the three and nine months ended September 30, 2024, respectively.

The following table summarizes the components of the Amended Term Loan, on the Company's unaudited condensed consolidated balance sheet at September 30, 2025:

| | September 30, 2025 | |
|--------------------------|---------------------------|--------|
| | (in thousands) | |
| Gross term loan proceeds | \$ | 20,000 |
| Accrued end-of-term fee | | 890 |
| Long-term debt | \$ | 20,890 |

The carrying value of the Amended Term Loan approximates its fair value. In October 2025, the Company executed a second amendment to the Hercules Loan and Security Agreement (see Note 13), which among other changes, extended the maturity of the Company's debt to October 2030. As a result, the Company's future principal payments of \$20.0 million as of September 30, 2025, which exclude the end of term fee, have been reclassified to long-term debt.

6. 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., its 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.

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).

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 nine months ended September 30, 2024 as services were performed. During the nine months ended September 30, 2025, the Company recorded \$0.4 million in research and development expense related to the Zenas Letter Agreement.

In January 2025, the Company entered into the third amendment to the license agreement (the "Third Amendment") to modify certain provisions of the Zenas Agreements, including provisions related to future milestones. The change to future milestones did not change the assessment of probability of achievement and it remains not probable that a significant revenue reversal would not occur. The Third Amendment had no effect on the transaction price determined at contract inception and the Company will continue to recognize the transaction price from the license agreement over the Company's estimated period to complete its activities.

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.

In July 2025, the Company entered into a side agreement with Zai Lab (the "Side Agreement"), with Zenas BioPharma as countersigner, pursuant to which the Company agreed to provide certain services directly to Zai Lab to support development and commercialization activities. Under the Side Agreement, the Company will charge Zai Lab a fixed hourly rate for services, plus reimbursement of out-of-pocket costs. In August 2025, the Company entered into a Material Transfer Agreement (the "MTA") with Zai Lab, to supply certain materials for clinical trial use in exchange for a fixed payment. The Side Agreement and MTA were evaluated under ASC 606 and determined to be contract modifications to the Zenas Agreements. The services provided under the Side Agreement and materials provided under the MTA to Zai Lab as a sublicensee of Zenas BioPharma are not distinct from those in the Zenas Agreements, as they are integral to the research and development activities enabled by the original license and therefore do not represent a separate performance obligation. As a result, the modifications do not meet the criteria to be accounted for as separate contracts.

During the three and nine months ended September 30, 2025, the Company recognized \$0.6 million and \$0.7 million, respectively, of collaboration revenue related to the Zenas Agreements, Side Agreement and MTA. During the three and nine months ended September 30, 2024, the Company recognized \$0.1 million and \$0.2 million, respectively, of collaboration revenue related to the Zenas Agreements.

The Zenas Agreements are considered related party transactions because Fairmount Funds Management LLC ("Fairmount") beneficially owns more than 5% of the Company's capital stock and a member of Fairmount has a seat on Zenas BioPharma's board of directors. The Side Agreement and MTA with Zai Lab are also considered related party transactions of the Company because Zenas BioPharma has determined Zai Lab is its related party, given that Zenas BioPharma's CEO and chairman also serves as a member of Zai Lab'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 (the "Amended Paragon Research Agreement") to include additional development activities to be performed by Paragon. Under the Amended Paragon Research Agreement, the Company made a one-time non-refundable payment of \$3.5 million to Paragon, which was recorded as research and development expense during the three months ended March 31, 2025 following the achievement of certain research and development objectives.

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. Upon achievement of a milestone in February 2025, the Company recorded \$1.0 million to research and development expense, which was paid to Paragon in May 2025. 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 three months ended September 30, 2025, there were no research and development costs related to the Amended Paragon Research Agreement and Amended Paragon License Agreement (collectively, the “Paragon Agreements”). During the nine months ended September 30, 2025, the Company recorded \$4.5 million in research and development costs related to the Paragon Agreements. During the three and nine months ended September 30, 2024, the Company recorded \$7.7 million and \$10.9 million, respectively, in research and development costs related to the Paragon Agreements. As of December 31, 2024, a related party balance with Paragon of \$0.8 million is included in prepaid expenses and other current assets on the unaudited condensed consolidated balance sheets.

The Paragon Agreements are considered related party transactions 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.

Collaboration and License Agreement with Kissei Pharmaceutical Co., Ltd.

In July 2025, the Company and Kissei Pharmaceutical Co., Ltd. (“Kissei”) entered into a Collaboration and License Agreement (the “Kissei Agreement”) pursuant to which the Company granted to Kissei an exclusive license to develop and commercialize products containing veligrotug and VRDN-003 for potential treatments, including treatment of TED, in Japan, and a non-exclusive license to manufacture such licensed products worldwide for use in Japan under certain limited circumstances.

The transaction price under the Kissei Agreement included a one-time, non-refundable and non-creditable upfront cash payment to the Company of \$70.0 million, which is included in unbilled revenue on the accompanying unaudited condensed consolidated balance sheet as of September 30, 2025, and was paid to the Company in October 2025. Additionally, the Company is eligible to receive up to an additional \$315.0 million of non-refundable milestone payments upon achieving specific milestone events during the contract term, as well as tiered royalty payments ranging from percentages in the twenties to the mid-thirties based on the annual net sales of any licensed products sold in Japan. Kissei is obligated to make royalty payments to the Company for the royalty term as defined in the Kissei Agreement.

The term of the Kissei Agreement will continue until expiration of the last to expire payment obligations, unless terminated earlier. Kissei has the right to terminate the Kissei Agreement for convenience with written notice of certain periods. The Company may terminate the Kissei Agreement under certain conditions. In addition, either party may terminate the Kissei Agreement for the other party’s material breach or insolvency.

The Company evaluated the Kissei Agreement in accordance with ASC 606 and concluded that the contract counterparty, Kissei, is a customer. The Company evaluated the promised goods and services within the Kissei Agreement and determined which goods and services were separate performance obligations. The Company determined the Kissei Agreement had two performance obligations: (i) granting the exclusive licenses to develop and commercialize veligrotug, and (ii) granting the exclusive license to develop and commercialize VRDN-003. The performance obligations were satisfied concurrently at a point in time upon the granting of the license rights at contract inception.

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. Under the Kissei Agreement, the Company may manufacture and provide clinical supply to Kissei to use in development and commercialization in the licensed territory for consideration, as defined within the Kissei Agreement. Certain of these provisions were determined to be options to acquire additional goods or services at a price that approximates the stand-alone selling price for that good or service and therefore do not represent material rights, or separate performance obligations, within the context of the Kissei Agreement.

During the three and nine months ended September 30, 2025, the Company recognized license revenue of \$70.0 million related to the Kissei Agreement, associated with the upfront cash payment.

7. 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. 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.

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 expired 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 issued 243,902 shares of its common stock to certain stockholders of the third-party. The shares were valued at \$5.7 million and recorded as research and development expense during the year ended December 31, 2023. Additionally, upon the date when the Company decided 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”). 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. As part of the amendment in March 2021, the lease maturity date was extended to December 31, 2024.

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, September 2024 and September 2025, 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.

In September 2025, the Company entered into a Sixth Amendment of the Massachusetts Lease (the “Sixth Amendment”) to lease an additional 5,240 square feet of office space in the same building. The Sixth Amendment provides for additional annual base rent of approximately \$0.2 million for the additional office space and includes annual base rent escalation clauses during the lease term. The Sixth 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 \$0.7 million related to the Sixth Amendment on the lease commencement date.

Future lease payments under noncancellable leases as of September 30, 2025 are as follows:

| | (in thousands) | |
|-------------------------------------|----------------|---------------------|
| 2025 (remainder) | \$ | 237 |
| 2026 | | 965 |
| 2027 | | 836 |
| 2028 | | 854 |
| 2029 | | 505 |
| 2030 | | — |
| Total future minimum lease payments | | <u>3,397</u> |
| Less: imputed interest | | (511) |
| Total lease liabilities | \$ | <u><u>2,886</u></u> |

As of September 30, 2025, the Company’s operating lease obligations were reflected as short-term operating lease liabilities of \$0.7 million within accrued liabilities and \$2.2 million of long-term lease obligations within other liabilities in the Company’s unaudited condensed consolidated balance sheets. As of September 30, 2025, the weighted average remaining lease term was 3.7 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 9.2%.

Amortization of the operating lease right-of-use assets, and corresponding reduction of operating lease obligations, amounted to \$0.2 million and \$0.5 million for the three and nine months ended September 30, 2025, respectively, which was included in operating expense in the unaudited condensed consolidated statements of operations and comprehensive loss. Amortization of the operating lease right-of-use assets, and corresponding reduction of operating lease obligations, amounted to \$0.2 million and \$0.8 million for the three and nine months ended September 30, 2024, respectively.

The Company is also required to pay for certain variable operating costs, taxes, and operating expenses related to both the Colorado Lease and Massachusetts Lease.

8. CAPITAL STOCK

Common Stock

Under the Company’s second restated certificate of incorporation, the Company is authorized to issue 200,000,000 shares of common stock 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.

Common Stock Sales Agreements - Jefferies LLC

In September 2022, the Company entered into an Open Market Sale AgreementSM (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 up to 3.0% of the gross proceeds of any shares of common stock sold under the September 2022 ATM Agreement. No shares were sold under the September 2022 ATM Agreement during the three months ended September 30, 2025. During the nine months ended September 30, 2025, the Company sold 245,388 shares under the September 2022 ATM Agreement at a weighted average price of \$20.14 per share, for aggregate net proceeds of approximately \$4.8 million, including commissions to Jefferies as a sales agent. During the nine

months ended September 30, 2024, the Company sold 1,561,570 shares under the September 2022 ATM Agreement at a weighted average price of \$23.22 per share, for aggregate net proceeds of approximately \$35.2 million, including commissions to Jefferies as a sales agent. The September 2022 ATM Agreement was terminated in March 2025 and no further offerings or sales of common stock will be conducted under the September 2022 ATM Agreement.

In March 2025, the Company entered into an Open Market Sale AgreementSM (the “March 2025 ATM Agreement”) with Jefferies LLC (“Jefferies”), pursuant to which the Company may offer and sell shares of its common stock having an aggregate offering price of up to \$300.0 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 up to 3.0% of the gross proceeds of any shares of common stock sold under the March 2025 ATM Agreement. During the three and nine months ended September 30, 2025, the Company sold 500,000 shares under the March 2025 ATM Agreement at a weighted average price of \$19.92 per share, for aggregate net proceeds of approximately \$9.8 million, including commissions to Jefferies as a sales agent.

Public Offerings

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 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.

Convertible Preferred Stock

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, with a par value of \$0.01 per share, 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 September 30, 2025 and December 31, 2024, there were 134,864 shares of Series A convertible preferred stock outstanding. No shares of Series A convertible preferred stock were converted into common stock during the nine months ended September 30, 2025.

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 September 30, 2025 and December 31, 2024, there were 145,160 shares of Series B convertible preferred stock outstanding. No shares of Series B convertible preferred stock were converted into common stock during the nine months ended September 30, 2025.

9. WARRANTS

The following table presents information about the Company's outstanding warrants:

| | Number of Underlying Shares ⁽¹⁾ | | Weighted-Average Exercise Price Per Share at September 30, 2025 | Remaining Contractual Life at September 30, 2025 (No. Years) |
|--------------------------------------|--|-------------------|---|--|
| | September 30, 2025 | December 31, 2024 | | |
| Liability-classified warrants | | | | |
| Issued April 2017 | — | 781 | \$— | |
| Equity-classified warrants | | | | |
| Acquired October 2020 | 29,446 | 29,446 | \$0.15 | 4.98 |
| Issued February 2020 ⁽²⁾ | — | 218,050 | \$— | |
| Subtotal | 29,446 | 247,496 | \$0.15 | |
| Total warrants | 29,446 | 248,277 | \$0.15 | |

(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 nine months ended September 30, 2025 is as follows:

| | Common Stock Warrants | |
|-----------------------------------|-----------------------|---|
| | Number | Weighted Average Exercise Price Per Share |
| Outstanding at December 31, 2024 | 248,277 | \$ 14.91 |
| Exercised ⁽¹⁾ | (207,492) | \$ 16.50 |
| Expired | (11,339) | \$ 24.18 |
| Outstanding at September 30, 2025 | 29,446 | \$ 0.15 |

⁽¹⁾Includes 92,346 warrants that were surrendered in cashless exercises

10. 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. In June 2025, 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 8,000,000 shares. The 2016 Plan will terminate in April 2035.

As of September 30, 2025, the Company had the following balances by plan:

| | Restricted Stock Units Outstanding | Stock Options Outstanding | Shares Available for Issuance |
|-------------------|------------------------------------|---------------------------|-------------------------------|
| Inducement Awards | — | 7,776,879 | — |
| 2020 Plan | — | 51,709 | — |
| 2016 Plan | 1,090,439 | 6,675,094 | 10,504,133 |
| 2008 Plan | — | — | — |
| Total | 1,090,439 | 14,503,682 | 10,504,133 |

Restricted Stock Units

RSUs granted under the Equity Incentive Plans and the Inducement Awards generally vest annually over a two or four-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 Per Share |
|-----------------------------------|-----------|--|
| Outstanding at December 31, 2024 | 314,075 | \$15.51 |
| Granted | 846,678 | \$14.46 |
| Vested | (8,547) | \$33.29 |
| Forfeited | (61,767) | \$15.29 |
| Outstanding at September 30, 2025 | 1,090,439 | \$14.57 |

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 Per Share | Weighted-Average Remaining Contractual Term (years) | Aggregate Intrinsic Value (in thousands) |
|--------------------------------------|-------------------|---|--|--|
| Outstanding as of December 31, 2024 | 11,348,519 | \$18.11 | 7.9 | \$ 37,138 |
| Granted | 5,633,527 | \$15.22 | | |
| Exercised | (281,475) | \$12.82 | | |
| Forfeited | (631,704) | \$20.57 | | |
| Expired | (1,565,185) | \$23.26 | | |
| Outstanding as of September 30, 2025 | 14,503,682 | \$16.43 | 8.6 | \$ 85,641 |
| Exercisable as of September 30, 2025 | 4,718,639 | \$17.74 | 7.9 | \$ 25,913 |

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 during the nine months ended September 30, 2025 and 2024 was \$10.43 and \$10.83, respectively. The fair value was determined by the Black-Scholes option pricing model using the following weighted-average assumptions:

| | Nine Months Ended September 30, | |
|---------------------------------|---------------------------------|---------|
| | 2025 | 2024 |
| Expected term (in years) | 5.0 | 5.1 |
| Expected volatility | 84% | 89% |
| Risk-free interest rate | 4.0% | 4.3% |
| Expected dividend yield | —% | —% |
| Weighted average exercise price | \$15.22 | \$15.08 |

Employee Stock Purchase Plan

The 2016 Employee Stock Purchase Plan (“2016 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 September 30, 2025, the Company had no shares available for issuance, and 186,982 cumulative shares had been issued under the 2016 ESPP. The 2016 ESPP terminated upon closing of the last offering period in September 2025.

In June 2025, the Company’s stockholders approved the 2025 Employee Stock Purchase Plan (“2025 ESPP”) and therefore, following the conclusion of the offering period in September 2025, no new offering periods under the 2016 ESPP will commence. The 2025 ESPP allows qualified employees to purchase shares of common stock at a price equal to 85% of the lower of: (i) the closing price on the first day of the offering period or (ii) the closing price on the purchase date. As of September 30, 2025, the Company had 2,000,000 shares available for issuance and no shares have been issued under the 2025 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 unaudited condensed consolidated statements of operations and comprehensive loss as follows:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|----------------------------------|-----------------|---------------------------------|------------------|
| | 2025 | 2024 | 2025 | 2024 |
| | (in thousands) | | (in thousands) | |
| Research and development | \$ 5,107 | \$ 4,673 | \$ 16,029 | \$ 17,142 |
| General and administrative | 6,143 | 4,047 | 16,285 | 16,033 |
| Total share-based compensation expense | <u>\$ 11,250</u> | <u>\$ 8,720</u> | <u>\$ 32,314</u> | <u>\$ 33,175</u> |

During the nine months ended September 30, 2025, the Company recorded \$1.6 million of incremental share-based compensation related to the acceleration of vesting for former executive officers. During the nine months ended September 30, 2024, the Company recorded \$4.6 million of incremental 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.

As of September 30, 2025, the Company had \$103.3 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 2.8 years. As of September 30, 2025, the Company had \$12.9 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 3.1 years.

11. 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 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 shares 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 common stock would be antidilutive.

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):

| | Three Months Ended September 30, 2025 | | | Nine Months Ended September 30, 2025 | | |
|--|--|--|--------------|--|--|--------------|
| | 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 | \$ (3,097) | \$ (3,333) | \$ (28,169) | \$ (19,934) | \$ (21,456) | \$ (180,856) |
| Denominator | | | | | | |
| Weighted-average shares outstanding | 134,864 | 145,160 | 81,784,499 | 134,864 | 145,160 | 81,576,987 |
| Net loss per share, basic and diluted | \$ (22.96) | \$ (22.96) | \$ (0.34) | \$ (147.81) | \$ (147.81) | \$ (2.22) |

| | 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) | \$ (144,098) |
| 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) |

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:

| | September 30, | |
|---|-------------------|-------------------|
| | 2025 | 2024 |
| Series A preferred stock (as converted to shares of common stock) | 8,991,383 | 8,991,383 |
| Series B preferred stock (as converted to shares of common stock) | 9,677,817 | 9,677,817 |
| Options to purchase common stock | 14,503,682 | 11,352,087 |
| Warrants to purchase common stock | 29,446 | 249,883 |
| Restricted stock units | 1,090,439 | 514,540 |
| Total | <u>34,292,767</u> | <u>30,785,710</u> |

12. SEGMENT INFORMATION

The Company manages its operations as one operating segment, focused on discovering, developing and commercializing potential best-in-class medicines for serious and rare diseases. The Company's 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:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|----------------------------------|------------------|---------------------------------|-------------------|
| | 2025 | 2024 | 2025 | 2024 |
| | (in thousands) | | (in thousands) | |
| Segment research and development expense (a) | \$ 81,106 | \$ 64,434 | \$ 233,544 | \$ 148,993 |
| Segment general and administrative expense (a) | 18,117 | 10,284 | 45,165 | 29,208 |
| Share-based compensation expense (see Note 10) | 11,250 | 8,720 | 32,314 | 33,176 |
| Total operating expenses | 110,473 | 83,438 | 311,023 | 211,377 |
| License revenue | (70,000) | — | (70,000) | — |
| Other items (b) | (5,874) | (6,749) | (18,777) | (21,153) |
| Consolidated net loss | <u>\$ 34,599</u> | <u>\$ 76,689</u> | <u>\$ 222,246</u> | <u>\$ 190,224</u> |

(a) Share-based payment expense of \$5,107 and \$4,673 related to research and development and \$6,143 and \$4,047 related to general and administrative have been excluded for the three months ended September 30, 2025 and 2024, respectively, and included within share-based compensation expense. Share-based payment expense of \$16,029 and \$17,142 related to research and development and \$16,285 and \$16,033 related to general and administrative have been excluded for the nine months ended September 30, 2025 and 2024, respectively, and included within share-based compensation expense.

(b) Other items consist primarily of collaboration revenue, interest income, interest expense and depreciation expense.

13. SUBSEQUENT EVENTS

Purchase and Sale Agreement

In October 2025, the Company and DRI Healthcare Acquisitions LP ("DRI") entered into a Purchase and Sale Agreement (the "DRI Purchase and Sale Agreement"), pursuant to which DRI purchased rights to certain revenue streams in the U.S. from the Company in exchange for up to \$300.0 million in consideration consisting of: (a) \$55.0 million that was paid on the signing date; (b) \$25.0 million that is payable following the achievement of certain milestones with respect to the Company's

VRDN-003 pivotal phase 3 clinical trials, REVEAL-1 and REVEAL-2, on or before a specified date; (c) \$75.0 million that is payable following receipt of marketing approval for veligrotug from the FDA on or before a specified date; (d) \$15.0 million that is payable if the events set forth in the foregoing clauses (b) and (c) are met; (e) \$50.0 million that is payable following receipt of marketing approval for VRDN-003 from the FDA on or before a specified date; (f) at the Company's election, \$50.0 million that is payable following the Company's achievement of net sales of certain products equal to or exceeding \$1.1 billion on or before a specified date; and (g) an additional \$30.0 million that may be payable to the Company at a time and pursuant to financial terms agreed upon by the Company and DRI at such time.

The DRI Purchase and Sale Agreement contains customary representations, warranties and indemnities of the Company and DRI and customary covenants on the part of the Company, as well as a limit on the amount of incurrence of certain types of indebtedness, which limit automatically terminates a certain period of time following receipt of marketing approval for veligrotug in the U.S. The Company will pay tiered royalties to DRI based on net sales of veligrotug, VRDN-003 and certain other related products (the "Net Sales"). The royalties consist of (i) 7.5% of annual U.S. net sales up to and including \$600.0 million, which royalties could increase to low-double digits if marketing approval for VRDN-003 is not received prior to a specified date, (ii) 0.8% of annual U.S. net sales above \$600.0 million and up to and including \$900.0 million, (iii) 0.25% of annual U.S. net sales above \$900.0 million and up to \$2.0 billion, and (iv) no royalty owed for annual U.S. net sales in excess of \$2.0 billion. The DRI Purchase and Sale Agreement may only be terminated upon (i) repayment by the Company of a certain multiplier of the consideration paid to the Company by DRI (less payments by the Company to DRI to date) on or prior to a certain date or (ii) repayment by the Company of a certain multiplier of the consideration paid by DRI to the Company (less payments by the Company to DRI to date) following a change of control of the Company on or prior to a certain date. In the event of a change of control on or prior to a certain date, the Company has the option to repurchase, and DRI may require the Company to repurchase, the revenue participation right from DRI for the multiplier amount (less payments to date).

Amendment to the Loan and Security Agreement

In October 2025, the Company executed a second amendment (the "Hercules Second Amendment") to its Hercules Loan and Security Agreement.

Under the Hercules Second Amendment, the term loan facility was amended to provide an aggregate principal amount of up to \$300.0 million (the "New Term Loan"), consisting of (1) an initial tranche of \$100.0 million ("Tranche 1"), comprised of \$50.0 million drawn upon execution of the Hercules Second Amendment, \$25.0 million ("Tranche 1B") available through September 15, 2026, and \$25.0 million available from the earlier to occur of the expiration or full funding of Tranche 1B through December 15, 2026, (2) a second tranche of \$50.0 million ("Tranche 2"), subject to achievement of certain regulatory milestones, available from (A) the earlier to occur of the full draw of Tranche 1 and December 15, 2025 through (B) the earlier to occur of June 15, 2027 and the date that is 60 days following such achievement of such regulatory milestones (the "Tranche 2 Expiration Date"), (3) a third tranche of \$50.0 million ("Tranche 3"), subject to achievement of certain regulatory milestones, available from (A) the earlier to occur of the full draw of Tranche 2 and the Tranche 2 Expiration Date through (B) the earlier to occur of June 15, 2027 and the date that is 60 days following such achievement of such regulatory milestones (the "Tranche 3 Expiration Date"), (4) a fourth tranche of \$50.0 million, subject to achievement of a certain revenue milestone, available from (A) the earlier to occur of the full draw of Tranche 3 and the Tranche 3 Expiration Date through (B) March 15, 2028, and (5) a fifth tranche of \$50.0 million, subject to approval by the Lenders' investment committee(s), available through October 17, 2030. The milestones for Tranche 2, Tranche 3 and Tranche 4 have not yet been achieved. The obligations of the Company under the Hercules Second Amendment are secured by substantially all of the assets of the Company.

The New Term Loan has a maturity date of October 17, 2030. The New Term Loan bears interest at a floating per annum rate equal to the greater of (i) 8.95% and (ii) 1.45% above the Prime Rate, provided that the New Term Loan interest rate shall not exceed a per annum rate of 9.45%. Interest is payable monthly in arrears on the first business day of each month.

Under the Hercules Second Amendment, the Company is obligated to make interest-only payments through October 17, 2029. If certain regulatory milestones are met, then the interest-only period will be extended to October 17, 2030. The Company is required to repay the New 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 17, 2030. In addition, the Company is required to pay an end-of-term fee equal to 4.25% of the principal amount of funded New Term Loan advances if the New Term Loan is repaid on or prior to October 17, 2027 or 6% of the principal amount of funded New Term Loan advances at maturity if the New Term Loan is repaid after October 17, 2027.

Public Offering

In October 2025, the Company sold 11,425,000 shares of the Company’s common stock in a public offering at a public offering price of \$22.00 per share (the “October 2025 Public Offering”). The aggregate gross proceeds to the Company from the October 2025 Public Offering were \$251.4 million, before deducting underwriting discounts and commissions and other offering expenses payable by the Company. In addition, the Company granted the underwriters a 30-day over-allotment option to purchase up to an additional 1,713,750 shares of its common stock on the same terms and conditions as the common stock sold in the offering, which was exercised in full in October 2025 for gross proceeds to the Company of \$37.7 million, before deducting underwriting discounts and commissions and other offering expenses payable by the Company.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read together with our unaudited condensed consolidated financial statements and the related notes thereto included in Part I, Item 1 of this Quarterly Report and our consolidated financial statements and related notes thereto for the year ended December 31, 2024 included in our Annual Report on Form 10-K filed with the SEC on March 3, 2025 ("2024 Annual Report on Form 10-K"). 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 Quarterly Report.

Overview and Recent Developments

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, commercialization in TED, and development of FcRn therapies.

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.

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, followed by a transition to a secondary chronic phase. The only medicine approved by the FDA for TED is Tepezza® (teprotumumab), which is an intravenously administered monoclonal antibody that targets IGF-1R. Tepezza is marketed in the United States by Amgen Inc. ("Amgen").

The results from clinical trials of teprotumumab 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.

Development of Therapies to Treat Thyroid Eye Disease (TED)

We are developing two product candidates, veligrotug 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. Veligrotug demonstrated positive durability at 52 weeks in THRIVE, showing that 70% of patients who were proptosis responders at week 15 maintained their response at week 52. To meet the 300 patient standard safety database requirements for the veligrotug 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. In May 2025, the U.S. FDA granted Breakthrough Therapy designation to veligrotug. We submitted a BLA for veligrotug in October 2025 and anticipate submitting an MAA to the EMA in the first quarter of 2026.

In addition to our intravenous veligrotug program, VRDN-003 is our subcutaneous product candidate currently in pivotal clinical studies 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 selected doses of VRDN-003 that are likely to have similar clinical responses at the exposure levels of veligrotug that demonstrated robust clinical activity in its phase 2 clinical trials in TED, which tested two doses of veligrotug at 3 mg/kg and 10 mg/kg, once every three 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 are evaluating subcutaneous VRDN-003 administered every four weeks or every eight weeks and will assess outcomes versus placebo. In September 2025, we announced that REVEAL-1 and REVEAL-2 completed enrollment, enrolling 132 and 204 patients, respectively, each exceeding its target enrollments of 117 and 195 patients, respectively, due to demand. 67% of REVEAL-1 patients were enrolled from the U.S., and 56% of REVEAL-2 patients were enrolled from the U.S. In addition, to enable BLA submission for VRDN-003, we are conducting a safety study to meet the 300 patient standard safety database requirement (to also include patients from the REVEAL-1 and REVEAL-2 trials) for which we completed enrollment in October 2025, enrolling 321 patients, exceeding its target enrollment of 284 patients due to demand, and an auto-injector study to enable launching VRDN-003 in an auto-injector device, if approved. We anticipate topline data for REVEAL-1 in the first quarter of 2026 and REVEAL-2 in the second quarter 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 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. In September 2025, we announced that data from an ongoing phase 1 clinical trial in healthy volunteers showed that VRDN-006 led to IgG reductions that are consistent with the FcRn inhibitor class, and that VRDN-006 was sparing of albumin and LDL and was generally well-tolerated to date with no dose-limiting toxicities or serious adverse events.

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, and IgG levels returned to baseline 35 days after VRDN-008 dosing, more than twice as long as efgartigimod, which returned to baseline 14 days after dosing. VRDN-008 spared albumin and LDL, consistent with efgartigimod. We anticipate submitting an IND for VRDN-008 by the end of 2025 with healthy volunteer data available in 2026.

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 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 (Hong Kong) Limited (“Zai Lab”) and assigned the Manufacturing Development and Supply Agreement to Zai Lab in connection with the sublicense transaction. In July 2025, the Company entered into a side agreement with Zai Lab (the “Side Agreement”), with Zenas BioPharma as countersigner, pursuant to which the Company agreed to provide certain services directly to Zai Lab to support development and commercialization activities. In August 2025, the Company entered into a Material Transfer Agreement (“MTA”) with Zai Lab, to supply certain materials for clinical trial use.

In July 2025, we entered into a Collaboration and License Agreement pursuant to which we granted to Kissei an exclusive license to develop and commercialize products containing veligrotug and VRDN-003 including for the treatment of TED, in Japan, and, under certain circumstances, a non-exclusive license to manufacture such licensed products worldwide for use in Japan. As consideration for the Kissei Agreement, the transaction price included an upfront cash payment of \$70.0 million, which was recognized as revenue during the three months ended September 30, 2025. Additionally, we are eligible to receive up to an additional \$315.0 million of non-refundable milestone payments upon achieving specific milestone events during the contract term, as well as tiered royalty payments ranging from percentages in the twenties to the mid-thirties based on the annual net sales of any licensed products sold in Japan.

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 and from customers. 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 clinical research organizations (“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 contract development and manufacturing organizations (“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 may need to secure additional capital and could 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 and various income items of a non-recurring nature. We earn interest income from interest-bearing accounts, money market funds, and short-term investments. Interest expense consists of cash and non-cash interest expense on our long-term debt.

Critical Accounting Policies and Estimates

Our significant accounting policies are disclosed in Note 2. *Summary of Significant Accounting Policies* to our unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report.

Results of Operations

Comparison of the Three Months Ended September 30, 2025 and 2024

| | Three Months Ended September 30, | | Increase (Decrease) |
|---------------------------------------|----------------------------------|--------|---------------------|
| | 2025 | 2024 | |
| | (in thousands) | | |
| License revenue | \$ 70,000 | \$ — | \$ 70,000 |
| Collaboration revenue - related party | 570 | 86 | 484 |
| Research and development expenses | 86,261 | 69,158 | 17,103 |
| General and administrative expenses | 24,322 | 14,408 | 9,914 |
| Other income, net | 5,414 | 6,791 | (1,377) |

Revenue

License revenue for the three months ended September 30, 2025 was attributable to the collaboration and license agreement with Kissei. Collaboration revenue for both the three months ended September 30, 2025 and 2024 was attributable to our collaboration agreement with Zenas BioPharma and the Side Agreement and MTA with Zai Lab.

Research and Development Expenses

| | Three Months Ended September 30, | | Increase (Decrease) |
|--|----------------------------------|-----------|---------------------|
| | 2025 | 2024 | |
| | (in thousands) | | |
| Direct research and development expenses | | | |
| TED portfolio | \$ 55,191 | \$ 37,859 | \$ 17,332 |
| FcRn inhibitor portfolio | 11,121 | 16,414 | (5,293) |
| Other nonclinical and research and development costs | 1,247 | 750 | 497 |
| Unallocated expenses | | | |
| Personnel related expense (including share-based compensation) | 16,528 | 12,539 | 3,989 |
| Facility and other operating costs | 2,174 | 1,596 | 578 |
| Total research and development expenses | \$ 86,261 | \$ 69,158 | \$ 17,103 |

Direct costs related to the TED portfolio increased by \$17.3 million during the three months ended September 30, 2025 compared to the three months ended September 30, 2024, primarily attributable to:

- \$11.6 million increase in clinical trial costs and \$4.3 million increase in chemistry, manufacturing and controls costs to support the ongoing global phase 3 clinical trials for veligrotug and VRDN-003.

Direct costs related to the FcRn inhibitor portfolio decreased by \$5.3 million during the three months ended September 30, 2025 compared to the three months ended September 30, 2024, primarily attributable to:

- \$3.9 million decrease in milestone, license and option fees, primarily due to a \$4.0 million milestone payment to Paragon for an exclusive license agreement during the three months ended September 30, 2024; and
- \$1.8 million decrease in chemistry, manufacturing, and controls costs for FcRn inhibitor portfolio assets.

Personnel-related costs increased by \$4.0 million during the three months ended September 30, 2025 compared to the three months ended September 30, 2024, primarily attributable to increased headcount to support our ongoing research and development efforts, including share-based compensation and other employee compensation and recruiting costs.

Facility and other operating costs increased \$0.6 million during the three months ended September 30, 2025 compared to the three months ended September 30, 2024, primarily attributable to an increase in professional services fees for consultants and

contractors to support the planned BLA submission for veligrotug, which occurred in October 2025, and to advance clinical trials for VRDN-003.

We expect our research and development expenses to remain consistent as we continue to advance our clinical and nonclinical programs.

General and Administrative Expenses

General and administrative expenses were \$24.3 million during the three months ended September 30, 2025, compared to \$14.4 million during the three months ended September 30, 2024. The \$9.9 million increase in general and administrative expenses is primarily attributable to the following:

- \$4.9 million increase in personnel related costs, due primarily to increased headcount to support the growing organization;
- \$3.4 million increase in market research and related costs to prepare for the potential commercialization of veligrotug; and
- \$1.7 million increase in legal, accounting and other professional service fees to support the growing organization.

Other Income, net

Other income, net was \$5.4 million during the three months ended September 30, 2025 compared to \$6.8 million during the three months ended September 30, 2024 primarily comprised of interest income earned on short-term investments.

Comparison of the Nine Months Ended September 30, 2025 and 2024

| | Nine Months Ended September 30, | | Increase (Decrease) |
|---------------------------------------|---------------------------------|---------|---------------------|
| | 2025 | 2024 | |
| | (in thousands) | | |
| License revenue | \$ 70,000 | \$ — | \$ 70,000 |
| Collaboration revenue - related party | 717 | 230 | 487 |
| Research and development expenses | 249,721 | 166,294 | 83,427 |
| General and administrative expenses | 61,642 | 45,499 | 16,143 |
| Other income, net | 18,400 | 21,339 | (2,939) |

Revenue

License revenue for the nine months ended September 30, 2025 was attributable to the collaboration and license agreement with Kissei. Collaboration revenue for both the nine months ended September 30, 2025 and 2024 was attributable to our collaboration agreement with Zenas BioPharma and the Side Agreement and MTA with Zai Lab.

Research and Development Expenses

| | Nine Months Ended September 30, | | Increase (Decrease) |
|--|---------------------------------|-------------------|---------------------|
| | 2025 | 2024 | |
| | (in thousands) | | |
| Direct research and development expenses | | | |
| TED portfolio | \$ 151,640 | \$ 91,239 | \$ 60,401 |
| FcRn inhibitor portfolio | 41,498 | 27,276 | 14,222 |
| Other nonclinical and research and development costs | 2,402 | 1,599 | 803 |
| Unallocated expenses | | | |
| Personnel related expense (including share-based compensation) | 49,352 | 40,841 | 8,511 |
| Facility and other operating costs | 4,829 | 5,339 | (510) |
| Total research and development expenses | <u>\$ 249,721</u> | <u>\$ 166,294</u> | <u>\$ 83,427</u> |

Direct costs related to the TED portfolio increased by \$60.4 million during the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024, primarily attributable to:

- \$52.2 million increase in clinical trial costs and \$10.5 million increase in chemistry, manufacturing and controls costs to support the ongoing global phase 3 clinical trials for veligrotug and VRDN-003.

Direct costs related to the FcRn inhibitor portfolio increased by \$14.2 million during the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024, primarily attributable to:

- \$8.4 million increase in chemistry, manufacturing, and controls costs to support IND-enabling activities for assets across the FcRn inhibitor portfolio; and
- \$5.1 million increase in nonclinical research and clinical study activity to advance the FcRn inhibitor portfolio.

Personnel-related costs increased by \$8.5 million during the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024, primarily attributable to:

- \$11.4 million increase due primarily to increased headcount to support our ongoing research and development efforts, including share-based compensation, travel costs, and other employee compensation and recruiting costs; partially offset by,
- \$2.9 million decrease in severance costs primarily related to separation agreements with former executive officers, including a \$1.6 million decrease in share-based compensation due to the acceleration of stock option vesting during the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024.

Facility and other operating costs decreased \$0.5 million during the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024, primarily attributable to a decrease in professional services fees for consultants and contractors.

We expect our research and development expenses to remain consistent as we continue to advance our clinical and nonclinical programs.

General and Administrative Expenses

General and administrative expenses were \$61.6 million during the nine months ended September 30, 2025, compared to \$45.5 million during the nine months ended September 30, 2024. The \$16.1 million increase in general and administrative expenses is primarily attributable to the following:

- \$9.0 million increase in personnel related costs, due primarily to increased headcount to support the growing organization and to prepare for the potential commercialization of veligrotug; and
- \$6.7 million increase in market research and related costs to prepare for the potential commercialization of veligrotug.

Other Income, net

Other income, net was \$18.4 million during the nine months ended September 30, 2025 compared to \$21.3 million during the nine months ended September 30, 2024, primarily comprised of interest income earned on short-term investments.

Additional 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. We have no products approved for commercial sale and have not generated any revenue from product sales. Since our inception and through September 30, 2025, we have generated an accumulated deficit of \$1,218.1 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.

In addition, we may continue to incur additional operating losses as a result of planned expenditures for research and development activities, our drug development programs, including clinical trial and manufacturing costs, and the continued build-out of clinical, manufacturing, commercial, and compliance capabilities. Our ability to generate revenues from sales of veligrotug and VRDN-003 in the U.S., if regulatory approval is granted, depends on us being able to establish sales and marketing capabilities and gain acceptance in the marketplace, which we may be unable to do in a timely manner or at all. In addition, we cannot predict with any certainty whether and to what extent the timing or availability of additional funds under the DRI Purchase and Sale Agreement or the Hercules Second Amendment, if at all. Our ability to achieve milestones under the DRI Purchase and Sale Agreement or drawdown on the remaining tranches under the Hercules Second Amendment are subject to our achievement of certain regulatory and commercial milestones on or before certain dates or, for certain milestones, on mutual agreement of the applicable party.

The Company expects that its existing cash, cash equivalents and short-term investments as of September 30, 2025 of \$490.9 million will enable the Company to fund its planned operations for at least twelve months from the date of issuance of these unaudited condensed consolidated financial statements. Based on our current business plans, we believe that the \$272.4 million in net proceeds from the October 2025 Public Offering, together with our existing current cash, cash equivalents, short-term investments, the \$70.0 million upfront payment receivable from Kissei, which was paid in the fourth quarter 2025, the \$55.0 million upfront payment that we received in connection with our entry into the DRI Purchase and Sale Agreement and the \$115.0 million in potential near-term milestones anticipated under the DRI Purchase and Sale Agreement, the \$30.0 million received by the Company from the Hercules Second Amendment, and anticipated revenue from veligrotug and VRDN-003 sales, if each is approved on our anticipated timelines, will be sufficient to fund our planned operations to break even where our anticipated revenues fund our anticipated operating expenses.

Due to numerous factors described in more detail under the caption Part II, Item 1A, “Risk Factors” of this Quarterly Report on Form 10-Q, we may require significant additional capital earlier than we currently expect under our present business plans.

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.

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.

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, which was available through February 15, 2025; (3) a third tranche of \$20.0 million, subject to achievement of certain regulatory milestones, which was available through March 31, 2025; and (4) a fourth tranche of \$60.0 million subject to approval by the Lenders’ investment committee(s), which was available through June 15, 2025. 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 Amended 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 September 30, 2025 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 our 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.

As a subsequent event, in October 2025, we executed a second amendment to our Hercules Loan and Security Agreement extending the maturity date to October 17, 2030 and increasing the aggregate principal amount of up to \$300.0 million, see Note 13 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

Purchase and Sale Agreement with DRI

As a subsequent event, in October 2025, we entered into a Purchase and Sale Agreement with DRI, pursuant to which DRI purchased rights to certain revenue streams in the U.S. from the Company in exchange for up to \$300.0 million in consideration, see Note 13 to our unaudited condensed consolidated financial statements included elsewhere in this report.

Public Offerings

In January 2024, we 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 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.

As a subsequent event, in October 2025, we sold 11,425,000 shares of our common stock in a public offering at a price of \$22.00 per share and granted the underwriters a 30-day over-allotment option to purchase up to an additional 1,713,750 shares of our common stock on the same terms and conditions as the common stock sold in the offering, which option was exercised in full in October 2025, see Note 13 to our unaudited condensed consolidated financial statements included elsewhere in this report.

ATM Agreement

In September 2022, we entered into an Open Market Sale AgreementSM (the “September 2022 ATM Agreement”) with Jefferies pursuant to which we could 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 received a commission of up to 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, we sold 3,058,751 shares 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 nine months ended September 30, 2025, we sold 245,388 shares under the September 2022 ATM Agreement at a weighted average price of \$20.14 per share, for aggregate net proceeds of approximately \$4.8 million, including commissions to Jefferies as a sales agent. During the three months ended September 30, 2025, there were no sales under the September 2022 ATM Agreement. The September 2022 ATM Agreement was terminated in March 2025 and no further offerings or sales of common stock will be conducted under the September 2022 ATM Agreement.

In March 2025, we entered into an Open Market Sale AgreementSM (the “March 2025 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 \$300.0 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 up to 3.0% of the gross proceeds of any shares of common stock sold under the March 2025 ATM Agreement. During the three and nine months ended September 30, 2025, we sold 500,000 shares under the March 2025 ATM Agreement at a weighted average price of \$19.92 per share, for aggregate net proceeds of approximately \$9.8 million, including commissions to Jefferies as a sales agent.

Summarized cash flows for the nine months ended September 30, 2025 and 2024 are as follows:

| | Nine Months Ended September 30, | | Increase (Decrease) |
|---|---------------------------------|------------------|---------------------|
| | 2025 | 2024 | |
| | (in thousands) | | |
| Net cash provided by (used in): | | | |
| Operating activities | \$ (252,637) | \$ (158,987) | \$ (93,650) |
| Investing activities | 301,857 | (165,736) | 467,593 |
| Financing activities | 20,833 | 422,213 | (401,380) |
| Net increase in cash and cash equivalents | <u>\$ 70,053</u> | <u>\$ 97,490</u> | <u>\$ (27,437)</u> |

Operating Activities

Net cash used in operating activities was \$252.6 million for the nine months ended September 30, 2025, and primarily consisted of our net loss of \$222.2 million, adjusted for non-cash items of \$27.9 million (primarily share-based compensation of \$32.3 million, offset by the accretion and amortization of premiums and discounts on available-for-sale securities of \$5.0 million), and changes in working capital of \$58.3 million. The change in working capital was primarily related to an increase of \$70.0 million in unbilled revenue due to timing of upfront fee under the Kissei Agreement, partially offset by a decrease of \$8.9 million in prepaid expenses and other current assets and a net increase of \$2.8 million in accounts payable and accrued and other liabilities due to the timing of payments to vendors for ongoing clinical trial and manufacturing activities.

Net cash used in operating activities was \$159.0 million for the nine months ended September 30, 2024, and primarily consisted of a net loss of \$190.2 million, adjusted for non-cash items of \$22.1 million (primarily share-based compensation of \$33.2 million, partially offset by accretion and amortization of premiums and discounts on available-for-sale securities of \$12.4 million) and changes in working capital of \$9.1 million. The change in working capital was primarily related to a net increase of \$14.6 million in accounts payable and accrued and other liabilities, partially offset by an increase of \$5.3 million in prepaid expenses and other current assets due to the timing of payments to vendors for ongoing clinical trial and manufacturing activities.

Investing Activities

Net cash provided by investing activities was \$301.9 million during the nine months ended September 30, 2025, and consisted primarily of \$302.1 million in net maturities of short-term investments.

Net cash used in investing activities was \$165.7 million during the nine months ended September 30, 2024, and consisted primarily of \$165.3 million in net purchases of short-term investments.

Financing Activities

Net cash provided by financing activities was \$20.8 million during the nine months ended September 30, 2025, and consisted of primarily of net proceeds of \$14.5 million from the March 2025 ATM Agreement and the September 2022 ATM Agreement, as well as \$3.6 million in proceeds from the exercise of stock options.

Net cash provided by financing activities was \$422.2 million during the nine months ended September 30, 2024, and consisted primarily of net proceeds of \$419.4 million from the January 2024 Public Offering, September 2024 Public Offering and the September 2022 ATM Agreement, as well as \$2.2 million in proceeds from the exercise of stock options.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There were no material changes to our market risks in the nine months ended September 30, 2025, when compared to the disclosures in Item 7A of our 2024 Annual Report on Form 10-K.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed 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, as appropriate, 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.

As required by Rule 13a-15(b) and Rule 15d-15(b) of the Exchange Act, an evaluation was carried out under the supervision and with the participation of management, including our principal executive officer and principal financial officer, of the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e) and 15d-15(e)) as of the end of the quarter covered by this Quarterly Report. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at a reasonable level of assurance.

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 affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. 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 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 the other information contained in this Quarterly Report on Form 10-Q, including “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the unaudited condensed consolidated financial statements and related notes.

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 nine months ended September 30, 2025 and 2024, our net loss was \$222.2 million and \$190.2 million, respectively. As of September 30, 2025, we had an accumulated deficit of \$1,218.1 million and cash, cash equivalents, and short-term investments of \$490.9 million.

We expect that our current cash, cash equivalents and short-term investments, will enable us to fund our planned operations for at least twelve months from the date of issuance of these unaudited condensed consolidated financial statements. We may 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, our ability to generate revenues from sales of veligrotug and VRDN-003 in the U.S., if approved, 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, the Hercules Loan and Security Agreement, the Kissei Agreement, and the DRI Purchase and Sale 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 September 30, 2025, we had \$490.9 million of cash, cash equivalents, and short-term investments. We expect that our current cash, cash equivalents and short-term investments, will enable us to fund our planned operations for at least twelve months from the date of issuance of these unaudited condensed consolidated financial statements. We may need to secure additional capital to continue to fund our operations and service our obligations in the future. If we are unable to secure 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 operating expenses to increase in connection with our ongoing activities, particularly as we advance our product candidates through clinical trials, pre-commercial, and commercial activities. We may 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, until we begin to generate revenue from product sales, if any of our product candidates are approved, 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 secure 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 until our product candidates receive marketing authorization, if ever. Even if we receive such authorization, 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 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 capital 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 capital 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 March 2025 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, and other arrangements, such as the DRI Purchase and Sale 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, CROs, 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.

We may not be entitled to obtain additional milestone payments under the DRI Purchase and Sale Agreement.

In October 2025, we entered into the Purchase and Sale Agreement with DRI. In addition to the \$55 million we received at signing, this agreement makes available to us up to an additional \$245 million in milestone payments. However, these additional milestone payments are subject to satisfaction of certain conditions related to certain VRDN-003 clinical trials and regulatory approvals or commercial sales of veligrotug and VRDN-003 on or prior to a certain date. Should we not satisfy the

conditions of the applicable milestones, or if we fail to meet our obligations or default under this agreement, the actual amount of additional milestone payments to us could be substantially less than the maximum amounts available thereunder. In the event of a change of control on or prior to a certain date, the Company has the option to repurchase, and DRI may require the Company to repurchase, the revenue participation right from DRI for the multiplier amount (less payments to date).

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 rely, 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 at least 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, where we expect that the REVEAL-1 and REVEAL-2 phase 3 clinical trials, together with a safety database comprising at least 300 treated patients (safety database inclusive of REVEAL-1 and REVEAL-2 patients), will support global health authority registration for VRDN-003 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. Additionally, Viridian is performing an autoinjector PK study for VRDN-003 to bridge bioequivalence from the vial/syringe used in the REVEAL-1 and REVEAL-2 trials and the autoinjector, with which we plan to launch commercially. However, the results may not show bioequivalence and/or global health authorities may not agree with the methodologies employed to support bioequivalence. If either of these occur, our BLA for VRDN-003 and/or its marketing approval may be significantly delayed.

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 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 (“U.S.”), 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” in our 2024 Annual Report on Form 10-K.

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 current presidential administration and the prospect of potential downsizing, reforming and restructuring of federal health agencies, there may be substantial loss of key FDA staff. Also, as a result of the government shutdown, the FDA staff may be unable to process and review regulatory submissions in a timely manner or at all. If there are significant gaps in subject matter expertise or certain government operations remain suspended for an extended period, the 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 U.S., we anticipate seeking regulatory approval to commercialize our product candidates in Europe and anticipate seeking regulatory approval to commercialize veligrotug 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 U.S.

The process of obtaining regulatory approvals, both in the U.S. 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 U.S. 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.

There is substantial uncertainty as to whether and to what extent measures implemented by the current presidential administration in the U.S. will impact the FDA. Any substantial changes to FDA's operations, policies, and workforce could adversely affect our business.

Since the start of the current presidential administration in 2025, U.S. policy changes have been implemented at a rapid pace and additional changes are likely. It is difficult to predict how executive actions that may be taken under the current administration may affect the FDA's ability to exercise its regulatory authority. If any actions impose constraints on the FDA's ability to engage in routine oversight and product review activities in the normal course, our business may be negatively impacted. Additionally, the new administration and federal government could adopt legislation, regulations, policies, or guidances that adversely affect our business or negatively impact the development, approval, and commercialization of our products, including creating a more challenging or costly environment in which to work.

The President and his cabinet have also undertaken significant efforts to reduce the size and spending of the federal government, including at FDA. A significant reduction in FDA's workforce or FDA's budget, or other disruptions at FDA, could materially impact FDA's ability to engage in a variety of activities that may affect our business, including routine regulatory and oversight activities.

Any reduction in FDA’s workforce could delay or materially impact FDA’s feedback on our development programs, including through meetings and other informal interactions, and affect FDA’s review and oversight of our product candidates. Additionally, changes in FDA personnel under the current presidential administration may lead to changes in the regulations, policies, and operations of the FDA, which may impact our clinical development plans. Any of these actions could adversely affect the development and approval of our product candidates.

Any reduction in FDA’s workforce could also lead to disruptions and delays in FDA’s review and oversight of our product candidates and impact FDA’s ability to provide timely feedback on our development programs, including through Type C or Type D meetings or informal interactions. Additionally, reductions in workforce or other disruptions to the agency, particularly in the review or inspection divisions, could extend BLA review timelines, including for our BLA for veligrotug submitted in October 2025, delay or prevent pre-approval inspections, and limit opportunities for FDA feedback on pending applications. Further, FDA may pursue legislative, regulatory, or policy changes regarding the standards or processes for approving our product candidates that we may be unable to satisfy. Any of these actions may delay or limit our ability to obtain FDA approval and commercialize our product candidates.

A prolonged U.S. federal government shutdown could materially and adversely affect our business and operations.

Any disruption in the operations of the U.S. federal government, including the current shutdown resulting from the failure of Congress to enact appropriations bills, could materially and adversely affect our business, operations and financial condition. The current federal government shutdown has resulted, and may continue for a prolonged period of time to result, in the furlough of federal employees, reduced availability of government services, and suspension or delay of activities by key agencies that regulate, fund, or interact with our business, including the FDA, the Department of Health and Human Services, and the U.S. Patent and Trademark Office. During this period, review and approval of our filings, applications, and submissions could be delayed, and we may be unable to access or rely upon certain government data or systems. In particular, it may lead to disruptions and delays in FDA’s review and oversight of our product candidates and impact the FDA’s ability to provide timely feedback on our development programs, including through formal Prescription Drug User Fee Act (“PDUFA”) meetings or informal interactions. Additionally, it could delay submission or filing of or extend BLA review timelines, including for our BLA for veligrotug submitted in October 2025, delay or prevent pre-approval inspections, and limit opportunities for FDA feedback on pending applications.

Any of these actions may delay or limit our ability to obtain FDA approval and commercialize our product candidates, which in turn may limit or otherwise impact our ability to obtain additional milestone payments under the DRI Purchase and Sale Agreement. In addition, the federal government shutdown may adversely affect the broader U.S. economy, investor confidence, and capital markets. Such conditions could negatively impact the liquidity or trading volume of our securities, which in turn could have a material adverse effect on our business, results of operations, and stock price.

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 FeRn 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” in our 2024 Annual Report on Form 10-K.

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. In December 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.

In September 2024, we announced topline data from the phase 3 THRIVE trial of veligrotug in patients with active TED. In December 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. The final results of clinical trials may include additional outcome measurements made throughout the duration of the clinical trial. This creates a risk that the final results could be materially different from the preliminary results reported, including those reported to date, and may include additional outcome measurements made throughout the duration of the clinical trial that are not positive or favorable. Additionally, differences in patient populations across our clinical trials may lead to inconsistent or unrepresentative data.

Negative or unfavorable additional outcomes measurements made throughout the duration of a clinical trial or 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, Alumis, Inc. (merged with ACELYRIN, Inc. in May 2025), 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 and Immunovant, Inc. 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-IL-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" in our 2024 Annual Report on Form 10-K.

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 hire and retain an adequate number of effective commercial personnel, including at a pace required to be ready to launch our products, if approved;

- 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 timely 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. 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. For example, our first in human or early clinical studies for a product candidate may be done at a single site. A disruption of operations at the single site could delay or terminate our clinical trial, and we may not be able to enter into arrangements with alternative CROs in a timely manner or do so on commercially reasonable terms. If this happens, 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 Biologics (Hong Kong) Limited (“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 with 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 health 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 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 U.S. 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.

We currently rely on certain foreign manufacturers to manufacture our drug substance and drug product. The current presidential administration has announced plans to increase tariffs, including on pharmaceuticals, though it remains unclear whether and to what extent new tariffs will be adopted, or the effect that any such actions would have on us or our industry. Any unfavorable tariffs may make it more difficult for us to manufacture our product candidates, increase the cost of, and affect the demand for, our product candidates or products, if approved, which could have an adverse effect on our business.

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 current presidential 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 U.S. 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 U.S. 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 U.S. 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 U.S., 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S., 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 secure 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 U.S. can be less extensive than those in the U.S. 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 U.S. 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 U.S. 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 U.S. 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 of 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.” See “Business—Government Regulation—Orphan Drug Designation” in our 2024 Annual Report on Form 10-K. Our ability to obtain and maintain orphan drug designation and the benefits thereof, including orphan drug exclusivity, may materially impact our financial performance.

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 or Priority Review for a product candidate, we may not receive such designations or review from the FDA. However, even if we receive Fast Track or Breakthrough Therapy designation, it does not ensure that we will receive Priority Review or 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 or Priority Review 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" in our 2024 Annual Report on Form 10-K.

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 U.S., there have been and continue to be a number of executive, legislative, and regulatory initiatives to contain healthcare costs and reexamine drug pricing and payment models. 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 and executive initiatives designed to, among other things, bring more transparency to product pricing, and reform government program reimbursement methodologies for products. 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. Legal challenges to the IRA have been initiated and many remain underway. In April 2025, President Trump issued an Executive Order with multiple directives aimed at lowering drug prices, including refining the Medicare drug price negotiation program established by the IRA; accelerating competition for high-cost prescription drugs; and facilitating drug importation. In May 2025, President Trump issued another Executive Order that directed government agencies and officials to identify most-favored-nation pricing targets for prescription drugs and looked to pharmaceutical manufacturers to make significant progress towards delivering

target prices to patients. Many of these reform initiatives will require additional legal and/or administrative action to implement. There is uncertainty regarding the nature or impact of any drug or broader healthcare reform implemented by the current presidential administration through executive or administrative action or by Congress, and the extent to which any such action will be subject to legal challenges, including litigation, or other challenges. It is unclear how any such healthcare reform measures will impact our business. See “Business—Health Reform” in our 2024 Annual Report on Form 10-K.

We cannot predict the likelihood, nature, or extent of additional state or federal healthcare reform measures that may be adopted in the future, 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” in our 2024 Annual Report on Form 10-K.

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" in our 2024 Annual Report on Form 10-K.

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 disputes with other countries, natural disasters, public health crises, political crises, geopolitical events, 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 global military conflicts 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 conditions, 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 U.S. 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 may 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 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Rule 10b5-1 Trading Arrangements

During the three months ended September 30, 2025, none of our 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 of Regulation S-K.

ITEM 6. 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.

| Exhibit No. | Description of Exhibit | Incorporated by Reference | | |
|-------------------|---|---------------------------|-------------|--------|
| | | Form | Filing Date | Number |
| 3.1 | Second Restated Certificate of Incorporation of the Registrant, effective as of March 9, 2022. | 10-K | 3/11/2022 | 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 | 9/23/2021 | 3.1 |
| 4.1 | Specimen Common Stock Certificate. | S-1 | 3/19/2014 | 4.1 |
| 10.1 [^] | Collaboration and License Agreement, by and between Viridian Therapeutics, Inc. and Kissei Pharmaceutical Co. Ltd, dated July 30, 2025. | | | |

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| 10.2 | Sixth Amendment to Lease by and between Viridian Therapeutics, Inc. and Watch City Ventures MT, LLC dated as of September 8, 2025. | x |
| 31.1 | Certification of Principal Executive Officer pursuant to Rule 13a-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 Rule 13a-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 |
| 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 |

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- ^ 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.

SIGNATURES

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

VIRIDIAN THERAPEUTICS, INC.

Date: November 5, 2025

By: /s/ Stephen Mahoney
Stephen Mahoney
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: November 5, 2025

By: /s/ Seth Harmon
Seth Harmon
Chief Financial Officer
(Principal Financial Officer; Principal Accounting Officer)

Certain portions of this exhibit (indicated by “[***]”) have been omitted in compliance with Regulation S-K Item 601(b)(10)(iv) as the Company determined the omitted information (i) is not material and (ii) is the type that the Company customarily and actually treats as private or confidential.

COLLABORATION AND LICENSE AGREEMENT

by and between

Viridian Therapeutics, Inc.

and

Kissei Pharmaceutical Co., Ltd.

Dated as of July 30, 2025

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COLLABORATION AND LICENSE AGREEMENT

This COLLABORATION AND LICENSE AGREEMENT (this “**Agreement**”) is made as of July 30, 2025 (the “**Effective Date**”) by and between Viridian Therapeutics, Inc. (“**Viridian**”), having a place of business at 221 Crescent Street #103A, Waltham, MA 02453, and Kissei Pharmaceutical Co., Ltd. (“**Kissei**”), having a place of business at 19-48, Yoshino, Matsumoto City, Nagano Prefecture, 399-8710, Japan. Viridian and Kissei are referred to in this Agreement individually as a “**Party**” and collectively as the “**Parties**.”

RECITALS

WHEREAS, Viridian is a clinical-stage biopharmaceutical company engaged in the research and development of new drug therapies for the treatment of autoimmune conditions. Viridian is developing intravenous (IV) veligrotug and subcutaneous (SC) VRDN-003 for the treatment of thyroid eye disease (“**TED**”);

WHEREAS, Viridian Controls certain Know-How and Patent Rights relating to such proprietary compounds;

WHEREAS, Kissei is a pharmaceutical company engaged in the research, development, and commercialization of pharmaceutical and biologic products in Japan; and

WHEREAS, Kissei wishes to obtain from Viridian an exclusive license to develop, manufacture, and commercialize products containing veligrotug and VRDN-003 in the Territory, and Viridian is willing to grant such a license to Kissei, all in accordance with the terms and conditions set forth herein.

AGREEMENT

NOW, THEREFORE, the Parties hereby agree as follows:

Article 1 DEFINITIONS

Unless specifically set forth to the contrary herein, the following terms will have the respective meanings set forth below, whether used in the singular or plural:

- 1.1 “**Accounting Standards**” means US GAAP, Japan GAAP, or IFRS (as applicable to a Party).
 - 1.2 “**Additional Global Clinical Trial**” means any Global Clinical Trial conducted by Viridian to investigate (a) any Territory Development Indication or (b) any other indication for which (i) Kissei delivers an Additional Global Clinical Trial Participation Notice in accordance with Section 4.3.2 (Participation in Additional Global Clinical Trial), and (ii) the Parties, through the JSC, agree upon a Territory Development Plan for such indication in accordance with Section 4.3.2 (Participation in Additional Global Clinical Trial).
 - 1.3 “**Additional Global Clinical Trial Participation Notice**” means written notification to Viridian delivered by Kissei in accordance with Section 4.3.2 (Participation in Additional Global Clinical Trial) stating that Kissei elects to participate in a proposed Global Clinical Trial in an indication that is not a Territory Development Indication.
 - 1.4 “**Adverse Event**” means any unwanted or harmful medical occurrence in a patient or subject who is administered a Licensed Product, whether or not considered related to such Licensed Product,
-

including any undesirable sign (including abnormal laboratory findings of clinical concern), symptom or disease temporally associated with the use of such Licensed Product.

- 1.5 “**Affiliate**” means, with respect to a Person, any other Person that controls, is controlled by, or is under common control with such Person. For the purpose of this definition only, “control” (including, with correlative meaning, the terms “controlled by” and “under the common control”) means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of any Person, whether by the ownership of more than 50% of the voting security of such Person, by contract or otherwise.
- 1.6 “**Agreement**” has the meaning set forth in the Preamble.
- 1.7 “**Alliance Manager**” has the meaning set forth in Section 3.1 (Alliance Managers).
- 1.8 “**Anti-Corruption Laws**” means any local and other anti-corruption laws, including the provisions of the United States Foreign Corrupt Practices Act, as amended.
- 1.9 “**Applicable Law**” means collectively (a) all laws, rules, regulations, ordinances, decrees, judicial and administrative orders (and any license, franchise, permit, or similar right granted under any of the foregoing), (b) any policies and other requirements of any applicable Governmental Authority that govern or otherwise apply to a Party, including all Anti-Corruption Laws, and (c) any other practices related to environmental, social, ethical, and governance best practices that are generally accepted in the industry.
- 1.10 “**Approved Labeling**” means: (a) the Regulatory Authority-approved full prescribing information for the Licensed Products; and (b) the Regulatory Authority-approved labels and other written, printed, or graphic materials on any container, wrapper, or any package insert that is used with or for the Licensed Products.
- 1.11 “**Biosimilar**” means, with respect to a particular Licensed Product in a particular country, a pharmaceutical product that (a) contains the identical Licensed Antibody as the affected Licensed Product in the same dosage form, route of administration, and formulation (e.g., oral, injectable, or intranasal), (b) is marketed by a Person other than Kissei or its respective Affiliates or Sublicensees for at least one of the same Territory Development Indication as such Licensed Product, and such Person did not purchase such product in a chain of distribution that included any of Kissei or its Affiliates or Sublicensees, and that (c) (i) is subject to a license for administration to humans under Section 351(a) or 351(k) of the Public Health Service Act (42 U.S.C. § 201 et seq.), as amended, (ii) has been licensed as a similar biological medicinal product by the European Medicines Agency as described in Directive 2001/83/EC, as may be amended, or any subsequent or superseding law, statute or regulation, or (iii) approved in reliance on the Regulatory Approval for such Licensed Product (or any data included therein) under any equivalent law, statute, or regulation to (i) or (ii) outside of the United States or Europe.
- 1.12 “**Breach Notification**” has the meaning set forth in Section 13.2.2 (Termination for Material Breach).
- 1.13 “**Business Day**” means a day other than a Saturday, Sunday, or a day on which banking institutions in Boston, Massachusetts or Tokyo, Japan are required by Applicable Law to remain closed.
- 1.14 “**Buyers**” has the meaning set forth in Section 1.111 (“Net Sales”).
- 1.15 “**Calendar Quarter**” means the respective periods of three consecutive calendar months ending on March 31, June 30, September 30, and December 31.
- 1.16 “**Calendar Year**” means each 12-month period commencing on January 1.

- 1.17** “**cGMP**” means all current Good Manufacturing Practices and regulations applicable to the Manufacture of the Licensed Products that are promulgated by any applicable Regulatory Authority having jurisdiction over the Manufacture of the Licensed Products, including, as applicable, as promulgated under and in accordance with (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 4, 210, 211, 601, 610 and 820, (b) European Directive 2003/94/EC and Eudralex 4, (c) the principles detailed in the International Conference on Harmonization’s Q7 Guideline, and (d) the equivalent Applicable Law in any relevant country or region, each as may be amended and applicable from time to time.
- 1.18** “**Change of Control**” means, with respect to a Party, that: (a) any Third Party acquires directly or indirectly the beneficial ownership of any voting security of such Party, or if the percentage ownership of such Third Party in the voting securities of such Party is increased through stock redemption, cancellation, or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of voting securities representing more than 50% of the total voting power of all of the then outstanding voting securities of such Party; (b) any merger, consolidation, recapitalization, or reorganization of such Party is consummated that would result in shareholders or equity holders of such Party immediately prior to such transaction owning 50% or less of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction; (c) the shareholders or equity holders of such Party approve any plan of complete liquidation of such Party, or an agreement for the sale or disposition by such Party of all or substantially all of such Party’s assets, in each case, through one or more related transactions, other than to an Affiliate or pursuant to one or more related transactions that would result in shareholders or equity holders of such Party immediately prior to such transaction owning more than 50% of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction; or (d) the sale or transfer to any Third Party, in one or more related transactions, of all or substantially all of such Party’s consolidated assets taken as a whole.
- 1.19** “**Clinical Development**” means, with respect to any product, activities in furtherance of performing Clinical Trials to study such product. “**Clinically Develop**” and “**Clinically Developing**” will be construed accordingly.
- 1.20** “**Clinical Trial**” means any clinical trial in humans that is conducted in accordance with GCP, including any Territory-Specific Clinical Trial or Global Clinical Trial.
- 1.21** “**CMO**” means a contract manufacturing organization.
- 1.22** “**Collaboration Know-How**” means any Know-How [***] by or on behalf of a Party or its Affiliates, including by or on behalf of its licensees, Sublicensees, or, with respect to Know-How [***], in each case, in the performance of activities under this Agreement.
- 1.23** “**Collaboration Patent Right**” means any Patent Right that Covers any Know-How included in the Collaboration Know-How.
- 1.24** “**Collaboration Technology**” means Collaboration Know-How and Collaboration Patent Rights.
- 1.25** “**Combination Product**” means any single product comprising both (a) a Licensed Antibody and (b) one or more other therapies or pharmaceutically active compounds or substances that do not require the use of any Viridian Technology. The Licensed Antibody portion of any Combination Product will be deemed the “**Licensed Component**” and the other portion of such Combination Product the “**Other Component**,” and each Combination Product will be deemed a Licensed Product hereunder.
- 1.26** “**Commercialization**” means with respect to any product, any and all activities directed to the marketing, promotion, distribution, pricing, reimbursement, import, export, offering for sale, and sale of such product and interacting with Regulatory Authorities following receipt of Regulatory Approval in the applicable country or region for such product regarding the foregoing, including seeking and maintaining any required Reimbursement Approval, but excluding any activities

directed to Manufacturing or Development. “Commercialize,” “Commercializing,” and “Commercialized” will be construed accordingly.

- 1.27 “Commercially Reasonable Efforts” means, [***].
- 1.28 “Competing Product” means any product that Kissei and its Affiliates (and its and their (sub)licensees) are prohibited from [***].
- 1.29 “Confidential Information” means, subject to Section 9.3 (Exemptions), (a) Know-How and any technical, scientific, trade, research, manufacturing, business, financial, marketing, product, supplier, intellectual property, and other non-public or proprietary data or information (including unpublished patent applications) that may be disclosed by one Party or its Affiliates to the other Party or its Affiliates pursuant to this Agreement (including information disclosed prior to the Effective Date pursuant to the Confidentiality Agreement), regardless of whether such information is specifically marked or designated as confidential and regardless of whether such information is in written, oral, electronic, or other form, and (b) the terms of this Agreement.
- 1.30 “Confidentiality Agreement” means the Mutual Confidentiality Agreement, dated [***], between the Parties (as amended from time to time).
- 1.31 “Control” or “Controlled” means the possession by a Party (whether by ownership, license, or otherwise other than pursuant to this Agreement) of, (a) with respect to any tangible Know-How, the legal authority or right to physical possession of such tangible Know-How, with the right to provide such tangible Know-How to the other Party on the terms set forth herein, (b) with respect to intangible property or intangible property rights, including Patent Rights, Regulatory Approvals, Regulatory Submissions, intangible Know-How, or other intellectual property rights, the legal authority or right to grant a license, sublicense, access, or right to use (as applicable) to the other Party under such Patent Rights, Regulatory Approvals, Regulatory Submissions, intangible Know-How, or other intellectual property rights on the terms set forth herein, in each case ((a) and (b)), without breaching or otherwise violating the terms of, or incurring any payment obligations under, any arrangement or agreement with a Third Party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such access, right to use, licenses, or sublicense and without being required to make any payment to any Third Party, other than payment obligations pursuant to Third Party IP Agreements in accordance with Section 2.5.4 (Third Party In-Licenses) [***], and (c) with respect to any product, the legal authority or right to grant an exclusive license or sublicense under Patent Rights that Cover such product or Know-How that relates to such product. Notwithstanding the foregoing, a Party and its Affiliates will not be deemed to “Control” any of the foregoing (a) – (c) that, prior to the consummation of a Change of Control of such Party, is owned or in-licensed by a Third Party that becomes an Affiliate of such acquired Party (or that merges or consolidates with such Party) after the Effective Date solely as a result of such Change of Control.
- 1.32 “Cover” means, with respect to a particular subject matter at issue and a relevant Patent Right, that the manufacture, use, sale, offer for sale, or importation of such subject matter would [***] claims in such Patent Right.
- 1.33 “CREATE Act” has the meaning set forth in Section 12.2 (CREATE Act).
- 1.34 “CRO” means a contract research organization.
- 1.35 “Debarred/Excluded” means any Person becoming debarred or suspended under 21 U.S.C. §335(a) or (b), the subject of a conviction described in Section 306 of the FD&C Act, excluded, or having previously been excluded, from a federal or governmental health care program, debarred from federal contracting, convicted of or pled *nolo contendere* to any felony, or to any federal or state legal violation (including misdemeanors) relating to prescription drug products or fraud, the subject to OFAC sanctions or on the OFAC list of specially designated nationals, or the subject of any similar sanction of any Governmental Authority in the Territory.

- 1.36 “[***]” has the meaning set forth in Section 4.3.4 ([***]).
- 1.37 “[***] **Know-How**” means, [***], any data or other Know-How generated [***] in the performance of activities in furtherance of Clinical Trials to investigate such [***].
- 1.38 “[***] **Patent Right**” means, [***], any Patent Rights that (a) are owned or controlled [***] and (b) Cover [***] Know-How generated in the performance of Clinical Trials to investigate [***]. [***].
- 1.39 “[***] **Technology**” means, [***], the [***] Know-How generated in the performance of Clinical Trials to investigate [***] and all [***] Patent Rights Covering such [***] Know-How.
- 1.40 “**Deficient Site**” has the meaning set forth in Section 4.6.2 (Deficient Sublicensees and Replacement).
- 1.41 “**Deficient Sublicensee**” has the meaning set forth in Section 4.6.2 (Deficient Sublicensees and Replacement).
- 1.42 “**Development**” means, with respect to any product, any and all internal and external research, development and regulatory activities regarding such product, including (a) research, process development, non-clinical testing, toxicology, non-clinical activities, GLP toxicology and other preclinical studies, and Clinical Trials, and (b) preparation, submission, review, and development of data or information for the purpose of submission to a Regulatory Authority to obtain authorization to conduct Clinical Trials and to obtain, support, or maintain Regulatory Approval of such product, but excluding any activities directed to Manufacturing or Commercialization. Development will include research, development, and regulatory activities for additional presentations or indications for a product after receipt of Regulatory Approval of such product, including Clinical Trials initiated following receipt of Regulatory Approval or any Clinical Trial to be conducted after receipt of Regulatory Approval that was mandated by the applicable Regulatory Authority as a condition of such Regulatory Approval with respect to an approved indication (such as post-marketing approval studies and observational studies, if required by any Regulatory Authority in the Territory to support or maintain Regulatory Approval for a product in such country). “**Develop**,” “**Developing**,” and “**Developed**” will be construed accordingly.
- 1.43 “**Development Milestone Events**” has the meaning set forth in Section 8.2.1 (Development Milestone Events and Payments).
- 1.44 “**Development Milestone Payments**” has the meaning set forth in Section 8.2.1 (Development Milestone Events and Payments).
- 1.45 “**Disclosing Party**” has the meaning set forth in Section 9.1.1 (Duty of Confidence).
- 1.46 “**Dispute**” has the meaning set forth in Section 14.1 (General).
- 1.47 “**Dollar**” means the U.S. dollar, and “**\$**” will be interpreted accordingly.
- 1.48 “**Effective Date**” has the meaning set forth in the Preamble.
- 1.49 “**Ex-Territory Infringement**” has the meaning set forth in Section 12.4.1 (Notice).
- 1.50 “**Executive Officers**” has the meaning set forth in Section 3.5.2 (Decisions of the JSC).
- 1.51 “**Exploit**” means to Develop, Manufacture, Commercialize, or otherwise exploit. “**Exploitation**” will be construed accordingly.
- 1.52 [***]

- 1.53** “**FD&C Act**” means the United States Federal Food, Drug and Cosmetic Act, as amended from time to time, together with any rules, regulations, and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).
- 1.54** “**FDA**” means the United States Food and Drug Administration or any successor entity thereto having essentially the same function.
- 1.55** “**Field**” means the treatment, prevention, diagnosis, cure, and maintenance treatment of any and all non-oncology indications in humans.
- 1.56** “**First Commercial Sale**” means, with respect to a Licensed Product in the Territory, the first sale of such Licensed Product to a Third Party for distribution, use, or consumption in such country or region after receipt of Regulatory Approval for such Licensed Product in the Territory. First Commercial Sale excludes (a) any sale of the Licensed Product for use in a Clinical Trial or other Development activity, or (b) any sale or other distribution of the Licensed Product for compassionate or named-patient use, in each case, sold at or below the applicable Seller’s costs.
- 1.57** “**Full Manufacturing Cost**” means, with respect to a Licensed Product supplied by or on behalf of the applicable Party to the other Party or its Affiliates hereunder, [***].
- 1.58** “**GAAP**” means, in the United States or in Japan, generally accepted accounting principles, consistently applied.
- 1.59** “**GCP**” means all applicable good clinical practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of Clinical Trials, including, as applicable (a) as set forth in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Harmonized Tripartite Guideline for Good Clinical Practice E6 (the GCP Guideline) and any other guidelines for good clinical practice for trials on medicinal products in the Territory, (b) the Declaration of Helsinki (2013) as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto, (c) U.S. C.F.R. Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards), and 312 (Investigational New Drug Application), as may be amended from time to time, and (d) the equivalent Applicable Law in the Territory, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.
- 1.60** “**General Publication**” has the meaning set forth in Section 9.5.1 (Kissei’s Publication of Clinical Trial Data).
- 1.61** “**Global Brand Elements**” has the meaning set forth in Section 12.7.1 (Global Brand Elements).
- 1.62** “**Global Brand Strategy**” has the meaning set forth in Section 7.2 (Territory Commercialization Plan).
- 1.63** “**Global Clinical Trial**” means a Clinical Trial for a Licensed Product the data from which is intended to be used to obtain or support Regulatory Approval in countries and jurisdictions both inside and outside of the Territory.
- 1.64** “**Global Clinical Trial Costs**” has the meaning set forth in Section 4.5.2 (Additional Global Clinical Trials).
- 1.65** “**Global Development Plan**” has the meaning set forth in Section 4.2 (Territory Development).
- 1.66** “**GLP**” means all applicable good laboratory practice standards, including, as applicable, as set forth in the then-current good laboratory practice standards promulgated or endorsed by FDA, as

defined in 21 C.F.R. Part 58, and the equivalent Applicable Law in the Territory, each as may be amended and applicable from time to time.

- 1.67** “**Governmental Authority**” means any federal, national, state, provincial, or local government, or political subdivision thereof, or any multinational organization or any authority, agency, regulatory body, or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, or any court or tribunal (or any department, bureau or division of any of the foregoing, or any governmental arbitrator or arbitral body). Governmental Authorities include all Regulatory Authorities.
- 1.68** “**GSP**” means all applicable current Good Distribution or Supply Practices required by Applicable Law in any relevant country, each as may be amended and applicable from time to time.
- 1.69** “**GVP**” means the then-current good pharmacovigilance practice standards, practices, and procedures promulgated or endorsed by the applicable Regulatory Authority as set forth in the guidelines imposed by such Regulatory Authority, as may be updated from time to time.
- 1.70** “**GxP**” means, collectively, all relevant good practice quality guidelines and regulations, encompassing such internationally recognized standards as cGMP, GCP, GLP, GSP, and GVP, and applicable from time to time to the Development, Manufacturing, Commercialization, or other Exploitation of a Licensed Product or any intermediate thereof pursuant to Applicable Law.
- 1.71** “**IFRS**” means International Financial Reporting Standards, consistently applied.
- 1.72** [***]
- 1.73** [***]
- 1.74** “**IND**” means an Investigational New Drug application required pursuant to 21 C.F.R. Part 312 required to commence human clinical trials in the U.S. or equivalent application in a foreign jurisdiction, and including all supplements or amendments that may be filed with respect to the foregoing.
- 1.75** “**Indemnified Party**” has the meaning set forth in Section 11.3 (Indemnification Procedure).
- 1.76** “**Indemnifying Party**” has the meaning set forth in Section 11.3 (Indemnification Procedure).
- 1.77** “**Joint Collaboration Know-How**” means all Collaboration Know-How (other than Know-How within the Licensed Product Technology) developed or invented jointly by or on behalf of a Party or its Affiliates, including by or on behalf of its licensees, Sublicensees, or, with respect to Know-How included in the Licensed Product Technology, Subcontractors, on the one hand, and the other Party or its Affiliates, including by or on behalf of its licensees, Sublicensees, or Subcontractors on the other hand.
- 1.78** “**Joint Collaboration Patent Rights**” means all Collaboration Patent Rights that Cover Joint Collaboration Know-How.
- 1.79** “**Joint Collaboration Technology**” means the Joint Collaboration Know-How and the Joint Collaboration Patent Rights.
- 1.80** “**JSC**” has the meaning set forth in Section 3.2.1 (Formation and Purpose of the JSC).
- 1.81** “**JSC Chairperson**” has the meaning set forth in Section 3.2.1 (Formation and Purpose of the JSC).
- 1.82** “**Kissei**” has the meaning set forth in the Preamble.

- 1.83** “**Kissei Collaboration Know-How**” means Collaboration Know-How developed or invented solely by or on behalf of Kissei or its Affiliates, including by or on behalf of its licensees (other than Viridian), Sublicensees, or, with respect to Know-How included in the Licensed Product Technology, Subcontractors. [***].
- 1.84** “**Kissei Collaboration Patent Rights**” means any Collaboration Patent Right that Covers Kissei Collaboration Know-How.
- 1.85** “**Kissei Collaboration Technology**” means the Kissei Collaboration Know-How and Kissei Collaboration Patent Rights.
- 1.86** “**Kissei Excluded Indication**” means (a) [***], or (b) [***].
- 1.87** “**Kissei Generated Data**” means all data (whether generated in the performance [***] activities or any Clinical Trial for any Territory Development Indication for the Licensed Products) developed or invented solely by or on behalf of Kissei or its Affiliates, including by or on behalf of its licensees (other than Viridian), Sublicensees, or Subcontractors in the performance of Development activities under any Territory Development Plan.
- 1.88** “**Kissei Identified Rights**” has the meaning set forth in Section 2.5.3 (Kissei Identified Rights).
- 1.89** “**Kissei Indemnitee(s)**” has the meaning set forth in Section 11.2 (By Viridian).
- 1.90** “**Kissei Know-How**” means all Know-How (other than Know-How within the Licensed Product Technology) that is (a) Controlled by Kissei or any of its Affiliates as of the Effective Date or during the Term, and (b) [***] used to Exploit the Licensed Products in the Field, including Kissei Collaboration Know-How.
- 1.91** “**Kissei Patent Rights**” means all Patent Rights (other than Patent Rights that Cover the Licensed Product Technology) that (a) are Controlled by Kissei or any of its Affiliates as of the Effective Date or during the Term, and (b) Cover any Kissei Know-How, including all Kissei Collaboration Patent Rights.
- 1.92** “**Kissei Prosecution Patent Rights**” has the meaning set forth in Section 12.3.2(a) (Right to Prosecute).
- 1.93** “**Kissei Technology**” means Kissei Know-How and Kissei Patent Rights.
- 1.94** “**Know-How**” means any information and materials, including records, discoveries, improvements, modifications, processes, techniques, methods, assays, chemical or biological materials, designs, protocols, formulas, data (including physical data, chemical data, toxicology data, animal data, raw data, clinical data, and analytical and quality control data), dosage regimens, control assays, product specifications, marketing, pricing and distribution costs, inventions, algorithms, technology, forecasts, profiles, strategies, plans, results in any form whatsoever, know-how and trade secrets (in each case, patentable or not patentable, copyrightable or not copyrightable, or otherwise). For the avoidance of doubt, Know-How will not include Patent Rights.
- 1.95** “**Knowledge**” means the actual knowledge, [***], of (a) with respect to Viridian, [***]; and (b) with respect to Kissei, [***].
- 1.96** “**Licensed Antibody**” means each of the monoclonal antibodies known as (a) veligrotug (formally known as VRDN-001) having the chemical structure set forth in **Schedule 1.96(a)** (Licensed Antibodies), and (b) VRDN-003, having the chemical structure set forth in **Schedule 1.96(b)** (Licensed Antibodies).
- 1.97** “**Licensed Component**” has the meaning set forth in Section 1.25 (“Combination Product”).

- 1.98** “**Licensed Product**” means (a) any pharmaceutical or biologic product, dosage, substance, or formulation that incorporates or comprises a Licensed Antibody, either alone or in combination with other active ingredients (to the extent not proprietary to Viridian) or (b) any devices with respect to the administration of any such pharmaceutical or biologic product to patients.
- 1.99** “**Licensed Product Technology**” has the meaning set forth in Section 12.1.1 (Ownership).
- 1.100** “**Local Marks**” has the meaning set forth in Section 12.7.2 (Product Marks in the Territory).
- 1.101** “**Losses**” means damages, compensation, debts, obligations, and other liabilities, losses, claims, taxes, interest obligations, deficiencies, judgments, assessments, fines, fees, penalties, or expenses (including amounts paid in settlement, interest, court costs, costs of investigators, reasonable fees and expenses of attorneys, accountants, financial advisors, consultants, and other experts, and other expenses of litigation).
- 1.102** “**Manufacture**” means with respect to any product, any and all activities directed to manufacturing, processing, filling, finishing, assembly, quality assurance, quality control, testing, and release, Packaging and Labeling, shipping, supply, or storage of such product (or any components or process steps involving such product), as the case may be, including qualification, validation, and scale-up, preclinical, clinical, and commercial manufacture and analytic development, product characterization, and stability testing, but excluding any activities directed to Development or Commercialization. “**Manufacturing**” and “**Manufactured**” will be construed accordingly.
- 1.103** “**Manufacturing Activities**” has the meaning set forth in Section 6.6.1 (Audits by Viridian).
- 1.104** “[***] **Initiation**” has the meaning set forth in Section 6.3 (Supply by Kissei).
- 1.105** “**Marketing Authorization Application**” or “**MAA**” means any new drug application, biologics license application, or other marketing authorization application, in each case, filed with the applicable Regulatory Authority in a country or other regulatory jurisdiction, which application is required to commercially market or sell a pharmaceutical or biologic product in such country or jurisdiction (and any amendments thereto), including any new drug application filed with the PMDA and approved by the MHLW.
- 1.106** “**Material Adverse Impact**” means, with respect to any decision, that such decision [***].
- 1.107** “**MHLW**” means the Ministry of Health, Labour, and Welfare, otherwise referred to as “Koseirodo-Sho,” or any successor entity thereto having essentially the same function.
- 1.108** “**Milestone Events**” has the meaning set forth in Section 8.2.4 (Notification of and Invoice for Milestone Events).
- 1.109** “**Milestone Payments**” has the meaning set forth in Section 8.2.4 (Notification of and Invoice for Milestone Events).
- 1.110** “**MTT Plan**” has the meaning set forth in Section 6.3 (Supply by Kissei).
- 1.111** “**Net Sales**” means the [***] of Kissei and its Affiliates and Sublicensees (each of the foregoing, a “**Seller**”) to independent, unrelated persons (including Third Party Distributors) (“**Buyers**”) in bona fide arm’s length transactions with respect to a Licensed Product, less the following deductions, in each case, to the extent actually allowed and taken by such Buyers and not otherwise recovered by or reimbursed to Seller in connection with such Licensed Product:

[***]

If Seller receives [***].

[***].

All deductions in clauses (a) through (f) above [***]. Calculations of Net Sales will be consistently applied across all products of Seller and will be consistent between periods.

Such amounts will be determined from the books and records of Seller, and will be calculated in accordance with applicable Accounting Standards.

Transfers or sales between Kissei and its Affiliates and Sublicensees will be disregarded for purposes of calculating Net Sales, except if such purchaser is an end user.

If Kissei or any of its Affiliates, or Sublicensees, sells a Licensed Product as a Licensed Component of a Combination Product in the Territory in any Calendar Quarter, then Net Sales will be calculated by [***].

For purposes of calculating the average Net Sales per unit sold of a Licensed Component and Other Component(s) of a Combination Product, any of the deductions described herein that apply to such Combination Product will be [***].

In the event that no separate sales of the Licensed Component or any Other Component(s) included in a Combination Product are made by Kissei or its Affiliates, or Sublicensees, during a Calendar Quarter in which such Combination Product is sold, [***].

1.112 “**New Third Party IP Agreement**” has the meaning set forth in Section 2.5.4 (Third Party In-Licenses).

1.113 “**New Viridian In-Licensed Rights**” has the meaning set forth in Section 2.5.4 (Third Party In-Licenses).

1.114 “**OFAC**” means the Office of Foreign Assets Control of the United States Department of the Treasury or any successor agency thereto.

1.115 “**Opt-In Notification Date**” has the meaning set forth in Section 4.3.5 (Opt-In to a [***]).

1.116 “**Other Component**” has the meaning set forth in Section 1.25 (“Combination Product”).

1.117 [***]

1.118 “**Packaging and Labeling**” means secondary or tertiary packaging and labeling of the Licensed Products (in its commercial packaging presentation) for sale or use in a country, including the Approved Labeling and insertion of materials such as patient inserts, patient medication guides, and professional inserts and any other written, printed, or graphic materials accompanying the Licensed Products and any brand security or anti-counterfeiting measures included in the packaging elements for the Licensed Products considered to be part of the finished packaged Licensed Product, serialization, and all testing and release (including technical and market release) thereof.

1.119 “**Party**” or “**Parties**” has the meaning set forth in the Preamble.

1.120 “**Patent Challenge**” has the meaning set forth in Section 13.2.3 (Termination for Patent Challenge).

- 1.121** “**Patent Prosecution**” means activities directed to (a) preparing, filing, and prosecuting applications (of all types) for any Patent Right, (b) maintaining any Patent Right, and (c) deciding whether to abandon or maintain any Patent Right.
- 1.122** “**Patent Rights**” means any and all (a) patents, patent applications, and utility models in any country or jurisdiction, including provisional applications, priority applications, and international applications, (b) patent applications filed either from such patents or patent applications or from an application claiming priority from any of these, including divisionals, provisionals, continuations, and continuations-in-part, (c) patents that have issued or in the future issue from the foregoing patent applications, (d) substitutions, renewals, registrations, confirmations, revalidations, reissues, and re-examinations of the foregoing patents or patent applications, and (e) extensions, restorations, supplemental protection certificates, and the like based on any of the foregoing patents or patent applications. For the avoidance of doubt, Patent Rights will not include Know-How.
- 1.123** “**Paying Party**” has the meaning set forth in Section 8.12.2 (Tax Cooperation).
- 1.124** “**Person**” means any corporation, limited or general partnership, limited liability company, joint venture, joint stock company, trust, unincorporated association, governmental body, authority, bureau, or agency, or any other entity or body, or an individual.
- 1.125** “**Phase 3 Clinical Trial**” means a human clinical trial in any country that would satisfy the requirements of 21 C.F.R. § 312(c), as amended from time to time, and the foreign equivalent thereof.
- 1.126** “**Phase 4 Clinical Trial**” means a human clinical trial in any country that the Regulatory Authority requires for a product in such country following the date of receipt of Regulatory Approval for such product in such country.
- 1.127** “**Pivotal Clinical Trial**” means a Phase 3 Clinical Trial or any other human clinical trial in any country that at the time of initiation (or any later expansion of patient enrollment, if applicable), is expected to be the basis for Regulatory Approval of such product a sufficient basis for Regulatory Approval of such product.
- 1.128** “**PMDA**” means the Pharmaceuticals and Medical Devices Agency in Japan or any successor thereto that conducts scientific reviews of marketing authorization applications for pharmaceuticals and monitoring of their post-marketing safety in Japan.
- 1.129** “[***] **Royalty**” has the meaning set forth in Section 8.3.5 ([***] Royalty).
- 1.130** “**Prime Rate**” means for any day a per annum rate of interest equal to the “prime rate,” as published in the “Money Rates” column of The Wall Street Journal, from time to time, or if for any reason such rate is no longer available, a rate equivalent to the base rate on corporate loans posted by at least [***] U.S. banks.
- 1.131** “**Product Complaint**” means a written or oral expression of dissatisfaction regarding the identity, quality, durability, reliability, usability, safety, purity, potency, or performance of a product after it has been released for distribution.
- 1.132** “**Product Infringement**” has the meaning set forth in Section 12.4.1 (Notice).
- 1.133** “**Product Marks**” has the meaning set forth in Section 12.7.2 (Product Marks in the Territory).
- 1.134** “**Promotional Materials**” has the meaning set forth in Section 7.4 (Coordination of Commercialization Activities).

- 1.135** “**Public Official**” means (a) any officer, employee or representative of any regional, federal, state, provincial, county or municipal government or government department, agency or other division; (b) any officer, employee or representative of any commercial enterprise that is owned or controlled by a government, including any state-owned or controlled veterinary, laboratory or medical facility; (c) any officer, employee or representative of any public international organization, such as the International Monetary Fund, the United Nations or the World Bank; or (d) any person acting in an official capacity for any government or government entity, enterprise, or organization identified above.
- 1.136** “**Publication**” has the meaning set forth in Section 9.5.1 (Kissei’s Publication of Clinical Trial Data).
- 1.137** “**PVA**” has the meaning set forth in Section 5.6.1 (Pharmacovigilance Agreement).
- 1.138** “**Quality Agreement**” has the meaning set forth in Section 6.1 (Quality Agreement).
- 1.139** “**Receiving Party**” has the meaning set forth in Section 9.1.1 (Duty of Confidence).
- 1.140** “**Recipient**” has the meaning set forth in Section 8.12.2 (Tax Cooperation).
- 1.141** “**Regulatory Approval**” means, with respect to a particular country or other regulatory jurisdiction, any approval of an MAA or other approval, product, or establishment license, registration, or authorization of any Regulatory Authority necessary for the commercial marketing or sale of a pharmaceutical or biologic product in such country or other regulatory jurisdiction, excluding, in each case, Reimbursement Approval.
- 1.142** “**Regulatory Authority**” means any applicable Governmental Authority with jurisdiction or authority over the Development, Manufacture, Commercialization, or other Exploitation (including Regulatory Approval or Reimbursement Approval) of pharmaceutical or biologic products in a particular country or other regulatory jurisdiction, including the PMDA, MHLW, and any corresponding national or regional regulatory authorities.
- 1.143** “**Regulatory Exclusivity**” means, with respect to a Licensed Product in a country or region, any exclusive marketing rights or data exclusivity rights under Applicable Laws in such country or region or conferred by any Regulatory Authority in such country or region with respect to such Licensed Product in such country or region.
- 1.144** “**Regulatory Milestone Event**” has the meaning set forth in Section 8.2.2 (Regulatory Milestone Events and Payments).
- 1.145** “**Regulatory Milestone Payment**” has the meaning set forth in Section 8.2.2 (Regulatory Milestone Events and Payments).
- 1.146** “**Regulatory Submissions**” means any filing, application, or submission with any Regulatory Authority in support of Developing, Manufacturing, or Commercializing a pharmaceutical or biologic product (including to obtain, support, or maintain Regulatory Approval from that Regulatory Authority) and any proposed Approved Labeling, and all correspondence or communication with or from the relevant Regulatory Authority, as well as minutes of any substantive meetings, telephone conferences, or discussions with the relevant Regulatory Authority. Regulatory Submissions include all INDs, MAAs, and other applications for Regulatory Approval and their equivalents.
- 1.147** “**Reimbursement Approval**” means an approval, agreement, determination, or other decision by the applicable Governmental Authority that establishes prices charged to end-users for pharmaceutical or biologic products at which a particular pharmaceutical or biologic product will be reimbursed by the Regulatory Authorities or other applicable Governmental Authorities in the Territory.

- 1.148 “**Remedial Action**” has the meaning set forth in Section 5.9 (Remedial Actions).
- 1.149 “**Replacement Site**” has the meaning set forth in Section 4.6.2 (Deficient Sublicensees and Replacement).
- 1.150 “**Residual Knowledge**” has the meaning set forth in Section 9.8 (Residual Knowledge).
- 1.151 “**Review Period**” has the meaning set forth in Section 9.5.1 (Kissei’s Publication of Clinical Trial Data).
- 1.152 “**Royalty Patent Rights**” means the [***] Patent Rights, [***] Patent Rights, and [***] Patent Rights.
- 1.153 “**Royalty Payments**” has the meaning set forth in Section 8.3.1 (Royalty Rates).
- 1.154 “**Royalty Report**” has the meaning set forth in Section 8.3.4 (Royalty Reports and Payments).
- 1.155 “**Royalty Term**” has the meaning set forth in Section 8.3.2 (Royalty Term).
- 1.156 “**Sales Milestone Event**” has the meaning set forth in Section 8.2.3 (Sales Milestone Events and Payments).
- 1.157 “**Sales Milestone Payment**” has the meaning set forth in Section 8.2.3 (Sales Milestone Events and Payments).
- 1.158 “**Securitization Transaction**” has the meaning set forth in Section 15.1.2 (Securitization Transaction).
- 1.159 “**Seller**” has the meaning set forth in Section 1.111 (“Net Sales”).
- 1.160 “**Subcommittee**” has the meaning set forth in Section 3.2.4(l) (JSC Roles and Responsibilities).
- 1.161 “**Subcontractor**” means (a) a Third Party contractor engaged by a Party to perform certain obligations or exercise certain rights of such Party under this Agreement on a fee-for-service basis (including CROs, CMOs, and contract sales organizations), or (b) a Third Party Distributor.
- 1.162 “**Sublicensee**” means any Person (a) with respect to Kissei, to whom Kissei grants a sublicense of, or other authorization or permission granted under, the licenses granted to Kissei in Section 2.1 (License Grant to Kissei), and (b) with respect to Viridian, to whom Viridian grants a sublicense of, or other authorization or permission granted under, the licenses granted to Viridian in Section 2.3 (License Grant to Viridian).
- 1.163 “**Supply Agreement**” has the meaning set forth in Section 6.2 (Supply by Viridian).
- 1.164 “[***]”
- 1.165 “**Target**” means insulin-like growth factor receptor-1 (IGF-1R).
- 1.166 “**Tax**” or “**Taxes**” means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including any interest thereon). For the avoidance of doubt, Taxes includes VAT.
- 1.167 “**TED**” has the meaning set forth in the Recitals.
- 1.168 “**Term**” has the meaning set forth in Section 13.1 (Term).
- 1.169 “**Territory**” means Japan.

- 1.170** “**Territory Commercialization Plan**” means the written high-level strategic and tactical plans for the Commercialization activities for the Licensed Products to be conducted in the Territory in the Field, which plan will be prepared and updated by or on behalf of Kissei as provided in Section 7.2 (Territory Commercialization Plan).
- 1.171** “**Territory Development**” has the meaning set forth in Section 4.1 (Development Diligence and Responsibilities).
- 1.172** “**Territory Development Indication**” or “**TDI**” means each of the following diseases: (a) [***], (b) [***], and (c) [***] (i) [***] or (ii) [***].
- 1.173** “**Territory Development Plan**” has the meaning set forth in Section 4.2 (Territory Development).
- 1.174** “**Territory-Specific Clinical Trial**” means a Clinical Trial (including a Phase 4 Clinical Trial) for a Licensed Product, the data from which at the time of commencement of such Clinical Trial is intended to be used to obtain or maintain Regulatory Approval for such Licensed Product in the Territory, but not to obtain or maintain Regulatory Approval outside of the Territory.
- 1.175** “**Third Party**” means any Person other than a Party or an Affiliate of a Party.
- 1.176** “**Third Party Claims**” means collectively, any and all Third Party demands, claims, actions, suits, and proceedings (whether criminal or civil, in contract, tort, or otherwise).
- 1.177** “**Third Party Distributor**” means any Third Party that purchases Licensed Products from Kissei or its Affiliates or Sublicensees, takes title to the Licensed Products, and distributes the Licensed Products directly to customers, but does not Develop, Manufacture, or otherwise Commercialize the Licensed Products and does not make any upfront, milestone, royalty, profit-share, or other payment to Kissei or its Affiliates or Sublicensees, other than payment for the purchase of the Licensed Products for resale.
- 1.178** “**Third Party Expert**” has the meaning set forth in Section 3.6.2(d)(i) (Third Party Expert Determination).
- 1.179** “**Third Party IP Agreement**” means any agreement between Viridian or its Affiliate and a Third Party (a) entered into prior to the Effective Date pursuant to which such Third Party grants Viridian (or any of its Affiliates) a license to any of the Viridian Technology that is sublicensed to Kissei hereunder as of the Effective Date or (b) to acquire or license any Viridian Identified Rights or Kissei Identified Rights that would be licensed to Kissei hereunder if Controlled by Viridian or its Affiliates during the Term. The existing Third Party IP Agreements as of the Effective Date are set forth on **Schedule 1.179** (Third Party IP Agreements).
- 1.180** [***]
- 1.181** “**United States**” or “**U.S.**” means the United States of America and its territories and possessions.
- 1.182** “**Upfront Payment**” has the meaning set forth in Section 8.1 (Upfront Payment).
- 1.183** “**Valid Claim**” means a claim of [***].
- 1.184** “**VAT**” means value-added taxes or other similar taxes.
- 1.185** “**Viridian**” has the meaning set forth in the Preamble.
- 1.186** “**Viridian Collaboration Know-How**” means (a) Collaboration Know-How developed or invented solely by or on behalf of Viridian or its Affiliates, including by or on behalf of its

licensees (other than Kissei), Sublicensees, or Subcontractors, [***], and (b) the Licensed Product Technology. Viridian Collaboration Know-How includes [***].

- 1.187 “Viridian Collaboration Patent Rights”** means any Collaboration Patent Right that Covers Viridian Collaboration Know-How.
- 1.188 “Viridian Generated Data”** means all data [***] developed or invented solely by or on behalf of Viridian or its Affiliates, including by or on behalf of its licensees (other than Kissei), Sublicensees (other than Kissei), or Subcontractors in the performance of Development activities [***].
- 1.189 “Viridian Identified Rights”** has the meaning set forth in Section 2.5.2 (Viridian Identified Rights).
- 1.190 “Viridian Indemnitee(s)”** has the meaning set forth in Section 11.1 (By Kissei).
- 1.191 “Viridian Know-How”** means any Know-How, including the Know-How included in the Licensed Product Technology and the Viridian Collaboration Know-How, in each case, that is (a) Controlled by Viridian as of the Effective Date or during the Term, and is (b) [***] to Develop or Commercialize the Licensed Antibodies and Licensed Products in the Territory in the Territory Development Indications in the Field, but expressly excluding (i) Joint Collaboration Know-How and [***].
- 1.192 “Viridian Manufacturing Know-How”** means any Know-How that is (a) Controlled by Viridian as of the Effective Date or during the Term, and (b) [***] used for the Manufacturing of the Licensed Antibodies or Licensed Products.
- 1.193 “Viridian Manufacturing Patent Rights”** means any Patent Rights that (a) are Controlled by Viridian as of the Effective Date or during the Term, and (b) Cover any Viridian Manufacturing Know-How or are [***] used for the Manufacturing of the Licensed Antibodies or Licensed Products.
- 1.194 “Viridian Manufacturing Technology”** means all Viridian Manufacturing Know-How and Viridian Manufacturing Patent Rights.
- 1.195 “Viridian Patent Rights”** means any Patent Right that (a) is Controlled by Viridian as of the Effective Date or during the Term, in the Territory and (b) Covers any Viridian Know-How or are [***] to Develop or Commercialize the Licensed Antibodies and Licensed Products in the Territory in the Field, but expressly excluding (i) Viridian Manufacturing Patent Rights, (ii) Joint Collaboration Patent Rights, and (iii) [***].
- 1.196 “Viridian Prosecution Patent Rights”** has the meaning set forth in Section 12.3.1(a) (Right to Prosecute).
- 1.197 “Viridian Support Plan”** has the meaning set forth in Section 4.11 (Viridian Support Plan).
- 1.198 “Viridian Technology”** means Viridian Know-How, Viridian Patent Rights, and Viridian’s interest in the Joint Collaboration Technology.
- 1.199 “[***] Agreement”** means that certain [***].

Article 2 LICENSES

2.1. License Grant to Kissei.

- 2.1.1 **In the Territory.** Subject to the terms of this Agreement (including Viridian's retained rights set forth in Section 2.4 (No Implied Licenses; Retained Rights)), during the Term, Viridian hereby grants to Kissei an exclusive, royalty-bearing license, with the right to grant sublicenses solely in accordance with Section 2.2 (Sublicensing and Subcontractors), under the Viridian Technology to (a) perform (i) Clinical Trials for or (ii) non-clinical testing (including stability studies, acceptance tests, and related analytical test activities), toxicology, non-clinical activities, GLP toxicology, and other preclinical studies, in each case, solely to the extent required to perform Clinical Trials, but excluding all other research, (b) perform Development activities other than Clinical Trials necessary to (i) obtain and maintain Regulatory Approval or (ii) Commercialize, or (c) Commercialize, in each case ((a)-(c)), the Licensed Antibodies and Licensed Products in the Field in the Territory in accordance with the terms of this Agreement.
- 2.1.2 **Packaging and Labeling License.** Subject to the terms of this Agreement (including Viridian's retained rights set forth in Section 2.4 (No Implied Licenses; Retained Rights)), Viridian hereby grants to Kissei an exclusive, royalty-bearing license, with the right to grant sublicenses solely in accordance with Section 2.2 (Sublicensing and Subcontractors), under the Viridian Manufacturing Technology to Package and Label the Licensed Products in the Field anywhere in the world for Development and Commercialization of the Licensed Products in the Field in the Territory in accordance with the terms of this Agreement, *provided that* [***].
- 2.1.3 **Manufacturing License.** Subject to the terms of this Agreement (including Viridian's retained rights set forth in Section 2.4 (No Implied Licenses; Retained Rights)), solely upon the earlier to occur of (a) a [***] and (b) [***], in each case ((a) and (b)), Viridian will grant to Kissei a non-exclusive, royalty-bearing license, with the right to grant sublicenses solely in accordance with Section 2.2 (Sublicensing and Subcontractors), under the Viridian Manufacturing Technology to Manufacture and have Manufactured (including CMC activities) the Licensed Antibodies and Licensed Products in the Field in and outside the Territory for Development and Commercialization of the Licensed Products in the Field in the Territory in accordance with the terms of this Agreement; *provided that*, in the event of [***], Kissei will not [***].

2.2. Sublicensing and Subcontractors.

2.2.1 Right to Subcontract and Sublicense.

- (a) **Restrictions.** Kissei will not engage or propose to engage any Sublicensee or other Subcontractor that is Debarred/Excluded.
- (b) **Sublicenses to Subcontractors.** Subject to the terms of this Agreement (including Section 2.2.1(c) (Sublicenses under the [***])), Kissei will have the right to grant sublicenses of the rights granted under Section 2.1 (License Grant to Kissei) to Subcontractors (to the extent such Subcontractors require a sublicense under the rights granted to Kissei in Section 2.1 (License Grant to Kissei) to perform the applicable activities for which they were engaged), for the sole purpose of performing Kissei's obligations and exercising Kissei's rights with respect to the Development, Packaging and Labeling, or Commercialization of the Licensed Products in accordance with this Agreement. Each Sublicensee will hold its rights contingent on the rights licensed to Kissei under the terms of this Agreement and may not grant further sublicenses of its rights to any Third Party. Any termination of the licenses granted to Kissei under Section 2.1

(License Grant to Kissei) as a result of a termination of this Agreement will cause the Sublicensees to automatically lose the same rights under any sublicense.

- (c) **Sublicenses under the [***] Agreement.** [***].
- (d) **Other Sublicensees.** Kissei will not grant a sublicense to a Third Party of all or substantially all of Kissei's rights or obligations under this Agreement in the Territory without Viridian's prior written consent, (i) [***] and (ii) [***].

2.2.2 **Terms of Sublicenses to Third Parties.** Each (a) sublicense to any Subcontractor or that requires a sublicense under the rights granted to Kissei in Section 2.1 (License Grant to Kissei) to perform the applicable activities for which they were engaged or (b) sublicense to any other Sublicensee that requires a sublicense under the rights granted to Kissei in Section 2.1 (License Grant to Kissei) and is approved by Viridian in accordance with Section 2.2.1(d) (Other Sublicensees) will be granted under a written agreement that is consistent with and subject to the terms of this Agreement, to the extent required pursuant to the terms of any Third Party IP Agreement that have been approved by Viridian, and that:

- (a) contains the requirements set forth under Section 2.2.3 (Terms of Sublicenses and Subcontracts with Third Parties);
- (b) requires each such Sublicensee or other Subcontractor to comply with the terms of this Agreement that are applicable to such Sublicensee or other Subcontractor (including the Milestone Event and Royalty Payment reporting obligations set forth under Section 8.2 (Milestone Payments) and Section 8.3 (Royalty Payments), the record keeping and audit requirements set forth under Section 4.6 (Clinical Trial Audit Rights), and Section 8.11 (Financial Records and Audits));
- (c) requires each such Sublicensee or other Subcontractor to perform the activities that they are engaged to perform (as applicable) in accordance with the terms of all Third Party IP Agreements, GLP, cGMP, GCP, GVP, and GSP, as applicable, and otherwise in compliance with Applicable Law;
- (d) includes Viridian as an intended third party beneficiary under the sublicense with the right to enforce the applicable terms of such sublicense;
- (e) precludes the granting of further sublicenses to any Third Party without the prior written consent of Viridian, not to be unreasonable withheld, conditioned, or delayed;
- (f) prohibits such Sublicensee or other Subcontractor from engaging in, independently or for or with any other Third Party, any Development, Manufacturing, or Commercialization of any Competing Product in the Territory (which provision Kissei will enforce against all Subcontractors and Sublicensees); and
- (g) is subject in all respects to any applicable Third Party IP Agreement under which Viridian is granted any right that will be sublicensed to such Sublicensee or other Subcontractor under such proposed sublicense.

2.2.3 **Terms of Sublicenses and Subcontracts with Third Parties.** In addition to the requirements set forth in Section 2.2.2 (Terms of Sublicenses to Third Parties) with respect to any grant of rights to a Sublicensee, any sublicense agreement with a Third Party and any agreement pursuant to which Kissei engages any Subcontractor must be consistent with, and subject to, the terms of this Agreement and contain (a) (i) with respect to a Subcontractor (including a Subcontractor that is granted a sublicense), an assignment back to Kissei of all Know-How included in the Licensed Product

Technology developed or invented by or on behalf of such Subcontractor; [***], and (c) confidentiality and non-use provisions that are at least as stringent as those set forth in Article 9 (Confidentiality; Publication). [***].

- 2.2.4 **Notice of Sublicensees.** Kissei will provide Viridian with a true and complete copy of each agreement between Kissei and any Sublicensee entered into pursuant to Section 2.2.1(d) (Other Sublicensees) no later than [***] days after the execution thereof; *provided* that, [***]. If any such agreement between Kissei and any Sublicensee is not in English, then Kissei will also provide to Viridian an English translation thereof in accordance with Section 15.16 (Language; Translations), at Kissei's expense, no later than [***] days following the execution thereof.
- 2.2.5 **Kissei Audits of Sublicensees and Subcontractors.** Kissei will provide Viridian with copies of material quality oversight or audit reports from audits that Kissei (or its agent) has conducted on any Sublicensees or other Subcontractors engaged by Kissei to perform its obligations or exercise its rights under this Agreement to the extent such reports are relevant to such Sublicensees' or other Subcontractors' performance of such obligations or exercise of such rights no later than [***] days after receiving or preparing, as applicable, any such report. Kissei will provide to Viridian all quality oversight or audit reports from audits that Kissei (or its agent) conducts, and, if any such report is not in English, a summary in English of any such report.
- 2.2.6 **Responsibility for Sublicensees and Subcontractors.** Notwithstanding any sublicense or subcontract, Kissei will remain primarily liable to Viridian for the performance of all of its obligations under, and Kissei's and its Sublicensees' and other Subcontractors' compliance with all provisions of, this Agreement. Kissei will be fully responsible and liable for any breach of the terms of this Agreement by any of its Sublicensees or other Subcontractors to the same extent as if Kissei itself has committed any such breach, and Kissei will promptly terminate the sublicense or subcontract, as applicable, with any Sublicensee or other Subcontractor if such Sublicensee or Subcontractor is in material breach of this Agreement and does not cure such breach in a timely manner in accordance with the terms of this Agreement.
- 2.3. **License Grant to Viridian.** Subject to the terms of this Agreement, Kissei hereby grants to Viridian (a) a worldwide, exclusive, fully-paid, royalty free, perpetual, irrevocable, and sublicensable (through multiple tiers) license under the Kissei Collaboration Technology to Exploit the Licensed Products in the Territory outside of the Field and outside of the Territory and (b) a worldwide, non-exclusive, fully-paid, royalty-free, perpetual, irrevocable, and sublicensable (through multiple tiers) license, with the right to grant sublicenses through multiple tiers, under the Kissei Collaboration Technology to Manufacture the Licensed Antibodies and Licensed Products in the Territory to support the Development and Commercialization of the Licensed Antibodies and Licensed Products outside of the Territory, *provided* that [***]. Notwithstanding any provision to the contrary set forth in the preceding sentence, as between the Parties, Kissei has the sole right to use the Kissei Collaboration Technology to Exploit any products other than Licensed Products.
- 2.4. **No Implied Licenses; Retained Rights.** Nothing in this Agreement will be interpreted to grant a Party any rights under any intellectual property rights owned or Controlled by the other Party, including Viridian Technology, Viridian Manufacturing Technology, or Kissei Technology, in each case, that are not expressly granted herein, whether by implication, estoppel, or otherwise. Any rights not expressly granted to Viridian by Kissei under this Agreement are hereby retained by Kissei. Any rights not expressly granted to Kissei by Viridian under this Agreement are hereby retained by Viridian. Notwithstanding any provision to the contrary set forth in this Agreement:
- 2.4.1 Viridian may, and hereby expressly retains (on behalf of itself and its Affiliates, licensees, and sublicensees, other than Kissei and its Sublicensees) (a) the non-exclusive right under the Viridian Technology and the Viridian Manufacturing Technology to,

Manufacture the Licensed Antibodies and Licensed Products in the Territory in compliance with Applicable Laws and support the Development and Commercialization of the Licensed Antibodies and Licensed Product outside of the Territory, *provided* that [***], (b) the exclusive (even as to Kissei and its Affiliates) right under the Viridian Technology and Viridian Manufacturing Technology to, Develop, Commercialize, and otherwise Exploit the Licensed Product in each [***], and (c) exclusive rights under all [***] Technology unless and until Kissei exercises its right, on a [***] basis, to opt into the applicable [***] in accordance with Section 4.3.5 (Opt-In to a [***]).

- 2.4.2 Kissei will not practice (a) the Viridian Technology other than as expressly licensed and permitted under this Agreement or (b) the Viridian Manufacturing Technology, in each case, unless otherwise agreed by the Parties in writing.

2.5. Third Party In-Licenses.

- 2.5.1 **Existing Third Party IP Agreements.** Viridian will remain solely responsible for the payment of all royalties, license fees, milestone payments, and other payment obligations under all Third Party IP Agreements ([***]) existing as of the Effective Date.
- 2.5.2 **Viridian Identified Rights.** If, after the Effective Date during the Term, Viridian or its Affiliate intends to obtain Control of any Know-How or Patent Rights from a Third Party (whether by acquisition or license) [***] to Exploit the Licensed Products in the Field in the Territory (other than through a Change of Control of Viridian or any of its Affiliates or as a result of the acquisition by Viridian of a Third Party by merger, acquisition, or similar transaction or series of related transactions), other than any Patent Rights or Know-How related to any [***], unless and until Kissei exercises its right, on a [***] basis, to opt into the applicable [***] in accordance with Section 4.3.5 (Opt-In to a [***]) and for which [***] (such Know-How and Patent Rights, “**Viridian Identified Rights**”), then Viridian will notify Kissei in writing of such Viridian Identified Rights and Section 2.5.4 (Third Party In-Licenses) will apply.
- 2.5.3 **Kissei Identified Rights.** If Kissei determines that a license under any Know-How or Patent Rights controlled by a Third Party (a) is [***] to Exploit the Licensed Products in the Field in the Territory or (b) [***] (such Know-How and Patent Rights set forth in the foregoing clause (a) or clause (b), “**Kissei Identified Rights**”), then Kissei will so notify Viridian. Viridian will have the first right to acquire rights to any such Kissei Identified Rights from such Third Party (whether by acquisition or license), and if Viridian intends to acquire such rights, then Viridian will notify Kissei of such intention within [***] days after receipt of Kissei’s written notice from Kissei, and the terms of Section 2.5.4 (Third Party In-Licenses) will apply. If Viridian notifies Kissei of its intention not to so acquire such rights within such [***] day period, or otherwise fails within [***] days after the date of Kissei’s written request to acquire rights under such Kissei Identified Rights, then, in each case, Kissei will have the right to acquire rights under such Kissei Identified Rights from such Third Party solely for the Territory, and Kissei will use reasonable efforts to ensure that all such Kissei Identified Rights are fully sublicensable (through multiple tiers) to Viridian to the extent of the licenses granted to Viridian hereunder. If thereafter Kissei so acquires such rights, then such Know-How or Patent Rights will be included in the Kissei Know-How or Kissei Patent Rights, as applicable, and Kissei will bear (and will pay) 100% of the payments made to such Third Party in consideration for the acquisition of rights under such Kissei Identified Rights (whether by acquisition or license), [***].
- 2.5.4 **Third Party In-Licenses.** Prior to Viridian’s or its Affiliate’s execution of any Third Party IP Agreement after the Effective Date (the Viridian Identified Rights or Kissei Identified Rights included under such Third Party IP Agreement, together, “**New Viridian In-Licensed Rights**” and any such agreement, a “**New Third Party IP Agreement**”), Viridian will (a) [***] (b) [***] and (c) [***]. Upon execution of such New Third Party IP Agreement, Viridian will notify Kissei in writing and will provide a

copy of the New Third Party IP Agreement to Kissei, which may be redacted to exclude information that is not necessary for Kissei to determine the scope of the rights sublicensed to Kissei or for Kissei to determine whether such New Third Party IP Agreement will relieve or modify Viridian's performance of its obligations under this Agreement. [***].

- 2.5.5 **Responsibility for Costs.** Following Viridian's or its Affiliate's execution of the applicable New Third Party IP Agreement, (a) such New Viridian In-Licensed Rights will be included in the Viridian Know-How, Viridian Patent Rights, Viridian Manufacturing Know-How, or Viridian Manufacturing Patent Rights (as applicable) and licensed or sublicensed (as applicable) to Kissei under the licenses granted in Section 2.1 (License Grant to Kissei), subject to the terms of this Agreement and the applicable Third Party IP Agreement, and (b) [***] any such payments under such Third Party IP Agreement that [***] and (ii) [***]% of any [***].
- 2.5.6 **Compliance.** Kissei will comply with Viridian's obligations under the Third Party IP Agreements to the extent applicable to Kissei.

2.6. Exclusivity Covenants.

- 2.6.1 **Exclusivity for [***].** During the Term, Kissei will not, and Kissei will ensure that its Affiliates and its and their (sub)licensees do not, directly or indirectly, independently or for or with any Third Party (including through the grant of any license or similar rights to any Third Party), [***]; *provided that* [***].
- 2.6.2 **Exclusivity for [***].** During the Term, Kissei will not, and Kissei will ensure that its Affiliates and its and their (sub)licensees do not, directly or indirectly, independently or for or with any Third Party (including through the grant of any license or similar rights to any Third Party), [***]; *provided that* [***].
- 2.6.3 **Exclusivity for [***].**
- (a) During the Term, Kissei will not, and Kissei will ensure that its Affiliates and its and their (sub)licensees do not, directly or indirectly, independently or for or with any Third Party (including through the grant of any license or similar rights to any Third Party), [***]; *provided that* [***].
- (b) [***], Kissei will not, and Kissei will ensure that its Affiliates and its and their (sub)licensees do not, directly or indirectly, independently or for or with any Third Party (including through the grant of any license or similar rights to any Third Party) [***]; *provided that* [***].
- 2.6.4 **Exclusivity for [***].** [***], Kissei will not, and Kissei will ensure that its Affiliates and its and their (sub)licensees do not, directly or indirectly, independently or for or with any Third Party (including through the grant of any license or similar rights to any Third Party), [***]; *provided that* [***].

Article 3 GOVERNANCE

- 3.1. **Alliance Managers.** Each Party will appoint an individual to act as its alliance manager under this Agreement as soon as practicable after the Effective Date (each an "**Alliance Manager**"). The Alliance Managers will: (a) serve as the primary points of contact between the Parties for the purpose of providing the other Party with information on the progress of a Party's activities under this Agreement; (b) be responsible for facilitating the flow of information and otherwise promoting communication, coordination, and collaboration between the Parties, all of which communications between the Parties will be in English; (c) facilitate the prompt resolution of any disputes; and (d) attend JSC meetings as a non-voting member. An Alliance Manager may also

bring any matter to the attention of the JSC if such Alliance Manager reasonably believes that such matter warrants such attention. Each Party will use reasonable efforts to keep an appropriate level of continuity but may replace its Alliance Manager at any time upon written notice to the other Party.

3.2. Joint Steering Committee.

- 3.2.1 **Formation and Purpose of the JSC.** No later than [***] days after the Effective Date, the Parties will establish a joint steering committee (the “JSC”) to coordinate and oversee the Exploitation of the Licensed Products in the Territory. The JSC will be composed of an equal number of representatives from each Party and a minimum of [***] representatives of each Party who are fluent in English and who have the appropriate and direct knowledge and expertise and requisite decision-making authority. Any such representative who serves on the JSC or any committee under this Agreement may also serve on one or more other committees under this Agreement. Each Party may replace any of its representatives on the JSC and appoint a person to fill the vacancy arising from each such replacement. A Party that replaces a representative will notify the other Party at least [***] days prior to the next scheduled meeting of the JSC. Both Parties will use reasonable efforts to keep an appropriate level of continuity in representation. Representatives may be represented at any meeting by another person designated by the absent representative. A representative of Viridian will chair the JSC (“JSC Chairperson”) until the first anniversary of the Effective Date. Thereafter, a Kissei representative will become the JSC Chairperson for the next [***] months of the Term and then the role of JSC Chairperson will rotate between the Parties every [***] months during the Term. Each Party’s representatives on the JSC will inform and coordinate within their respective organization to enable each Party to fulfill its obligations as agreed upon between the Parties under this Agreement, including within the time frames set forth hereunder.
- 3.2.2 **Meeting Agendas.** Each Party will disclose to the other Party the proposed agenda items along with appropriate information at least [***] days in advance of each meeting of the JSC; *provided* that under exigent circumstances requiring JSC input, a Party may provide its agenda items to the other Party within a shorter period of time in advance of a meeting, or may propose that there not be a specific agenda for a particular meeting, so long as such other Party consents to such later addition of such agenda items or the absence of a specific agenda for such JSC meeting.
- 3.2.3 **Meetings.** The JSC will hold meetings at such times as it elects to do so, but will meet no less frequently than quarterly, unless otherwise agreed by the Parties. All meetings will be conducted in English. The JSC may meet in person or by means of teleconference, Internet conference, video conference, or other similar communication method; *provided* that, if practicable, at least one meeting each Calendar Year will be conducted in person at a location selected alternatively by Viridian and Kissei or such other location as the Parties may agree. Each Party will be responsible for all of its own costs and expenses of participating in any JSC meeting. The Alliance Managers will jointly prepare and circulate minutes for each JSC meeting within [***] days after each such meeting and will ensure that such minutes are reviewed and approved by their respective companies within [***] days thereafter.
- 3.2.4 **JSC Roles and Responsibilities.** The responsibilities of the JSC will be to:
- (a) provide a forum for the discussion of the Parties’ activities under this Agreement;
 - (b) discuss a summary of Viridian’s Development and Commercialization activities for the Licensed Products in the Territory Development Indications to the extent related to the Development and Commercialization the Licensed Products in the Territory in the Territory Development Indications;

- (c) discuss each proposed Additional Global Clinical Trial (and Kissei's participation therein), as described in Section 4.3.1 (Notice of New Global Clinical Trial);
- (d) review, discuss, and determine whether to approve (i) each additional Territory Development Plan for any indication other than chronic TED or active TED and (ii) any updates to each Territory Development Plan for the Licensed Products, as described in Section 4.3.2 (Participation in Additional Global Clinical Trial) and Section 4.2 (Territory Development), respectively;
- (e) review, discuss, and determine whether to approve the Viridian Support Plan and any updates thereto, as described in Section 4.11 (Viridian Support Plan);
- (f) review, discuss, and determine whether to approve the regulatory strategy for receipt of Regulatory Approval in the Territory, as described in Section 5.1 (Regulatory Strategy);
- (g) to the extent the Parties do not agree on actions to take with respect to remedying a Remedial Action, determine the proper actions to be taken in the Territory with respect to such Remedial Action, as described in Section 5.9 (Remedial Actions);
- (h) review, discuss, and determine whether to approve the MTT Plan, as described in Section 6.3 (Supply by Kissei);
- (i) to the extent the Parties do not agree on a remediation plan, determine whether a remediation plan for deficiencies with respect to Manufacturing Activities identified by Viridian in the course of an audit, as described in Section 6.6.1 (Audits by Viridian);
- (j) serve as a forum to receive updates on and discuss market access, reimbursement, and pricing strategy for the Licensed Products in the Field in the Territory, and to discuss potential implications on global pricing of the Licensed Products;
- (k) review, discuss, and determine whether to approve the Territory Commercialization Plan and any updates thereto for the Licensed Products, as described in Section 7.2 (Territory Commercialization Plan); *provided* that no members of Viridian's commercial organization may approve sections of the Territory Commercialization Plan related to the performance of medical affairs with respect to the Licensed Products;
- (l) establish joint subcommittees (each, a "**Subcommittee**") as necessary or advisable to further the purpose of this Agreement; and
- (m) perform such other functions as expressly set forth in this Agreement or allocated to the JSC by the Parties' written agreement.

3.3. Subcommittees. Pursuant to Section 3.2.4 (JSC Roles and Responsibilities), the JSC will have the authority to establish Subcommittees, including a joint development committee to oversee and coordinate Development of Licensed Antibodies and Licensed Products, and a joint commercialization committee to oversee the Commercialization of Licensed Product, in each case, in the Field in the Territory. Each Subcommittee will be composed of an equal number of representatives from each Party. Each Party may replace its Subcommittee representatives upon written notice to the other Party. All decisions of a Subcommittee will be made by unanimous vote, with each Party's representatives having one vote. In the event the Parties are unable to reach a unanimous vote with respect to a matter, such matter will be referred to the JSC for resolution.

3.4. Non-Member Attendance. Each Party may from time to time invite a reasonable number of participants, in addition to its representatives (which may include legal counsel), to attend a meeting of the JSC (in a non-voting capacity), if such participants have expertise that is relevant to the planned agenda for such JSC meeting; *provided* that, if either Party intends to have any Third Party (including any consultant) attend such a meeting, then such Party will provide prior written notice to the other Party reasonably in advance of such meeting and will ensure that such Third Party is bound by obligations of confidentiality and non-use at least as stringent as those set forth in Article 9 (Confidentiality; Publication). Notwithstanding any provision to the contrary set forth in this Agreement, if the other Party objects in good faith to the participation of such Third Party in such meeting due to a bona fide concern regarding competitively sensitive information that is reasonably likely to be discussed at such meeting (i.e., a consultant that also provides services to a Third Party with a Competing Product), then such Third Party will not be permitted to participate in such meeting (or the portion thereof during which such competitively sensitive information is reasonably likely to be discussed).

3.5. Decision-Making.

3.5.1 **General Process.** The JSC will only have the powers expressly assigned to it in this Article 3 (Governance) and elsewhere in this Agreement and will not have the authority to: (a) modify or amend the terms of this Agreement; or (b) waive either Party's compliance with or rights under the terms of this Agreement. All decisions of the JSC will be made by unanimous vote, with each Party's representatives having one vote (i.e., one vote per Party). No action taken at any meeting of the JSC will be effective unless there is a quorum at such meeting, and at all such meetings, a quorum will be reached if [***] voting representatives of each Party are present or participating in such meeting. Except as otherwise expressly set forth in this Agreement, the phrases "determine," "designate," "confirm," "approve," or "determine whether to approve" by the JSC and similar phrases used in this Agreement will mean approval in accordance with this Section 3.5 (Decision Making), including the escalation and tie breaking provisions herein. For the avoidance of doubt, matters that are specified in Section 3.2.4 (JSC Roles and Responsibilities) to be reviewed and discussed (as opposed to reviewed, discussed, and approved) do not require any agreement or decision by either Party and are not subject to the voting and decision-making procedures set forth in this Section 3.5 (Decision-Making) or in Section 3.6 (Resolution of JSC Disputes).

3.5.2 **Decisions of the JSC.** The JSC will use good faith efforts, in compliance with this Section 3.5.2 (Decisions of the JSC), to promptly resolve any such matter for which it has authority. If, after the use of good faith efforts, the JSC is unable to resolve any such matter that is within the scope of the JSC's authority within a period of [***] days, then a Party may refer such matter for resolution in accordance with Section 3.6.1 (Referral to Executive Officers) to the Chief Executive Officer of Viridian (or an executive officer of Viridian designated by the Chief Executive Officer of Viridian who has the power and authority to resolve such matter) and the Chief Executive Officer of Kissei (or a senior corporate officer or any individual holding the position of senior director or higher of Kissei designated by the Chief Executive Officer of Kissei who has the power and authority to resolve such matter) (collectively, the "**Executive Officers**").

3.6. Resolution of JSC Disputes.

3.6.1 **Referral to Executive Officers.** If a Party makes an election under Section 3.5.2 (Decisions of the JSC) to refer a matter on which the JSC cannot reach a consensus decision for resolution by the Executive Officers, then the JSC will submit in writing the respective positions of the Parties to their respective Executive Officers. The Executive Officers will use good faith efforts to resolve any such matter so referred to them as soon as practicable, and any final decision that the Executive Officers agree to in writing will be conclusive and binding on the Parties.

3.6.2 **Final Decision-Making Authority.** If the Executive Officers are unable to reach agreement on any such matter referred to them within [***] days after such matter is so referred (or such longer period as the Executive Officers may agree upon), then:

- (a) **Kissei Final Decision-Making Authority.** [***].
- (b) **Viridian Final Decision-Making Authority.** [***].
- (c) **Deadlocked Matters.** [***].
- (d) **Third Party Expert Determination Matters.** [***].

3.6.3 **Disputes over Final Decision-Making Authority.** [***].

3.6.4 **Limitations on Decision-Making.** Notwithstanding any provision to the contrary set forth in this Agreement, without the other Party's prior written consent, neither Party (in the exercise of a Party's final decision-making authority), the JSC, the Third Party Experts, nor a Party's Executive Officer, in each case, may make a decision that could reasonably be expected to (a) require the other Party to take any action that such other Party reasonably believes would (i) require such other Party to violate any Applicable Law, the requirements of any Regulatory Authority, or any agreement with any Third Party entered into by such other Party or (ii) require such other Party to infringe or misappropriate any intellectual property rights of any Third Party or (b) conflict with, amend, modify, or waive compliance under this Agreement, any Supply Agreement, the PVA, or any other agreement between the Parties related to the subject matter set forth herein.

3.7. **Discontinuation of Committees.** The JSC and each Subcommittee will continue to exist until the first to occur of (a) the Parties agree to disband the JSC or such Subcommittee or (b) Viridian provides written notice to Kissei of its intention to disband and no longer participate in the JSC or such Subcommittee. Once the JSC or such Subcommittee is disbanded, the disbanded JSC or Subcommittee will have no further obligations under this Agreement and, thereafter, the Alliance Managers will be the points of contact for the exchange of information between the Parties under this Agreement that would otherwise be reported to the disbanded JSC or Subcommittee and any references in this Agreement to decisions of the disbanded JSC or Subcommittee will automatically become references to decisions by and between the Parties in writing, subject to the other terms of this Agreement and consistent with the terms of Section 3.6.2 (Final Decision-Making Authority). If the JSC is disbanded, then any Subcommittees will also be disbanded automatically unless otherwise agreed the Parties.

Article 4 DEVELOPMENT PROGRAM

4.1. **Development Diligence and Responsibilities.** Subject to the terms of this Agreement, Kissei will be responsible, and will use Commercially Reasonable Efforts, to Develop and to seek, obtain, and maintain Regulatory Approval in the Territory for at least one Licensed Product in each of [***] ("**Territory Development**"). Without limiting the generality of the foregoing, Kissei will perform the activities set forth in, and Develop the Licensed Products in accordance with, each Territory Development Plan for the Licensed Products and achieve the objectives set forth therein. Kissei will not perform any Development activities for the Licensed Products other than those expressly set forth in a Territory Development Plan, without Viridian's prior written consent, such consent not to be unreasonably withheld, conditioned, or delayed.

4.2. **Territory Development.** All Development of the Licensed Products in the Territory will be conducted pursuant to separate written development plans for each distinct indication, each of which will be approved by the JSC (as each such plan is updated from time to time in accordance with this Section 4.2 (Territory Development) and Section 3.2 (Joint Steering Committee), a "**Territory Development Plan**"), and Kissei will be primarily responsible for all Territory

Development activities for the Licensed Products. The initial Territory Development Plan for the Licensed Products is set forth on **Schedule 4.2** (Territory Development Plan) attached hereto, and includes Territory-Specific Clinical Trials designed to obtain Regulatory Approval of Licensed Products containing each Licensed Antibody for the treatment of each of active TED and chronic TED. Each Territory Development Plan and all updates thereto will contain in reasonable detail (a) [***], (b) [***], and (c) [***]. In addition, at least annually during the Term (or more frequently, as required, upon the occurrence of significant milestone events, such as data readouts or regulatory interactions, or the decision to Develop and obtain regulatory approval for the Licensed Antibodies and Licensed Products), the JSC will review, discuss, and determine whether to approve any updates to each Territory Development Plan. Notwithstanding any provision to the contrary set forth in this Agreement, [***], each Territory Development Plan and all updates thereto must be consistent with a written plan for worldwide development of the Licensed Products as provided to Kissei by Viridian from time to time (the “**Global Development Plan**”). Upon delivery by Kissei of an Additional Global Clinical Trial Participation Notice in accordance with Section 4.3.1 (Notice of New Global Clinical Trial) for an indication that is not at such time a Territory Development Indication, as further described in Section 4.3.2 (Participation in Additional Global Clinical Trial), the Parties will develop a new Territory Development Plan for such indication and submit such Territory Development Plan to the JSC to review, discuss, and determine whether to approve within the applicable [***] day period. Without limiting the foregoing, within [***] days following Kissei’s receipt from Viridian of each updated Global Development Plan, Kissei will submit to the JSC updated Territory Development Plans for each Territory Development Indication that align with the most recent Global Development Plan and the JSC will review, discuss, and determine whether to approve any such update to each Territory Development Plan. Once approved by the JSC, each update to each Territory Development Plan required pursuant to this Section 4.2 (Territory Development) will become effective and supersede the applicable then-current Territory Development Plan. In the event of any conflict or inconsistency between any Territory Development Plan and the Global Development Plan, the Global Development Plan will control and take precedence.

4.3. Additional Global Clinical Trials.

- 4.3.1 **Notice of New Global Clinical Trial.** If Viridian decides to commence a Global Clinical Trial for a Licensed Product in any indication, then, no later than [***] days before [***], Viridian will notify Kissei through the JSC of the proposed Additional Global Clinical Trial, which will include, to the extent reasonably available, [***]. If the proposed Additional Global Clinical Trial is to investigate the Licensed Product for use in an indication that is not at such time a Territory Development Indication that is the subject of activities under a Territory Development Plan, then Kissei will have [***] days to determine whether or not to participate in such proposed Additional Global Clinical Trial in the Territory by delivering an Additional Global Clinical Trial Participation Notice during such [***]-day period. Upon Kissei’s reasonable request, the Parties will engage in good faith discussions through the JSC to assist Kissei with its determination as to whether to participate in such proposed Additional Global Clinical Trial for any indication that is not a form of TED.
- 4.3.2 **Participation in Additional Global Clinical Trial.** If Kissei delivers to Viridian an Additional Global Clinical Trial Participation Notice during such [***]-day period, in accordance with Section 4.3.1 (Notice of New Global Clinical Trial), then, for a period of [***] days following receipt of such notice, the Parties will develop and submit to the JSC to review, discuss, and determine whether to approve a Territory Development Plan for Development of the Licensed Products in the indication that is being investigated in such proposed Additional Global Clinical Trial. The Parties, through the JSC, will develop a separate Territory Development Plan for each indication that [***]. With respect to an indication that is being investigated in such proposed Additional Global Clinical Trial that [***], if the Parties or the JSC, as applicable, cannot, during such [***]-day period, reach agreement as to the Territory Development Plan for Development of the Licensed Products in such indication [***], then such indication will become [***]

upon expiration of such [***]-day period. For clarity, in no event will Kissei initiate any activities in furtherance of any proposed Additional Global Clinical Trial or otherwise investigate any indication that is not at such time a Territory Development Indication until the Parties have agreed in writing on a Territory Development Plan for Development of the Licensed Products in the indication that is being investigated in such proposed Additional Global Clinical Trial in accordance with Section 4.2 (Territory Development).

4.3.3 **Conduct of Additional Global Clinical Trials.** [***]

4.3.4 [***]. If, within the applicable [***]-day period set forth above in Section 4.3.1 (Notice of New Global Clinical Trial), (a) Kissei [***]. Further, in such case, notwithstanding any provision to the contrary set forth in this Agreement, unless required by Applicable Law or to comply with its pharmacovigilance obligations, Kissei will not [***].

4.3.5 **Opt-In to a [***].** On a [***] basis, if, [***], Kissei notifies Viridian in writing that it would like to use the [***] Technology related to such [***] (the date of such notification, the “**Opt-In Notification Date**”), then:

4.3.6 [***]. For the avoidance of doubt, prior to Kissei’s notification in accordance with the first sentence of this Section 4.3.5 (Opt-In to a [***]), the JSC will discuss in good faith the [***] to assist Kissei with its determination as to whether to exercise its opt-in right for [***].

4.4. **Standard of Conduct.** Kissei will perform, and will cause its Affiliates, Sublicensees, and Subcontractors to perform, all Development activities for the Licensed Products in a timely and professional manner, and in compliance with the Territory Development Plans and all Applicable Law, including as applicable GLP, GCP, cGMP, GVP, and GSP. In addition, Kissei will conduct its obligations with respect to any Global Clinical Trial or Territory-Specific Clinical Trial under the Territory Development Plans in strict adherence with the study design set forth in the applicable protocol therefor and as set forth in such Territory Development Plan, as may be amended from time to time, and will comply with each statistical analysis plan.

4.5. **Responsibility for Development Costs.**

4.5.1 **Local Development Costs.** Except as otherwise set forth in this Agreement, Kissei will be solely responsible for all costs and expenses incurred by or on behalf of Kissei in connection with the Development of the Licensed Products in the Field in the Territory on or after the Effective Date, including the performance of Development activities for the Licensed Products under the Territory Development Plans. In addition, Kissei will be responsible for all costs arising from any compassionate use or open labels arising from the Development of the Licensed Products in the Field in the Territory on or after the Effective Date.

4.5.2 **Additional Global Clinical Trials.** For any Additional Global Clinical Trial in which Kissei participates in accordance with Section 4.3.2 (Participation in Additional Global Clinical Trial), Kissei will be responsible for (a) 100% of the costs and expenses incurred in the performance of activities in furtherance of such Additional Global Clinical Trial that are performed in or specifically for the Territory and (b) [***]% of all out-of-pocket costs incurred by or on behalf of Viridian in the performance of activities outside of the Territory in furtherance of such Additional Global Clinical Trial (the “**Global Clinical Trial Costs**”).

4.6. Clinical Trial Audit Rights.

4.6.1 Conduct of Audits.

- (a) **Audits by Viridian.** Upon reasonable notification by Viridian and at Viridian's cost and expense, Viridian or its representatives may conduct an audit of Kissei, its Affiliates, or any of its or their Sublicensees or Subcontractors (including Clinical Trial sites) engaged by Kissei or its Affiliates or Sublicensees to perform Kissei's obligations under any Territory Development Plan to ensure that the applicable Global Clinical Trials and Territory-Specific Clinical Trials are conducted in compliance with the Territory Development Plans, GCP, GMP, GVP, and Applicable Law; *provided* that, with respect to any audit of Subcontractors pursuant to this Section 4.6.1(a) (Audits by Viridian), Viridian will only have the right to conduct audits of Clinical Trial sites and other Subcontractors, in each case, that perform activities in furtherance of one or more Global Clinical Trials or if such audit is otherwise required by Applicable Law. Notwithstanding any provision to the contrary set forth in this Agreement, there will be no limit on the number of "for cause" audits that Viridian may conduct of Kissei or any of its Affiliates, Sublicensees, or Subcontractors. Viridian will use reasonable efforts to notify Kissei in writing of any "for cause" audit at least [***] in advance thereof. After preparing or receiving an audit report, Viridian will provide Kissei with a written summary of Viridian's findings of any deficiencies or other areas of remediation that Viridian identifies during any such audit. Kissei will (i) provide a written response stating how it plans to remediate such deficiencies or other areas of remediation identified by Viridian and (ii) use reasonable efforts to remediate any such deficiencies no later than [***] days after Kissei's receipt of such report, at Kissei's cost and expense.
- (b) **Audits by Kissei.** Upon reasonable notification by Kissei and at Kissei's cost and expense, Kissei or its representatives may conduct an audit of Viridian, its Affiliates, or any (sub)licensees or subcontractors engaged by Viridian or its Affiliates to perform Global Clinical Trials for which Kissei is conducting one or more Territory-Specific Clinical Trials to ensure such Global Clinical Trials are conducted in compliance with the Global Development Plan, GCP, GMP, GVP, and Applicable Law; *provided* that Kissei will only have the right to conduct audits of subcontractors and Clinical Trial sites that perform activities in furtherance of one or more Global Clinical Trials or if such audit is otherwise required by Applicable Law. Notwithstanding any provision to the contrary set forth in this Agreement, there will be no limit on the number of "for cause" audits that Kissei may conduct of Viridian or any of its Affiliates, (sub)licensees, or subcontractors. Kissei will use reasonable efforts to notify Viridian in writing of any "for cause" audit at least [***] in advance thereof. After preparing or receiving an audit report, Kissei will provide Viridian with a written summary of Kissei's findings of any deficiencies or other areas of remediation that Kissei identifies during any such audit. Viridian will (i) provide a written response stating how it plans to remediate such deficiencies or other areas of remediation identified by Kissei and (ii) use reasonable efforts to remediate any such deficiencies no later than [***] days after Viridian's receipt of such report, at Viridian's cost and expense.

- 4.6.2 **Deficient Sublicensees and Replacement.** With respect to any Global Clinical Trial or Territory-Specific Clinical Trial, if any audit of a Kissei Clinical Trial site identifies any deficiencies (each, a "**Deficient Site**") that, as agreed by the Parties, may cause a Regulatory Authority to reject or otherwise deem deficient the Clinical Trial data from Kissei's conduct of any such Global Clinical Trial or Territory-Specific Clinical Trial (as applicable) at such Deficient Site, then subject to Kissei's right to remediate under Section 4.6.1 (Conduct of Audits), if Kissei is unable to successfully remediate the situation and reasonably eliminate the condition causing the Clinical Trial site to be a

Deficient Site, then Kissei will promptly remove such Deficient Site from the applicable Global Clinical Trial or Territory-Specific Clinical Trial or, if needed, replace such Deficient Site with a new Clinical Trial site (a “**Replacement Site**”) within the Territory at Kissei’s sole cost and expense in accordance with the Quality Agreement or such other similar written agreement between the Parties (unless not permitted by Applicable Law, if required by Regulatory Authority, or for ethical reasons). Any such Replacement Site will be compliant in all respects with Applicable Law and the Quality Agreement or such other similar agreement agreed upon by the Parties. In addition, if the Parties agree in writing, as a result of any audit conducted pursuant to Section 4.6.1 (Conduct of Audits) that any Sublicensee or Subcontractor (including any contract research organizations) is not performing its activities in accordance with GLP, cGMP, GCP, GVP, or GSP, as applicable, or in compliance with Applicable Law or that any deficiencies identified as a result of any such audit related to any such Sublicensee’s or Subcontractor’s performance, as agreed by the Parties, may cause a Regulatory Authority to reject or otherwise deem deficient the Clinical Trial data from Kissei’s conduct of any such Global Clinical Trial or Territory-Specific Clinical Trial (as applicable) (each, a “**Deficient Sublicensee**”), then Kissei will promptly remove such Deficient Sublicensee from performing further activities under the Territory Development Plans and replace such Deficient Sublicensee with a new Sublicensee engaged in accordance with Section 2.2 (Sublicensing and Subcontractors) to perform the applicable Development activities at Kissei’s sole cost and expense. If Kissei is unable to mitigate the deficiencies or replace any Deficient Site with a Replacement Site or Deficient Sublicensee with a replacement Sublicensee, as applicable, or, as agreed by the Parties in writing, is unable to do so in a timely manner so as not to jeopardize the Parties’ ability to meet the timelines for Regulatory Submissions set forth in the Territory Development Plans, as applicable, [***].

- 4.6.3 **Kissei Audits.** Kissei will provide Viridian with copies of all material quality oversight or audit reports (which will include all such reports that include any critical or major observations) prepared in connection with any audit that Kissei or its Affiliates or Sublicensees conduct of any Sublicensee, Subcontractor, or Clinical Trial site that Kissei or its Affiliates or Sublicensees have engaged or are evaluating to potentially engage to fulfill Kissei’s obligations under a Territory Development Plan as soon as Kissei receives or prepares any such report (as applicable), and Viridian may provide any such reports to any counterparty to any Third Party IP Agreement if required by the terms of such Third Party IP Agreement. If Viridian believes in good faith that any such quality oversight or audit report may be necessary in connection with obtaining, supporting, or maintaining one or more Regulatory Approvals for the Licensed Products or for other communications with Regulatory Authorities outside of the Territory, then upon Viridian’s request, Kissei will provide a copy of any such quality oversight or audit report to Viridian and, if such report is not in English, a translation in English in accordance with Section 15.16 (Language; Translations).
- 4.6.4 **Regulatory Inspections by Regulatory Authorities Outside the Territory.** In the event that any Regulatory Authority outside the Territory, such as the U.S. FDA, intends to conduct an inspection of Kissei, any of its Affiliates, or any of its or their Sublicensees or Subcontractors (including Clinical Trial sites) in the Territory that is related to the Exploitation of one or more Licensed Products, Viridian will notify Kissei of such inspection within [***] days after Viridian receives notice from such Regulatory Authority or becomes aware of an unannounced inspection. Kissei will permit such inspection and ensure that all Affiliates and Sublicensees that are not Subcontractors permit, and use reasonable efforts to ensure that all Subcontractors permit (to the extent permitted under any agreement between Kissei and such Subcontractor), such inspection. To the extent permitted by Applicable Law, Kissei will promptly provide Viridian with all reasonably available information related to any such inspection that is related to the Exploitation of one or more Licensed Products. Viridian will have the right, but not the obligation, to be present at any such inspection of Kissei. In the event that such Regulatory Authority conducts an inspection of medical institutions or manufacturing

facilities in the Territory related to the MAA for the Licensed Products other than in the Field in the Territory, [***].

- 4.6.5 **Regulatory Inspections by Regulatory Authorities in the Kissei Territory.** In the event that any Regulatory Authority in the Territory, such as the PMDA, intends to conduct an inspection of Viridian, any of its Affiliates, or its or their (sub)licensees or subcontractors (including Clinical Trial sites) outside the Territory that is related to the Exploitation of one or more Licensed Products in the Field in the Territory, Kissei will notify Viridian of such inspection within [***] days after Kissei receives notice from such Regulatory Authority or becomes aware of an unannounced inspection. Viridian will permit such inspection and ensure that all Affiliates permit, and use reasonable efforts to ensure that all (sub)licensees and subcontractors permit (to the extent permitted under any agreement between Viridian and such subcontractor), such inspection. To the extent permitted by Applicable Law, Viridian will promptly provide Kissei with all reasonably available information related to any such inspection that is related to the Exploitation of one or more Licensed Products in the Field in the Territory. Kissei will have the right, but not the obligation, to be present at any such inspection of Viridian. In the event that such Regulatory Authority conducts an inspection of medical institutions or manufacturing facilities outside the Territory related to the MAA for the Licensed Products in the Field in the Territory, Kissei shall be responsible for the out-of-pocket costs associated with such inspection incurred by Viridian or its Affiliates.
- 4.7. **Development Records.** Kissei will, and will cause its Affiliates, Sublicensees, and Subcontractors to, maintain reasonably complete, current, and accurate records of all Development activities conducted by or on behalf of Kissei, and its Affiliates, Sublicensees, and Subcontractors, respectively, pursuant to this Agreement and all data and other information resulting from such activities consistent with its usual practices, in validated computer systems that are compliant with in accordance with Applicable Law of the Territory and ICH guidelines. Kissei will maintain all such records for a period of [***] years after the end of the Term, or for such longer time as required by Applicable Law. Such records will fully and properly reflect all work done and results achieved in the performance of the Development activities for the Licensed Products in good scientific manner appropriate for regulatory and patent purposes; *provided* that [***]. Kissei will document all non-clinical and preclinical studies and Clinical Trials in formal written study reports in accordance with GLP, cGMP, and GCP, as applicable, and in compliance with Applicable Law of the Territory and ICH guidelines. Upon Viridian's reasonable request, not more frequently than [***] during which Kissei or its Affiliates, Sublicensees, or Subcontractors are performing or having performed Development activities for the Licensed Products, Kissei will, and will cause its Affiliates, Sublicensees, and Subcontractors to, allow Viridian to access, review, and copy such records (including access to relevant databases); *provided* that, unless the Parties otherwise agree, [***]. [***]. If any such records are not in English, then Kissei will provide copies in English in accordance with Section 15.16 (Language; Translations). Viridian and its Affiliates, licensees, licensors, and Sublicensees will have the right to use the data and results generated by or on behalf of Kissei and its Affiliates, Sublicensees, and Subcontractors hereunder to Exploit the Licensed Products outside of the Territory and, subject to Viridian's receipt of Kissei's written consent in accordance with Section 4.3.4 ([***]), to perform Development activities in the Territory in furtherance of a [***].
- 4.8. **Development Reports.** At each meeting of the JSC, Kissei will provide the JSC, at Kissei's sole cost and expense, with a reasonably detailed written report, in any format (including a slide deck), summarizing [***]. Such reports will be in English. Kissei may establish a secure link that includes adequate encryption safeguards to provide Viridian with electronic access to such information in accordance with all Applicable Law, *provided* that Viridian will reasonably cooperate in the establishment of such secure link. Without limiting the foregoing, such reports will contain sufficient detail to enable Viridian to assess Kissei's compliance with its Development diligence obligations set forth in Section 4.1 (Development Diligence and Responsibilities). Kissei will promptly respond to Viridian's reasonable requests from time to time for additional information regarding significant Development activities for the Licensed Products performed by or on behalf of Kissei or its Affiliates, Sublicensees, or Subcontractors.

The Parties will discuss the status, progress, and results of all Development activities at each JSC meeting. Such reports will be the Confidential Information of Kissei and subject to the terms of Article 9 (Confidentiality; Publication).

- 4.9. Data Exchange and Use.** In addition to its Adverse Event and safety data reporting obligations set forth in Section 5.6 (Adverse Events Reporting), each Party will promptly provide the other Party, through the JSC, with copies of all data and results and all supporting documentation [***] owned, controlled, or otherwise held for use by such Party that are generated by or on behalf of such Party or its Affiliates, Sublicensees, or Subcontractors, if applicable, in the Development of the Licensed Products in the Field, including all data and results (or on whose behalf such data and results are generated) in the course of conducting such non-clinical or preclinical studies or Clinical Trials for the Licensed Products. Each Party will provide such documents in English. Such data, results, and supporting documentation provided by a Party pursuant to this Section 4.9 (Data Exchange and Use) will be the Confidential Information of such Party, and such Party will be the Disclosing Party with respect thereto, in each case, subject to the terms of Article 9 (Confidentiality; Publication). Kissei will have the exclusive right to use and reference such data and results provided by Viridian, including Viridian Generated Data, for the purpose of performing Development activities in accordance with this Agreement (including under any Territory Development Plan), and obtaining, supporting, and maintaining Regulatory Approvals, and any Reimbursement Approval, as applicable, of the Licensed Products in the Field in the Territory without additional consideration. Viridian and its designees will have the exclusive right to use and reference such data and results provided by Kissei for the purpose of Developing the Licensed Products, and obtaining, supporting, or maintaining Regulatory Approval or any Reimbursement Approval, as applicable, of the Licensed Products outside the Territory, without additional consideration.
- 4.10. Dispatch.** [***].
- 4.11. Viridian Support Plan.** Viridian agrees to provide the cooperation and assistance to be expressly provided under Section 5.4 (Viridian's Responsibilities) and Section 7.1 (Commercialization Diligence and Responsibilities), or as may be requested by Kissei and agreed by Viridian from time to time, in each case, in accordance with a written support plan (such plan, as may be updated in accordance with this Section 4.11 (Viridian Support Plan), the "**Viridian Support Plan**"). The JSC will discuss, review, and determine whether to approve the Viridian Support Plan, *provided* that any such plan must (a) [***], (b) [***], (c) [***], and (d) [***]. At least annually during the Term, and as more frequently as may otherwise be requested by the Parties, the JSC will review, discuss, and determine whether to approve any updates to the Viridian Support Plan. [***]. Notwithstanding the foregoing, for the purpose of clarification, Viridian will provide to Kissei, free of charge, the Viridian Know-How in the possession and Control of Viridian and its Affiliates that is necessary for Regulatory Submissions for the Licensed Products in the Territory.

Article 5 REGULATORY

- 5.1. Regulatory Strategy.** The JSC will discuss, develop, and determine whether to approve a regulatory strategy for the Licensed Products in the Field in the Territory (which, strategy will include the estimated timeline for submission of MAAs for the Licensed Products in the Field in the Territory) to be included in the Territory Development Plans. Notwithstanding any provision to the contrary set forth in this Agreement, including Kissei's final decision-making authority under Section 3.6.2(a) (Kissei Final Decision-Making Authority), such regulatory strategy and all updates thereto must be consistent with the global regulatory strategy set forth in the then-current Global Development Plan provided by Viridian to Kissei, unless otherwise agreed in writing by Viridian. From time to time the JSC may review, discuss, and determine whether to approve any update the regulatory strategy for the Licensed Products. Once approved by the JSC, each update to a regulatory strategy for the Licensed Products will become effective and supersede the then-current regulatory strategy for the Licensed Products.

5.2. Kissei's Responsibilities.

- 5.2.1 **Obtaining and Maintaining Regulatory Approvals.** Through its reports submitted to the JSC, Kissei will keep Viridian reasonably informed of regulatory developments related to each Licensed Product in the Field in the Territory and will promptly notify Viridian in writing of any decision by any Regulatory Authority in the Territory regarding each Licensed Product; *provided* that, without limiting the foregoing, Kissei will notify Viridian of receipt of each Regulatory Approval within [***] Business Days following such receipt. Subject to this Section 5.2.1 (Obtaining and Maintaining Regulatory Approvals), for each Territory Development Indication for each Licensed Product, Kissei will be the marketing authorization holder in the Field in the Territory and will be responsible for all regulatory activities leading up to and including obtaining, and thereafter maintaining, Regulatory Approvals and any Reimbursement Approvals in the Field in the Territory, in its own name or in the name of its Affiliate.
- 5.2.2 **Regulatory Assistance.** Each Party will cooperate fully and in a timely manner to assist the other Party (including, in the event Viridian is the other Party, to the extent a (sub)licensee of Viridian requests assistance) in its efforts to prepare and submit any Regulatory Submissions to obtain, support, or maintain Regulatory Approvals for the Licensed Products outside the Territory (in the case of Viridian) and in the Field in the Territory (in the case of Kissei), including by providing to the other Party all data and documentation related to the Licensed Products generated by such Party or its Affiliates, to the extent otherwise required to be provided to such Party under this Agreement, and which assistance and data generation must be in accordance with Applicable Law and requirements and standards by the FDA or other applicable Regulatory Authority, as well as any necessary samples and materials.
- 5.2.3 **Review of Regulatory Submissions.** Kissei will provide to Viridian (through the JSC, the Alliance Managers, or their designees) for review and comment drafts of all material Regulatory Submissions (including all INDs and MAAs) and all proposed Approved Labeling in the Field in the Territory for each Licensed Product in each Territory Development Indication, and [***]. The JSC will review any changes in regulatory strategy and, to the extent requested by Viridian, will discuss any Regulatory Submission for which Kissei is responsible and all proposed Approved Labeling in the Field in the Territory for each Licensed Product. All INDs, MAAs, Approved Labeling, and other Regulatory Submissions for the Licensed Products in the Field in the Territory will be consistent with the then-current regulatory strategy. In addition, Kissei will notify Viridian of any substantive Regulatory Submissions in the Territory and proposed Approved Labeling for each Licensed Product and any comments or other substantive correspondences related thereto submitted to or received from any Regulatory Authority in the Territory and will provide Viridian with copies thereof as soon as reasonably practicable, but in any event within [***] days after submission or receipt thereof (or such longer time period as may be necessary to obtain translations thereof). If any such Regulatory Submission or proposed Approved Labeling, comment, or correspondence is not in English, then Kissei will provide Viridian with an English translation in accordance with Section 15.16 (Language; Translations).
- 5.2.4 **Notice of Meetings.** Kissei will provide Viridian with notice of any meeting or discussion with any Regulatory Authority in the Field in the Territory related to the Licensed Products no later than [***] Business Days after receiving notice thereof or in any event with as much advanced notice as is possible prior to such meeting or discussion if Kissei receives notice thereof less than [***] Business Days in advance of the applicable meeting or discussion. Kissei (or its designee) will lead any such meeting or discussion and Viridian or its designee will have the right, but not the obligation, to attend and participate in any such meeting or discussion unless prohibited or restricted by Applicable Law or Regulatory Authority. At Viridian's request, Viridian may participate in any preparations of Kissei or its Affiliates or Sublicensees for any such meeting or discussion. If Viridian elects not to attend such meeting or discussion, then Kissei will

provide to Viridian a written summary thereof in English promptly following such meeting or discussion, as well as any formal minutes generated by the Regulatory Authority.

- 5.2.5 **Responsibility for Costs and Expenses.** Kissei will be responsible for all costs and expenses incurred by Kissei or its Affiliate and Sublicensees in connection with the performance of all regulatory activities leading up to and including obtaining and thereafter maintaining, Regulatory Approvals and any Reimbursement Approvals, as applicable, for the Licensed Products from Regulatory Authorities in the Field in the Territory. Notwithstanding any provision to the contrary set forth in this Agreement, Kissei will not be responsible for costs and expenses incurred by Viridian or its Affiliates and Sublicensees in connection with the performance of regulatory activities leading up to and including obtaining and thereafter maintaining, Regulatory Approvals or any Reimbursement Approvals, as applicable, for the Licensed Products from Regulatory Authorities outside the Field in the Territory and outside the Territory.
- 5.3. **Communications with Regulatory Authorities.** Unless otherwise agreed by the Parties (or unless otherwise set forth in this Agreement), Kissei will not, and will ensure that its Affiliates and its Sublicensees do not, communicate with any Regulatory Authority having jurisdiction outside of the Territory or outside of the Field in the Territory with respect to the Licensed Products, unless so ordered by such Regulatory Authority, in which case, Kissei will immediately notify Viridian of such order.
- 5.4. **Viridian's Responsibilities.** In accordance with the Viridian Support Plan, Viridian will reasonably cooperate with Kissei in obtaining any Regulatory Approvals and any Reimbursement Approvals, including any responses to inquiries by Regulatory Authorities, as applicable, for the Licensed Products in the indications that are the subject of each Territory Development Plan in the Field in the Territory by providing access to Regulatory Approvals, Regulatory Submissions, clinical data, and other data (including chemistry, manufacturing, and controls data necessary required by a Regulatory Authority in the Territory), information, documentation, samples and materials for the Licensed Products, both inside and outside of the Territory, in each case, to the extent (a) Controlled by Viridian, (b) not previously provided to Kissei, and (c) [***] for Kissei to obtain Regulatory Approvals in the Territory Development Indications in the Field, [***].
- 5.5. **Right of Reference.** Each Party will grant, and hereby does grant, to the other Party a right of reference to all Regulatory Submissions pertaining to the Licensed Products in the Territory Development Indications in the Field submitted by or on behalf of such Party or its Affiliates, which right of reference (a) to Regulatory Submissions submitted by or on behalf of Viridian is exclusive to Kissei in the Territory Development Indications in the Field in the Territory, and (b) to Regulatory Submissions submitted by or on behalf of Kissei is exclusive to Viridian outside the Territory. Kissei will not grant a right of reference to any Regulatory Submission pertaining to one or more Licensed Products to any Third Party outside of the Field in the Territory. Kissei may use such right of reference to Viridian's Regulatory Submissions solely for the purpose of performing Development activities for the Licensed Products in accordance with this Agreement and the Territory Development Plans and to seek, obtain, support, and maintain Regulatory Approvals and any Reimbursement Approvals, as applicable, for the Licensed Products in the Territory Development Indications in the Field in the Territory, [***]. Viridian may use such right of reference to Kissei's Regulatory Submissions, if any, solely for the purpose of Developing the Licensed Products and to seek, obtain, support, and maintain Regulatory Approval and any Reimbursement Approvals for the Licensed Products outside of the Territory. Each Party will bear its own costs and expenses associated with providing the other Party with the right of reference pursuant to this Section 5.5 (Right of Reference). Each Party will take such actions as may be reasonably requested by the other Party to give effect to the intent of this Section 5.5 (Right of Reference) and to give the other Party the benefit of the granting Party's Regulatory Submissions in the other Party's territory as provided herein. Such actions may include providing to the other Party copies of correspondence and communications received from the applicable Regulatory Authorities related to such Party's application for Regulatory Approval of the Licensed Products in the Field in the Territory (if Kissei is the Party seeking Regulatory

Approval) and of the Licensed Products outside of the Territory (if Viridian is the Party seeking Regulatory Approval).

5.6. Adverse Events Reporting.

5.6.1 **Pharmacovigilance Agreement.** No later than [***] days after the Effective Date, but in any event prior to [***], the Parties will enter into a written agreement setting forth worldwide safety and pharmacovigilance procedures for the Parties with respect to the Licensed Products, such as safety data sharing and exchange, Adverse Events reporting and prescription events monitoring in a written agreement (the “PVA”). The PVA will describe the obligations of both Parties with respect to the coordination of collection, investigation, reporting, and exchange of information between the Parties concerning any Adverse Event or any other safety problem of any significance, and product quality and Product Complaints involving Adverse Events, sufficient to permit each Party, its Affiliates, licensees or sublicensees to comply with its legal obligations. The PVA will be promptly updated if required by changes in legal requirements. Each Party hereby agrees to comply with its respective obligations under the PVA and to cause its Affiliates, licensees and Sublicensees to comply with such obligations. To the extent there is any disagreement between this Section 5.6 (Adverse Event Reporting), Section 5.7 (Safety and Regulatory Audits), or any related definitions and the PVA, the PVA will control with respect to safety matters and this Agreement will control with respect to all other matters. Notwithstanding any provision to the contrary in this Agreement or the PVA, each Party and its Affiliates, licensees, and Sublicensees will have the right to disclose information related to the safety of the Licensed Products to the extent that such disclosure is required for such Party to comply with its obligations under Applicable Law or the safety requirements of the applicable Regulatory Authorities. The Parties will cooperate with each other to address any safety-related inquiries or requests for safety assessment by any Regulatory Authority, including providing any necessary data or information in a timely manner. To the extent that there is a conflict between the terms of this Agreement and the terms of the PVA, the terms of the PVA will govern with respect to the subject matter set forth therein.

5.6.2 **Safety Databases.** Kissei will maintain an Adverse Event database for Clinical Trials for the Licensed Products conducted in the Field in the Territory under the Territory Development Plans, at its sole cost and expense. Kissei will be responsible for: (a) reporting to the applicable Regulatory Authorities all quality complaints, Adverse Events, and safety data related to the Licensed Products for all Territory-Specific Clinical Trials or Global Clinical Trials; and (b) responding to safety issues and to all requests of Regulatory Authorities related to the Licensed Products in the Field in the Territory. Kissei will provide Viridian, upon Viridian’s request, query results from Kissei’s safety database for the Licensed Products. Kissei will provide such query results in its original language and a translation in English in accordance with Section 15.16 (Language; Translations). Viridian will maintain a global safety database for Global Clinical Trials for the Licensed Products.

5.7. Safety and Regulatory Audits.

5.7.1 **Safety and Regulatory Audits by Viridian.** In addition to its rights to conduct audits pursuant to Section 4.6 (Clinical Trial Audit Rights), upon Viridian’s reasonable notification to Kissei and no more frequently [***], Kissei will, will cause its Affiliates and Sublicensees that are not Subcontractors to, and will use reasonable efforts to cause its Subcontractors (including Subcontractors that are granted a sublicense) to (to the extent permitted under any agreement between Kissei and such Subcontractor), permit Viridian or its representatives to conduct audits of safety and regulatory systems, procedures, or practices of Kissei or its Affiliates, Sublicensees, or Subcontractors relating to the Licensed Products, including the Adverse Event database maintained by Kissei pursuant to Section 5.6.2 (Safety Databases). With respect to any inspection of Kissei, its Affiliates, or its or their Sublicensees or Subcontractors (including Clinical

Trial sites) by any Governmental Authority relating to the Licensed Products, Kissei will notify Viridian of such inspection as soon as Kissei becomes aware of any such inspection. To the extent permitted by Applicable Law, Kissei will promptly provide Viridian with all reasonably available information related to any such inspection, and Kissei will also permit Governmental Authorities outside of the Territory to conduct inspections of it or its Affiliates or Sublicensees relating to the Licensed Products, and will ensure that all such Affiliates permit such inspections and will ensure that all Sublicensees permit such inspections. Viridian will have the right, but not the obligation (unless required by Applicable Law or any Governmental Authority), to be present at any such inspection of Kissei. Following any such regulatory inspection related to the Licensed Products, Kissei will (a) notify Viridian in writing of any critical or major observations contained in any findings, notice, or report provided by any Governmental Authority within one Business Day following Kissei's receipt of the same and (b) for any other observations, provide Viridian with an unredacted copy (and an English translation thereof) of any findings, notice, or report provided by any Governmental Authority related to such inspection (to the extent related to the Licensed Products) within [***] Business Days following Kissei's receipt of the same.

- 5.7.2 **Safety and Regulatory Audits by Kissei.** Upon Kissei's reasonable notification to Viridian and [***], Viridian will, will cause its Affiliates and (sub)licensees to, and will use reasonable efforts to cause its subcontractors to (to the extent permitted under any agreement between Viridian and such subcontractor), permit Kissei or its representatives to conduct audits of safety and regulatory systems, procedures, or practices of Viridian or any of its Affiliates, (sub)licensees, or subcontractors relating to the Licensed Products in the Field. With respect to any inspection of Viridian or its Affiliates, (sub)licensees, or subcontractors (including Clinical Trial sites) by any Governmental Authority relating to the Licensed Products in the Field, Viridian will notify Kissei of such inspection as soon as Viridian becomes aware of any such inspection. To the extent permitted by Applicable Law, Viridian will promptly provide Kissei with all reasonably available information related to any such inspection to the extent such information is controlled by Viridian and Viridian is not prohibited from sharing such information under contractual obligations of confidentiality and non-use owed to any Third Party. Following any such regulatory inspection related to the Licensed Products, Viridian will (a) notify Kissei in writing of any critical observations contained in any findings, notice, or report provided by any Governmental Authority within [***] Business Day following Kissei's receipt of the same and (b) provide Kissei with an unredacted copy of any findings, notice, or report provided by any Governmental Authority related to such inspection (to the extent related to the Licensed Products) within [***] Business Days following Viridian's receipt of the same.

5.8. Notice of Regulatory Action.

- 5.8.1 **Notice of Regulatory Action to Kissei.** If any Regulatory Authority takes or gives notice of its intent to take any regulatory action with respect to any activity Kissei relating to one or more Licensed Products, then Kissei will notify Viridian of such contact, inspection, or notice or action as soon as Kissei becomes aware of such contact, inspection, or notice of action. [***].
- 5.8.2 **Notice of Regulatory Action to Viridian.** If any Regulatory Authority takes or give notice of its intent to take any regulatory action with respect to any activity of Viridian that would reasonably be expected to materially affect the Development or Commercialization of one or more Licensed Products in the Field in the Territory, then Viridian will notify Kissei of such contact, inspection, or notice or action as soon as Viridian becomes aware of such contact, inspection, or notice of action. [***].
- 5.9. **Remedial Actions.** If a recall, withdrawal, or correction (including the dissemination of relevant information) of any Licensed Product in the Territory (a "**Remedial Action**") is required by a Regulatory Authority of competent jurisdiction in the Territory, then Kissei will

notify Viridian as soon as Kissei receives such Remedial Action notice from a Regulatory Authority. In addition, if Kissei desires to initiate a Remedial Action that is not required by a Regulatory Authority of competent jurisdiction in the Territory, then Kissei will provide written notice of such desire, and [***]; *provided that* [***]. Promptly after being notified of such Remedial Action, Viridian will provide Kissei with such assistance in connection with such Remedial Action as may be reasonably requested by Kissei but, for the avoidance of doubt, Kissei will be responsible for conducting Remedial Actions in the Territory. All costs and expenses in connection with a Remedial Action in the Territory, including the costs and expenses related to the dissemination of relevant information, collection and proper destruction of recalled Licensed Product, and replacement of recalled Licensed Product with Licensed Product will be borne by Kissei, *provided, however,* that [***]. In addition, if Viridian notifies Kissei that in Viridian's reasonable judgment a Remedial Action of a Licensed Product in the Territory is necessary for any reason (including for any Manufacturing issue related to a Licensed Product that Viridian reasonably believes could give rise to a Remedial Action), then Kissei will initiate such Remedial Action in accordance with Viridian's request, *provided that* [***].

Article 6 MANUFACTURING

- 6.1. Quality Agreement.** Prior to [***], the Parties will enter into a written agreement, approved by quality representatives of both Parties, that (a) defines and establishes the each Party's Manufacturing activities it will perform in accordance with this Agreement, (b) describes how each Party will comply with GMP and other Applicable Law, (c) and sets forth each Parties obligations with respect to the coordination of reporting, investigating, and exchanging information concerning Product Complaints to the extent not included in the PVA (the "**Quality Agreement**"). From time-to-time during the Term, the Parties may amend the then-current Quality Agreement upon written agreement of the Parties. Each Party will comply with its respective obligations under the Quality Agreement and to cause its Affiliates, licensees, Sublicensees, and Subcontractors to comply with such obligations. If there are any conflicts between this Agreement and the Quality Agreement, then the provisions of this Agreement will govern, except with respect to all matters related to GMP (e.g., manufacture, testing, release, storage and shipment of product, etc.), in which case, the Quality Agreement will take precedence.
- 6.2. Supply by Viridian.** Promptly after the Effective Date, the Parties will [***] enter into a supply agreement for the supply to Kissei of the Licensed Products for Development activities and a supply agreement for the supply to Kissei of Licensed Products for Commercialization activities pursuant to this Agreement (each such agreement, a "**Supply Agreement**"). The terms of the Supply Agreement and the Quality Agreement will be consistent with the terms of this Agreement and the terms of those supply agreements between Viridian and its Third Party CMOs, to the extent applicable to the supply of the Licensed Products in the Territory. Viridian will use Commercially Reasonable Efforts, in accordance with the Supply Agreement, to Manufacture, or have Manufactured, Licensed Products sufficient to meet Kissei's Development and Commercialization requirements of a Licensed Product in the Territory. Kissei will purchase from Viridian its requirements of the Licensed Products as necessary for Kissei to fulfill its obligations under this Agreement related to the Development and Commercialization of the Licensed Products in the Field in the Territory. Viridian will supply Licensed Product [***] to Kissei pursuant to this Section 6.2 (Supply by Viridian) at a transfer price equal to [***]. If Kissei's royalty obligations under Section 8.3 (Royalty Payments) [***] exceeds [***], then, upon Kissei's written request, the Parties will discuss the [***] of the Licensed Products. Viridian will invoice Kissei for the Licensed Products on the terms to be set forth in the applicable Supply Agreement, and Kissei will pay all undisputed invoiced amounts within [***] days after the date of the invoice. [***].
- 6.3. Supply by Kissei.** If (a) [***] (b) [***], then, in each case ((a) or (b)), Viridian will complete a technology transfer to Kissei of Viridian Manufacturing Know-How within Viridian's Control that is [***] to Manufacture or have Manufactured such Licensed Antibodies and Licensed

Products for use in the Territory in accordance with a technology transfer plan to be developed by Viridian and submitted to the JSC for its review, discussion, and approval (the initiation of such technology transfer, the “**Manufacturing Transfer Initiation**,” and such plan, the “**MTT Plan**”). Following completion of such technology transfer of such Viridian Manufacturing Know-How, Kissei will be responsible for Manufacturing Licensed Antibodies or Licensed Products for its own use in the Territory and all costs of Manufacturing will be at Kissei’s sole cost and expense.

- 6.4. Packaging and Labeling.** Kissei, in its capacity as manufacturer and MAA holder, will be responsible for the elaboration and filing of packaging artworks and mock-ups, and for the routine maintenance and production of Packaging and Labeling components for the Licensed Products for the Territory in or outside the Territory. Kissei must consult with Viridian during the development of the Approved Labeling for the Licensed Products in the Territory, and provide Viridian with the opportunity to review and provide comments on, all Licensed Product look and feel of Packaging and Labeling (including providing Viridian the right to review all mockups thereof prior to submission thereof to the Regulatory Authorities in the Territory). [***]. The Parties will discuss and agree in writing on the implementation of any label changes to the Approved Labeling based on then-current Licensed Product inventory labels prior to making any submission to any Regulatory Authority in the Territory regarding such label changes. Kissei will be solely responsible for all costs and expenses associated with Packaging and Labeling the Licensed Products received from Viridian as necessary to Commercialize the Licensed Products in the Territory, including any costs or expenses associated with any label changes or remanufacturing of any Licensed Product due to changes requested or required by any Regulatory Authority in the Territory. Kissei will provide to Viridian the most up-to-date version of prescribing information, labels, inserts, and other materials to be included in the Approved Labeling of such Licensed Product in the Territory in the form of image files for Viridian’s reference purposes (a) [***] prior to [***] and (b) [***]. Kissei will provide such prescribing information, labels, inserts, and other materials in their original language and, if not in English, translated versions of such prescribing information, labels, inserts, and other materials in English in accordance with Section 15.16 (Language; Translations).
- 6.5. Product Tracking in the Territory.** Kissei will, and will ensure that its Affiliates and Sublicensees, maintain adequate records to permit the Parties to trace the distribution, sale, and use of the Licensed Products in the Territory in accordance with the Quality Agreement. At Viridian’s reasonable request, Kissei will provide such records to Viridian, and, if such records are not in English, translated versions of such records in English in accordance with Section 15.16 (Language; Translations).
- 6.6. Audits of Packaging and Labeling and Manufacturing.**
- 6.6.1 Audits by Viridian.** If [***], then during normal business hours and upon reasonable written notice to Kissei, Kissei will, will cause its Affiliates and Sublicensees that are not Subcontractors to, and will use reasonable efforts to cause its Subcontractors (including Subcontractors that are granted a sublicense and to the extent permitted under any agreement between Kissei and such Subcontractor) to, provide Viridian with the opportunity to (a) audit all records of Kissei or its Affiliates, Subcontractors, and Sublicensees (as applicable) in connection with the Packaging and Labeling of Licensed Products or, following a [***], the Manufacturing of the Licensed Antibodies and Licensed Products by or on behalf of Kissei or its Affiliates (the “**Manufacturing Activities**”), and (b) visit the offices and laboratories of Kissei or its Affiliates, Subcontractors, and Sublicensees (as applicable) to discuss with such party the Manufacturing Activities for the sole purpose of conducting a technical audit with respect to the Manufacturing Activities, *provided* that [***]. Viridian will provide to Kissei in writing all material audit reports generated following the conduct of such audits that are in Viridian’s possession and Control and not prohibited by Applicable Law or any agreement with the applicable Third Party. In the event that the results of such audit reveal any deficiencies or other areas of remediation pursuant to GxP and Applicable Law with respect to Kissei’s (or its Affiliate’s, Subcontractor’s, or Sublicensee’s, as

applicable) Manufacturing Activities, then Viridian will notify Kissei in writing of the foregoing, and [***].

- 6.6.2 **Audits by Kissei.** During normal business hours and upon reasonable written notice to Viridian, Viridian will, will cause its Affiliates to, and will use reasonable efforts to cause its subcontractors (to the extent permitted under any agreement between Viridian and such subcontractor) to, provide Kissei with the opportunity to, to the extent permitted under the agreement between Viridian and the applicable Third Party (a) audit all records of Viridian or its Affiliates or Subcontractors (to the extent permitted pursuant to the applicable agreement between Viridian and such Subcontractor) (as applicable) that have been generated in connection with the Manufacturing of Licensed Products for use by Kissei in the Field in the Territory for the sole purpose of conducting a technical audit with respect to the manufacturing processes and procedures for the Licensed Product for use by Kissei in the Field in the Territory and (b) visit the offices and laboratories of Viridian or its Affiliates (as applicable) to discuss with such Third Party the Manufacturing Activities for the sole purpose of conducting a technical audit with respect to the Manufacturing Activities, [***]. Kissei will provide Viridian in writing all audit reports generated. In the event that the results of such audit reveal any deficiencies or other areas of remediation pursuant to GxP and Applicable Law with respect to Viridian's Manufacturing Activities for Licensed Product to be used for Clinical Development or Commercialization in the Territory, then Kissei will notify Viridian in writing of the foregoing, [***].

- 6.7. **Supply Following [***]. [***].**

Article 7 COMMERCIALIZATION

- 7.1. **Commercialization Diligence and Responsibilities.** Kissei will be responsible, and will use Commercially Reasonable Efforts, to obtain Reimbursement Approvals for and Commercialize the Licensed Products in each Territory Development Indication for which Regulatory Approval is granted in the Field in the Territory. Kissei will conduct Commercialization of the Licensed Products in the Territory solely in accordance with the Territory Commercialization Plan for the Licensed Products, at its sole cost and expense, and subject to the terms of this Agreement. Upon Kissei's reasonable request, Viridian will reasonably assist Kissei in such Commercialization of the Licensed Products to the extent in accordance with the Viridian Support Plan. [***].
- 7.2. **Territory Commercialization Plan.** No later than [***] months prior to the anticipated date of approval of the first filing of the first MAA for the first Licensed Product in the first Territory Development Indication in the Territory, Kissei will develop an initial draft of the Territory Commercialization Plan for the Licensed Products and provide such initial draft to Viridian at the JSC to review, discuss, and determine whether to approve. The JSC will consider and reasonably incorporate Viridian's comments on the Territory Commercialization Plan; *provided that*, [***]. The Territory Commercialization Plan for the Licensed Products will contain in reasonable detail, the major Commercialization activities to be undertaken ([***]) for the Licensed Products in the Field in the Territory and the estimated timelines for achieving such activities, including (a) [***], (b) [***], (c) [***], (d) [***], (e) [***], (f) [***], (g) [***] and (h) [***]. Thereafter, from time to time, but at least on an [***], the JSC will propose, discuss, and determine whether to approve updates to the Territory Commercialization Plan for the Licensed Products to reflect changes in such plans, [***]. The Territory Commercialization Plan (including each update thereto) must be consistent with Viridian's global brand strategy and global key messaging for the Licensed Products (the "**Global Brand Strategy**"), as provided to Kissei by Viridian from time to time during the Term.
- 7.3. **Commercialization Reports.** At each meeting of the JSC or, if the JSC is disbanded in accordance with Section 3.7 (Discontinuation of Committees), no later than the end of each Calendar Quarter for the first [***] months following the first Regulatory Approval and the end of each Calendar Year thereafter during the Term, Kissei will provide to Viridian a written report

that summarizes the Commercialization activities performed by or on behalf of Kissei and its Affiliates and Sublicensees in the Field in the Territory for the Licensed Products in the Territory since the prior report provided by Kissei. Each such report will contain sufficient detail to enable Viridian to assess Kissei's compliance with its Commercialization diligence obligations set forth in Section 7.1 (Commercialization Diligence and Responsibilities). Such reports will be Confidential Information of Kissei and subject to the terms of Article 9 (Confidentiality; Publication). Kissei will, or will cause its Affiliates or Sublicensees to, provide updates to any such report at each meeting of the JSC.

- 7.4. Coordination of Commercialization Activities.** The Parties recognize that each Party may benefit from the coordination of certain Commercialization activities for the Licensed Products in the Territory by Kissei in accordance with Section 7.2 (Territory Commercialization Plan) and outside of the Territory by Viridian (other than pricing for the Licensed Products inside and outside of the Territory, the responsibilities for which are set forth in Section 7.5 (Pricing; Reimbursement Approvals)). Accordingly, the Parties will coordinate such activities through the JSC where appropriate, [***]. Without limiting the preceding sentence, upon either Party's reasonable request and to the extent permitted under any agreement between the other Party and any Third Party, the other Party will provide to such Party any written sales, promotion, and advertising materials relating to the Licensed Products, and other printed, graphic, electronic, audio, video, or other media and materials used to promote the Licensed Products ("**Promotional Materials**"), in each case, developed by or on behalf of such other Party and relevant to the Commercialization of one or more Licensed Products in the Field. Kissei will ensure that all Promotional Materials developed by or on behalf of Kissei (a) comply with Applicable Law and the terms of all applicable Regulatory Approvals in the Territory and (b) do not conflict with the Global Brand Strategy or Promotional Materials developed by or on behalf of Viridian.
- 7.5. Pricing; Reimbursement Approvals.** Each Party will have the right to determine the price of each Licensed Product sold in its respective field and territory and neither Party will have the right to direct, control, or approve the pricing of a Licensed Product in the other Party's field or territory. Kissei will keep Viridian reasonably informed on the status of any application for Reimbursement Approval for each Licensed Product in the Field in the Territory, including any discussion with any Regulatory Authority with respect thereto.
- 7.6. Diversion.** Each Party agrees that it will not, and will ensure that its Affiliates and Sublicensees and Subcontractors will not, either directly or indirectly, promote, market, distribute, import, sell, or have sold the Licensed Products to any Third Party or to any address or Internet Protocol address or the like in the other Party's field or territory, including via the Internet (for which protections may include access by only Japan-specific health care providers or standard entry disclaimers) or mail order. Notwithstanding any provision to the contrary set forth in this Agreement, each Party will have the right to attend conferences and meetings of congresses in the other Party's field and territory and to promote and market the Licensed Products to Third Party attendees at such conferences and meetings, subject to this Section 7.6 (Diversion) and in accordance with the Global Brand Strategy. Neither Party will engage, nor permit its Affiliates or Sublicensees to engage, in any advertising or promotional activities relating to the Licensed Products for use directed primarily to customers or other buyers or users of the Licensed Products located in any country or jurisdiction in the other Party's territory, or solicit orders from any prospective purchaser located in any country or jurisdiction in the other Party's territory. If a Party or its Affiliates or Sublicensees receive any order for the Licensed Products from a prospective purchaser located in a country or jurisdiction in the other Party's territory, then such Party will immediately refer that order to such other Party and will not accept any such orders. Neither Party will, nor will either Party permit its Affiliates or Sublicensees to, deliver or tender (or cause to be delivered or tendered) the Licensed Products to Third Parties for use in the other Party's territory except in accordance with a Territory Development Plan.

**Article 8
PAYMENTS**

8.1. Upfront Payment. In partial consideration for the rights granted hereunder, Kissei will pay to Viridian a non-refundable, non-creditable upfront payment of \$70,000,000 in U.S. Dollars (the “Upfront Payment”), [***].

8.2. Milestone Payments.

8.2.1 Development Milestone Events and Payments. Subject to Section 8.2.4 (Notification of and Invoice for Milestone Events), no later than [***] days after the earliest achievement of each development milestone event set forth below for each of the first Licensed Product containing veligrotug and the first Licensed Product containing VRDN-003, Kissei will pay to Viridian the corresponding development milestone payments, as set forth below (the development milestone events set forth in Table 8.2.1, the “Development Milestone Events,” and the development milestone payments set forth in Table 8.2.1, the “Development Milestone Payments”). Each Development Milestone Payment for the corresponding Development Milestone Event will be payable only once upon the first achievement of such Development Milestone Event, and no Development Milestone Payment will be payable for subsequent or repeated achievements of the same corresponding Development Milestone Event.

| Table 8.2.1 – Development Milestones | | | |
|---|-------|---|---|
| <i>Development Milestone Events</i> | | <i>Development Milestone Payment (in U.S. Dollars)</i> | |
| | | <i>Licensed Product containing the Licensed Antibody veligrotug</i> | <i>Licensed Product containing the Licensed Antibody VRDN-003</i> |
| 1. | [***] | [***] | [***] |
| 2. | [***] | [***] | [***] |
| Subtotal | | [***] | [***] |

8.2.2 Regulatory Milestone Events and Payments. Subject to Section 8.2.4 (Notification of and Invoice for Milestone Events), no later than [***] days after the earliest achievement of each regulatory milestone event set forth below for each of the first Licensed Product containing veligrotug and the first Licensed Product containing VRDN-003, Kissei will pay to Viridian the corresponding regulatory milestone payment, as set forth below (the regulatory milestone events set forth in Table 8.2.2, the “Regulatory Milestone Events,” and the regulatory milestone payments set forth in Table 8.2.2, the “Regulatory Milestone Payments”). Each Regulatory Milestone Payment for the corresponding Regulatory Milestone Event will be payable only once upon the first achievement of such Regulatory Milestone Event, and no Regulatory Milestone Payment will be payable for subsequent or repeated achievements of the same corresponding Regulatory Milestone Event.

| Table 8.2.2 – Regulatory Milestones | | | |
|--|-------|---|---|
| <i>Regulatory Milestone Events</i> | | <i>Regulatory Milestone Payment (in U.S. Dollars)</i> | |
| | | <i>Licensed Product containing the Licensed Antibody veligrotug</i> | <i>Licensed Product containing the Licensed Antibody VRDN-003</i> |
| 1. | [***] | [***] | [***] |

| | | | |
|-----------------|-------|-------|-------|
| 2. | [***] | [***] | [***] |
| 3. | [***] | [***] | [***] |
| Subtotal | | [***] | [***] |

The Milestone Payment corresponding with (a) [***] and (b) [***] is intended to be successive with [***] set forth in this Section 8.2.2 (Regulatory Milestone Events and Payments). [***].

8.2.3 **Sales Milestone Events and Payments.** Subject to Section 8.2.4 (Notification of and Invoice for Milestone Events), no later than [***], in which each sales milestone event set forth below is achieved for the applicable Licensed Product(s) in the Territory, Kissei will pay to Viridian the corresponding sales milestone payment, as set forth below (the sales milestone events set forth in Table 8.2.3 the “**Sales Milestone Events**” and the sales milestone payments set forth in Table 8.2.3, the “**Sales Milestone Payments**”). Each Sales Milestone Payment for the corresponding Sales Milestone Event will be payable only once upon the first achievement of such Sales Milestone Event, and no Sales Milestone Payment will be payable for subsequent or repeated achievements of the same corresponding Sales Milestone Event. If in a given [***], during the Term more than one of the Sales Milestone Events set forth in Table 8.2.3 is achieved, then Kissei will pay to Viridian a separate Sales Milestone Payment with respect to each such Sales Milestone Event that is achieved for the first time in such [***].

| Table 8.2.3 – Sales Milestones | | | |
|---------------------------------------|-------|--|--|
| <i>Sales Milestone Events</i> | | | <i>Sales Milestone Payment (in U.S. Dollars)</i> |
| 1. | [***] | | [***] |
| 2. | [***] | | [***] |
| 3. | [***] | | [***] |
| 4. | [***] | | [***] |
| 5. | [***] | | [***] |
| 6. | [***] | | [***] |
| 7. | [***] | | [***] |
| 8. | [***] | | [***] |
| 9. | [***] | | [***] |
| Subtotal | | | [***] |

[***].

8.2.4 **Notification of and Invoice for Milestone Events.** Kissei will promptly notify Viridian in writing, but in no event later than (a) [***] and (b) [***], in which each Sales Milestone Event is achieved (together with the Development Milestone Events and the Regulatory Milestone Events, the “**Milestone Events**”). Upon receipt of such written notice, Viridian will issue an invoice to Kissei for the corresponding Milestone Payments within [***] Business Days after receiving such notice from Kissei. However, in no event will a failure by Kissei to deliver such notice of achievement of a Milestone Event relieve Kissei of its obligation to pay Viridian the corresponding Development Milestone Payment, Regulatory Milestone Payment, or Sales Milestone Payment (collectively, the “**Milestone Payments**”).

8.3. Royalty Payments.

8.3.1 **Royalty Rates.** Subject to the remainder of this Section 8.3 (Royalty Payments), Kissei will make royalty payments to Viridian for all Licensed Products sold in the Territory, calculated by multiplying the applicable royalty rate set forth below in Table 8.3.1 by the aggregate amount of Net Sales of all Licensed Products sold in the Territory in the applicable Calendar Quarter. The royalty payments due with respect to Net Sales of the Licensed Products pursuant to this Section 8.3 (Royalty Payments), collectively the “**Royalty Payments.**”

| Table 8.3.1 – Licensed Product Royalty Payments | |
|---|---------------------|
| <i>Portion of Aggregate Calendar Year Net Sales of the Licensed Products in the Territory (in U.S. Dollars)</i> | <i>Royalty Rate</i> |
| Up to and including \$[***] | [***] |
| Greater than \$[***] and up to and including \$[***] | [***] |
| Greater than \$[***] and up to and including \$[***] | [***] |
| Greater than \$[***] and up to and including \$[***] | [***] |
| Greater than \$[***] | [***] |

For example, [***].

8.3.2 **Royalty Term.** On a Licensed Product-by-Licensed Product basis, Kissei will pay to Viridian the Royalty Payments on the Licensed Products until the latest of: (a) the expiration of the last Valid Claim within the Royalty Patent Rights that Covers such Licensed Product or the Manufacture or use thereof in the Territory; (b) the [***] anniversary of the date of the First Commercial Sale of such Licensed Product in the Territory; and (c) the expiration of all Regulatory Exclusivity for such Licensed Product in the Territory (“**Royalty Term**”). On a Licensed Product-by-Licensed Product basis, upon expiration of the Royalty Term for such Licensed Product and satisfaction of all other payment obligations related to such Licensed Product ([***]), the license granted to Kissei under Section 2.1 (License Grant to Kissei) will become fully paid-up ([***]), perpetual, and exclusive, so long as at such time Kissei has paid to Viridian all amounts due under this Agreement with respect to such Licensed Product that accrued prior to the expiration of such Royalty Term in accordance with the terms hereof and is not at such time in breach of any obligation under this Agreement.

8.3.3 **Royalty Reductions.**

- (a) **Biosimilar Products.** With respect to a Licensed Product, if during any Calendar Quarter, (i) one or more Biosimilars with respect to such Licensed Product are launched in the Territory and (ii) the Net Sales of such Licensed Product in the Territory [***] relative to [***], then, the Net Sales of the Licensed Product used to calculate Royalty Payments under Section 8.3.1 (Royalty Rates) will be [***].
- (b) **Third Party Patent Rights.** Subject to Section 8.3.3(c) (Cumulative Reductions Floor), during any Calendar Quarter, Kissei may credit against the Royalty Payments payable to Viridian pursuant to Section 8.3 (Royalty Payments) with respect to the Licensed Product in the Territory in such Calendar Quarter up to [***] for which Kissei is responsible (i) under any Third Party IP Agreement pursuant to Section 2.5.5 (Responsibility for Costs), or (ii) under any agreement with a Third Party entered into by Kissei pursuant to Section 2.5.3 (Kissei Identified Rights) after the Effective Date.

- (c) **Cumulative Reductions Floor.** In no event will the aggregate amount of Royalty Payments due to Viridian for the Licensed Product in the Territory in any given Calendar Quarter during the Royalty Term be [***] of the amount that otherwise would have been due and payable to Viridian in such Calendar Quarter for the Licensed Product in the Territory but for the reductions set forth in Section 8.3.3(a) (Biosimilar Products) and Section 8.3.3(b) (Third Party Patent Rights).
- 8.3.4 **Royalty Reports and Payments.** Commencing with the Calendar Quarter during which the First Commercial Sale of the first Licensed Product is made anywhere in the Territory, Kissei will provide Viridian with (a) within [***] Business Days after the end of a Calendar Quarter, a good faith, non-binding estimate of the royalties due for such Calendar Quarter and (b) within [***] days after the end of each Calendar Quarter, a detailed royalty report showing the following information for the applicable Calendar Quarter (each, a “**Royalty Report**”): (i) the amount of gross sales and Net Sales of the Licensed Products sold by Kissei and its Affiliates and Sublicensees in the Territory and all deductions used to determine such Net Sales of the Licensed Products for such Calendar Quarter, (ii) a calculation of the Royalty Payment due on such Net Sales of the Licensed Products in the Territory, including any royalty reduction made in accordance with Section 8.3.3(b) (Third Party Patent Rights), (iii) the exchange rate used for converting any Net Sales recorded in a currency other than Dollars, (iv) any withholding taxes required to be made from such Royalty Payments, and (v) the quantity and description of the Licensed Products sold by Kissei or its Affiliate or Sublicensee in the Territory during such Calendar Quarter comprising such Net Sales, including detailed sales reports for the Licensed Products for each month of the Calendar Quarter in the Territory. Concurrently with the delivery of the applicable Royalty Report, but in any event within [***] days after each Calendar Quarter, Kissei will pay such amount of the Royalty Payments set forth in the applicable Royalty Report to Viridian in Dollars. If Viridian identifies any questions or issues related to a Royalty Report, then Viridian may notify Kissei within [***] Business Days following receipt by Viridian of each Royalty Report, and the Parties will seek to resolve such questions or issues within [***] Business Days following such notice by Viridian.
- 8.3.5 [***] **Royalty.** On a Licensed Product-by-Licensed Product basis, upon expiration of the Royalty Term for such Licensed Product and continuing for so long as such Licensed Product is Commercialized in the Territory by or on behalf of Kissei, to the extent that Viridian owes a royalty payment under the [***] (such royalty, the “[***] **Royalty**”). Viridian will provide Kissei with supporting documentation [***]. Kissei will pay the [***] Royalty in accordance with Section 8.3.4 (Royalty Reports and Payments) and Section 8.8 (Currency; Exchange Rate) through Section 8.12 (Taxes), inclusive. [***].
- 8.4. **Payments to Third Parties.** Subject to Section 2.5 (Third Party In-Licenses) and Section 8.3.3(b) (Third Party Patent Rights), each Party will be solely responsible for any payments due to Third Parties under any agreement entered into by such Party prior to or after the Effective Date.
- 8.5. **Other Amounts Payable.** With respect to any amounts owed under this Agreement by one Party to the other for which no other invoicing and payment procedure is specified hereunder, within [***] days after the end of each Calendar Quarter, each Party will provide an invoice, together with reasonable supporting documentation, to the other Party for such amounts owed in respect of such Calendar Quarter. The owing Party will pay any undisputed amounts within [***] days after the receipt of the invoice, and any disputed amounts owed by a Party will be paid within [***] days after resolution of the dispute.
- 8.6. **No Refunds.** Except as expressly provided herein, all payments under this Agreement will be irrevocable, non-refundable, and non-creditable.

- 8.7. Accounting Standards.** If a Party changes its general accounting principles from the then-current standard (e.g., from GAAP to IFRS) at any time during the Term, then at least 30 days prior to adopting such change in principles, such Party will provide written notice to the other Party of such change.
- 8.8. Currency; Exchange Rate.** All payments to be made by Kissei to Viridian or Viridian to Kissei under this Agreement will be made in Dollars by electronic funds transfer in immediately available funds to a bank account designated in writing by Viridian or Kissei, as applicable. Conversion of Net Sales recorded in local currencies will be converted to Dollars at the average exchange rate over all days in the Calendar Quarter in which the applicable payment obligation became due and payable as set forth in The Wall Street Journal or any successor thereto.
- 8.9. Blocked Payments.** If by reason of Applicable Law in the Territory, it becomes impossible or illegal for a Party to transfer, or have transferred on its behalf, payments owed the other Party hereunder, then such Party will promptly notify the other Party of the conditions preventing such transfer and such payments will be deposited in local currency in the Territory to the credit of the other Party in a recognized banking institution designated by the other Party or, if none is designated by the other Party within a period of [***] days, in a recognized banking institution selected by the transferring Party, as the case may be, and identified in a written notice given to the other Party.
- 8.10. Late Payments.** Any payments or portions thereof due hereunder that are not paid on the date such payments are due under this Agreement will bear interest at a rate equal to the lesser of: (a) [***]; or (b) the maximum rate permitted by Applicable Law; in each case, calculated on the number of days such payment is delinquent, [***].
- 8.11. Financial Records and Audits.** Kissei will maintain complete and accurate records in sufficient detail to permit Viridian to confirm the accuracy of the amount of Royalty Payments and other amounts payable under this Agreement. Upon reasonable prior notice, such records will be open during regular business hours for a period of [***] years from the creation of individual records for examination by an independent certified public accountant selected by Viridian and reasonably acceptable to Kissei for the sole purpose of verifying for Kissei the accuracy of the financial reports furnished by Kissei pursuant to this Agreement or of any payments made, or required to be made, by Kissei pursuant to this Agreement; *provided* that such independent accounting firm is subject to written obligations of confidentiality and non-use applicable to Kissei's Confidential Information that are at least as stringent as those set forth in Article 9 (Confidentiality; Publication). Such audit will not be (a) performed more frequently than [***] during the Term or once during the [***] year period after the expiration or termination of this Agreement, (b) conducted for any Calendar Year more than [***] years after the end of such year, or (c) repeated for any Calendar Year or with respect to the same set of records (unless a material discrepancy with respect to such records is discovered during a prior audit). Such auditor will not disclose Kissei's Confidential Information to Viridian or to any Third Party, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by Kissei or the amount of payments by Kissei under this Agreement. Kissei will pay any amounts shown to be owed to Viridian but unpaid within [***] days following receipt of the accountant's report plus interest in accordance with Section 8.10 (Late Payments) from the original due date. Viridian will pay any overpaid amounts by Kissei to Viridian within [***] days following receipt of the accountant's report plus interest in accordance with Section 8.10 (Late Payments) from the date that Kissei made such overpayment. Viridian will bear the full cost of such audit unless such audit reveals an underpayment by Kissei of more than [***]% of the amount actually due for the time period being audited, in which case Kissei will reimburse Viridian for the reasonable audit fees for such examination.
- 8.12. Taxes.**
- 8.12.1 Taxes on Income; Payments Free of Taxes.** Except as set forth in this Section 8.12 (Taxes), each Party will be solely responsible for the payment of any and all income Taxes levied on account of all payments it receives under this Agreement. Any and all

payments due to Viridian from Kissei pursuant to this Agreement will be paid without deduction or withholding for any Taxes, except as required by Applicable Law. Subject to the provisions of this Section 8.12 (Taxes), Kissei shall deduct and withhold from its payments any Taxes that it is required by Applicable Law to deduct or withhold. Notwithstanding the foregoing, Viridian and Kissei will exercise best efforts to obtain the lowest withholding tax rate available under the applicable Tax treaty, such that Viridian may deliver to Kissei or the appropriate Governmental Authority the prescribed forms necessary to reduce the applicable rate of withholding or to relieve Kissei of its obligation to withhold Tax as provided in Section 8.12.2 (Tax Cooperation). In the case where Viridian delivers all of the necessary documents and forms to Kissei and a reduced rate of withholding is available, Kissei will apply the lowest rate of withholding available. If, in accordance with the foregoing, Kissei withholds any amount, then it shall pay to Viridian the balance when due, make timely payment to the proper taxing authority of the withheld amount, and send Viridian proof of such payment as provided in Section 8.12.2 (Tax Cooperation).

- 8.12.2 **Tax Cooperation.** The Parties agree to cooperate with one another in accordance with Applicable Law and use best efforts to minimize Tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by each Party to the other Party under this Agreement. This will include obtaining the 0% rate of withholding under Article 12 of the US-Japan Income Tax Treaty. To the extent either Party (the “**Paying Party**”) is required to deduct and withhold Taxes on any payment to the other Party (the “**Recipient**”), the Paying Party will (a) pay the full amount of such Taxes to the proper Governmental Authority in a timely manner, and (b) promptly transmit to the Recipient an official tax certificate or other evidence of such payment sufficient to enable the Recipient to claim such payment of Taxes on the Recipient’s applicable tax returns. The Paying Party will provide the Recipient with advance notice prior to withholding any Taxes from payments payable to the Recipient and will provide the Recipient with a commercially reasonable period of time to claim an exemption or reduction in otherwise applicable Taxes. In the case where the Paying Party has an obligation to withhold, the Paying Party and Recipient will collaborate to apply the lowest withholding tax rate available through timely providing any tax forms that may grant a lower withholding tax rate or may eliminate any obligation to withhold. The Recipient will use reasonable efforts to provide any such tax forms to the Paying Party in advance of the due date. Each Party will provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Law, of withholding Taxes or similar obligations resulting from payments made under this Agreement. Recovery of any withheld tax amounts will be for the benefit of the Recipient, such that if a refund is transmitted to the Paying Party as the withholding agent that originally withheld and submitted those taxes to the relevant tax authorities on behalf of the Recipient, the Paying Party will transfer that amount to the Recipient in accordance with this Section 8.12 (Taxes). In addition, the Parties will cooperate in accordance with Applicable Law to minimize indirect Taxes (such as VAT, sales tax, consumption tax, and other similar Taxes) in connection with this Agreement. This Section 8.12.2 (Tax Cooperation) will be subject to the last sentence of Section 8.12.1 (Taxes on Income; Payments Free of Taxes).
- 8.12.3 **VAT and Other Indirect Taxes.** All payments or amounts due under this Agreement, whether monetary or non-monetary are exclusive of VAT, consumption Tax and their equivalents. Any Party receiving a supply under this agreement, hereby covenants that it will pay any such VAT correctly charged in addition to any amounts due under this agreement. Where the prevailing legislation requires a VAT reverse charge, then the receiving party covenants that it shall correctly account for VAT in respect of the services received. The supplying Party agrees that it will raise a tax invoice (or equivalent document) to support the charge to VAT. Any supply of goods under this agreement shall be taxed (where applicable) in accordance with the prevailing VAT legislation.
- 8.12.4 **Withholding Tax Actions.** Notwithstanding any provision to the contrary in this Agreement, the Parties acknowledge and agree that if Kissei is required by Applicable

Law to withhold Taxes in respect of any payments made by Kissei to Viridian pursuant to this Agreement, and if to the extent such withholding obligation arises or is increased solely as a result any action by Kissei or its assignee, Affiliate, successor or purchaser after the Effective Date, including (a) any assignment (as permitted pursuant to Section 15.1 (Assignment)), transfer or other disposition of some or all of its rights and obligations to any Person as permitted under this Agreement, (b) any change in tax residence or domicile or (c) exercise of its rights or discharge of its obligations under this Agreement through an Affiliate, then, in each case ((a) through (c)), any amount payable to Viridian under this Agreement will be increased or decreased to take into account such withheld Taxes as may be necessary so that, after making all required withholdings (including withholdings on the withheld amounts), Viridian receives an amount equal to the sum it would have received had no such withholding been made.

- 8.12.5 **Transaction Based Taxes.** All transfer, documentary, sales, use, stamp, registration, and other such taxes, and any conveyance fees, recording charges, and other fees and charges (including any penalties and interest) incurred in connection with consummation of the transactions contemplated hereby, if any, will be borne and paid by the Paying Party. The Parties will reasonably cooperate in accordance with Applicable Law to minimize transfer taxes in connection with this Agreement.

Article 9 CONFIDENTIALITY; PUBLICATION

9.1. Duty of Confidence. Subject to the other provisions of this Article 9 (Confidentiality; Publication):

- 9.1.1 except to the extent expressly authorized by this Agreement, all Confidential Information of a Party (the “**Disclosing Party**”) will be maintained in confidence and otherwise safeguarded, and not published or otherwise disclosed, by the other Party (the “**Receiving Party**”) and its Affiliates for the Term and thereafter until [***].
- 9.1.2 the Receiving Party will treat all Confidential Information provided by the Disclosing Party with the same degree of care as the Receiving Party uses for its own similar information, but in no event less than a reasonable degree of care;
- 9.1.3 the Receiving Party may only use any Confidential Information of the Disclosing Party for the purposes of performing its obligations or exercising its rights under this Agreement;
- 9.1.4 a Receiving Party may disclose Confidential Information of the Disclosing Party to: (a) such Receiving Party’s Affiliates, licensees and Sublicensees; and (b) employees, directors, officers, agents, contractors, consultants, attorneys, accountants, banks, investors, and advisors of the Receiving Party and its Affiliates, licensees, and Sublicensees, in each case ((a) and (b)), to the extent reasonably necessary for the purposes of, and for those matters undertaken pursuant to, this Agreement; *provided* that such Persons are bound by legally enforceable, written obligations of confidentiality and non-use with respect to the Disclosing Party’s Confidential Information no less stringent than the confidentiality and non-use obligations set forth in this Agreement. Each Party will remain responsible for any failure by its Affiliates, licensees, and Sublicensees, and its and its Affiliates’, licensees’, and Sublicensees’ respective employees, directors, officers, agents, contractors, consultants, attorneys, accountants, banks, investors, and advisors, in each case, to treat such Confidential Information as required under this Section 9.1 (Duty of Confidence) (as if such Affiliates, licensees, Sublicensees, employees, directors, officers, agents, contractors, consultants, attorneys, accountants, banks, investors, and advisors were Parties directly bound to the requirements of this Section 9.1 (Duty of Confidence)); and

9.1.5 each Party will promptly notify the other Party of any misuse or unauthorized disclosure of the other Party's Confidential Information.

9.2. Confidential Information. The Viridian Know-How and all [***] Know-How will be the Confidential Information of Viridian notwithstanding the fact that such information may be developed or invented and disclosed to Viridian by Kissei. The Kissei Know-How will be the Confidential Information of Kissei. The terms of this Agreement and all Joint Collaboration Know-How will be the Confidential Information of both Parties. Except as provided in Section 9.4 (Authorized Disclosures) and Section 9.7 (Publicity; Use of Names), neither Party nor its Affiliates may disclose the existence or the terms of this Agreement.

9.3. Exemptions. Information of a Disclosing Party will not be Confidential Information of such Disclosing Party to the extent that the Receiving Party can demonstrate through competent evidence that such information:

9.3.1 is known by the Receiving Party or any of its Affiliates without an obligation of confidentiality at the time of its receipt from the Disclosing Party, and not through a prior disclosure by or on behalf of the Disclosing Party, as documented by the Receiving Party's business records;

9.3.2 is available to the public before its receipt from the Disclosing Party;

9.3.3 became available to the public or otherwise part of the public domain after its disclosure by the Disclosing Party and other than through any act or omission of the Receiving Party or any of its Affiliates or disclosees in breach of this Agreement;

9.3.4 is subsequently disclosed to the Receiving Party or any of its Affiliates without obligation of confidentiality by a Third Party who may rightfully do so and is not under a conflicting obligation of confidentiality to the Disclosing Party; or

9.3.5 is developed by the Receiving Party or any of its Affiliates independently and without use of or reference to any Confidential Information received from the Disclosing Party, as documented by the Receiving Party's business records.

No combination of features or disclosures will be deemed to fall within the foregoing exclusions merely because individual features are published or available to the public or in the rightful possession of the Receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the Receiving Party.

9.4. Authorized Disclosures.

9.4.1 **Permitted Circumstances.** Notwithstanding the obligations set forth in Section 9.1 (Duty of Confidence) and Section 9.6 (Publication and Listing of Clinical Trials), a Party may disclose the other Party's Confidential Information (including this Agreement and only the specifically relevant terms herein) to the extent such disclosure is reasonably necessary in the following situations:

- (a) in connection with regulatory filings and other filings with Governmental Authorities (including Regulatory Authorities), as necessary for the Exploitation of the Licensed Products in accordance with this Agreement;
- (b) disclosure of this Agreement, its terms, and the status and results of Exploitation of the Licensed Products to actual or *bona fide* potential investors, acquirors, (sub)licensees, lenders, and other financial or commercial partners (including in connection with any royalty monetization transaction), and their respective attorneys, accountants, banks, investors, and advisors, solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition,

(sub)license, debt transaction, or collaboration; *provided* that, in each such case, on the condition that such Persons are bound by obligations of confidentiality and non-use at least as stringent as those set forth Article 9 (Confidentiality; Publication) or otherwise customary for such type and scope of disclosure any such disclosure is limited to the maximum extent practicable for the particular context in which it is being disclosed;

- (c) Viridian may share Confidential Information of Kissei with each Third Party to a Third Party IP Agreement between Viridian and such Third Party solely to the extent Viridian is required to provide such information to such Third Party;
- (d) if required by Applicable Law, including as may be required in connection with any filings made with, or by the disclosure policies of a major stock exchange (in which case the terms of such disclosures will be governed by Section 9.4.2 (Confidential Treatment)); *provided* that the Party seeking to disclose the Confidential Information of the other Party (other than as required by the disclosure policies of a major stock exchange): (i) use reasonable efforts to inform the other Party prior to making any such disclosures and reasonably cooperate with the other Party in seeking a protective order or other appropriate remedy (including redaction), and (ii) whenever possible, request confidential treatment of such information in accordance with Section 9.4.2 (Confidential Treatment); or
- (e) disclosure pursuant to Section 9.6 (Publication and Listing of Clinical Trials) and Section 9.7 (Publicity; Use of Name).

9.4.2 **Confidential Treatment.** Each Party acknowledges that the other Party may be legally required to make public disclosures (including in filings with the Securities and Exchange Commission or other agency) of certain material developments or material information generated under this Agreement and agrees that each Party may make such disclosures as required by Applicable Laws, *provided* that the Party seeking such disclosure first provides the other Party a copy of the proposed disclosure, and *provided, further*, that (except to the extent that the Party seeking disclosure is required to disclose such information to comply with Applicable Laws) if the other Party demonstrates to the reasonable satisfaction of the Party seeking disclosure, within [***] after such Party provides the copy, that the public disclosure of previously undisclosed information will materially adversely affect the development or commercialization of a Licensed Product being Developed or Commercialized, then the Party seeking disclosure will remove from the disclosure such specific previously undisclosed information as the other Party will reasonably request to be removed.

9.5. Publications.

9.5.1 **Kissei's Publication of Clinical Trial Data.** Kissei will not publicly present or publish (a "**Publication**") any Clinical Trial data from a Global Clinical Trial, any non-clinical or preclinical data related to the Licensed Product, or any associated results or conclusions generated by or on behalf of Kissei pursuant to this Agreement (each such proposed presentation or publication, a "**General Publication**") without Viridian's prior written consent, not to be unreasonably withheld, conditioned, or delayed, and subject to the additional limitations set forth in this Section 9.5 (Publications) and Section 9.6 (Publication and Listing of Clinical Trials). If Kissei desires to publicly present or publish a first General Publication in accordance with the foregoing sentence or a first Publication of any data from a Territory-Specific Clinical Trial, then Kissei will provide Viridian (through JSC, the Alliance Manager, or their designee) with a copy of such proposed Publication in English and Viridian will determine whether to approve such proposed Publication within [***] days following receipt of proposed Publication (such applicable period, the "**Review Period**"). Kissei will not submit or present any Publication until Viridian has approved such Publication or provided written comments

thereon, in each case, during the Review Period. Notwithstanding any provision to the contrary set forth in this Agreement, Kissei has the right to submit or present any Publication on the earlier of (a) Viridian's approval of such Publication or (b) expiration of the applicable Review Period. If Kissei receives written comments from Viridian on any Publication during the applicable Review Period, then it will incorporate such comments where appropriate. Notwithstanding any provision to the contrary set forth in this Agreement, Kissei will (i) delete any Confidential Information of Viridian that Viridian identifies for deletion in Viridian's written comments, (ii) delete any Clinical Trial data, results, conclusions, or other related information for the Licensed Products, the publication of which Viridian determines, in its sole discretion, could conflict with Viridian's global publication strategy with respect to the Licensed Products, and (iii) delay such Publication for a period of up to an additional [***] days after the end of the applicable Review Period to enable Viridian to draft and file one or more patent applications with respect to any subject matter to be made public in such Publication. Kissei will provide Viridian with a final copy of the Publication at the time of the submission or presentation thereof. Kissei agrees to acknowledge the contributions of Viridian and the employees of Viridian, in each case, in all Publications as scientifically appropriate. In addition, Viridian agrees to acknowledge the contributions of Kissei and the employees of Kissei, in each case, in all presentations and publications as scientifically appropriate to the extent related to any Global Clinical Trials in which Kissei assists in the enrollment of patients from the Territory. Kissei will require its Affiliates and Sublicensees to comply with the obligations of this Section 9.5 (Publications) as if they were Kissei, and Kissei will be liable for any non-compliance of such Persons. Once a first General Publication has been approved by Viridian, Kissei may make subsequent public disclosure of the contents of such General Publication without the further approval of Viridian; *provided* that such information remains accurate as of such time and is not presented with any new data, information, or conclusions or in a form or manner that materially alters the subject matter therein.

9.5.2 **Viridian's Publication Rights.** [***]. If Kissei is a co-author of a planned publication or Viridian desires to publicly present or publish any clinical data from a Territory-Specific Clinical Trial or other Confidential Information of Kissei, then Viridian will provide Kissei (through JSC, the Alliance Manager, or their designee) with a copy of such proposed publication, and Kissei will determine whether to approve such proposed publication within 30 days following receipt of proposed publication. Viridian may submit or present any publication after such 30-day review period, or earlier if Kissei has approved such publication. If Viridian receives written comments from Kissei on any publication during such 30-day review period, [***]. Notwithstanding any provision to the contrary set forth in this Agreement, Viridian will delete any Confidential Information of Kissei that Kissei identifies for deletion in Kissei's written comments. Viridian will provide Kissei with a final copy of the publication at the time of the submission or presentation thereof. Once a publication containing Confidential Information of Kissei or clinical data from a Territory-Specific Clinical Trial has been approved by Kissei, Viridian may make subsequent public disclosure of the contents of such publication without the further approval of Kissei; *provided* that such information remains accurate as of such time and is not presented with any new data, information, or conclusions or in a form or manner that materially alters the subject matter therein.

9.6. **Publication and Listing of Clinical Trials.** With respect to the listing of Clinical Trials or the publication of Clinical Trial results for the Licensed Products and to the extent applicable to a Party's activities conducted under this Agreement, each Party will comply with any Applicable Law or other local requirements. The Parties agree that any such listings or publications made pursuant to this Section 9.6 (Publication and Listing of Clinical Trials) will be considered a Publication for purposes of this Agreement and will be subject to Section 9.5 (Publications).

9.7. Publicity; Use of Names.

- 9.7.1 **Press Release.** The Parties will each issue a press release announcing this Agreement, which press releases will be agreed by the Parties and to be issued by the Parties on such date and time as may be agreed by the Parties. Other than such press releases to be agreed by the Parties announcing this Agreement, and the public disclosures permitted by this Section 9.7 (Publicity; Use of Names), and Section 9.4 (Authorized Disclosures), the Parties agree that, except as otherwise permitted under Section 9.7.2 (Disclosures by Viridian), the portions of any other news release or other public announcement relating to this Agreement or the performance hereunder that would disclose information other than that already in the public domain will first be reviewed and approved by both Parties (with such approval not to be unreasonably withheld, conditioned, or delayed). However, the Parties agree that after (a) a disclosure pursuant to Section 9.7 (Publicity; Use of Names) or Section 9.4 (Authorized Disclosures) or (b) the issuance of a press release (including the initial press release) or other public announcement pursuant to this Section 9.7.1 (Press Release) that has been reviewed and approved by the other Party, the disclosing Party may make subsequent public disclosures reiterating such information without having to obtain the other Party's prior consent and approval so long as the information in such press release or other public announcement remains true, correct, and the most current information with respect to the subject matters set forth therein. Similarly, after a Publication has been made available to the public, each Party may post such Publication or a link to it on its corporate website (or any website managed by such Party in connection with a Clinical Trial for the Licensed Products, as appropriate) without the prior written consent of the other Party, so long as the information in such Publication remains true, correct, and the most current information with respect to the subject matters set forth therein.
- 9.7.2 **Disclosures by Viridian.** Viridian and its designees will not publicly disclose any information relating to any Territory-Specific Clinical Trial, including the commencement, completion, material data, or key results of such Territory-Specific Clinical Trial, without Kissei's prior written consent (not to be unreasonably withheld, conditioned, or delayed). Once consent for Viridian's disclosure of such information has been provided by Kissei, Viridian may make subsequent public disclosure of such information without the further consent of Kissei; *provided* that such information remains accurate as of such time and is not presented in a form or manner that materially alters such information. Notwithstanding any provision to the contrary set forth in this Agreement, Viridian or its designees may publicly disclose (in written, oral, or other form): (a) the achievement of Milestone Events under this Agreement (including the amount, payment, and timing of any such Milestone Event); (b) any information relating to any Global Clinical Trial, including the commencement, completion, material data, or key results of such Global Clinical Trial; and (c) the receipt of Regulatory Approval or Reimbursement Approval for the Licensed Products, *provided* that Viridian will notify Kissei of such disclosure prior to such disclosure if such information has not been previously publicly disclosed.
- 9.7.3 **Use of Names.** Each Party will have the right to use the other Party's name and logo in presentations, its website, collateral materials, and corporate overviews to describe the collaboration relationship, as well as in taglines of press releases issued pursuant to this Section 9.7 (Publicity; Use of Names) and as required by Applicable Law; *provided* that neither Party will use the other Party's corporate name in such manner that the distinctiveness, reputation, and validity of any trademarks and corporate or trade names of such other Party will not be impaired, and consistent with best practices used by such other Party for its other collaborators. Except as permitted under this Section 9.7 (Publicity; Use of Names) or with the prior express written permission of the other Party, neither Party will use the name, trademark, trade name, or logo of the other Party or its Affiliates or their respective employees in any publicity, promotion, news release, or disclosure relating to this Agreement or its subject matter except as may be required by Applicable Law. Each Party will use the other Party's corporate name in all publicity

relating to this Agreement, including the initial press release and all subsequent press releases. [***].

9.8. [***] **Knowledge.** Notwithstanding any provision to the contrary set forth in this Agreement, [***].

Article 10
REPRESENTATIONS, WARRANTIES, AND COVENANTS

10.1. **Representations and Warranties of Each Party.** Each Party represents and warrants to the other Party as of the Effective Date as follows:

- 10.1.1 It is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including, without limitation, the right to grant the licenses granted by it hereunder; and
- 10.1.2 (a) It has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (b) it has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder; and (c) the Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms;
- 10.1.3 It is not a party to any agreement that would prevent it from granting the rights granted to the other Party under this Agreement or performing its obligations under the Agreement; and
- 10.1.4 In the course of performing its obligations or exercising its rights under this Agreement, it will comply with all Applicable Laws, including as applicable, GxP standards, and will not employ or engage any party who has been Debarred/Excluded, or, to such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority.
- 10.1.5 To its Knowledge, neither it nor any of its subsidiaries nor any of their Affiliates, directors, officers, employees, distributors, agents, representatives, sales intermediaries or other Third Parties acting on behalf of a Party or any of its subsidiaries or any of their Affiliates:
 - (a) has taken any action in violation of any applicable Anti-Corruption Laws; or
 - (b) has corruptly offered, paid, given, promised to pay or give, or authorized the payment or gift of anything of value, directly or indirectly, to any Public Official, for the purposes of:
 - (i) influencing any act or decision of any Public Official in his or her official capacity;
 - (ii) inducing such Public Official to do or omit to do any act in violation of his or her lawful duty;
 - (iii) securing any improper advantage; or
 - (iv) inducing such Public Official to use his or her influence with a government, governmental entity, or commercial enterprise owned or controlled by any government (including state-owned or controlled

veterinary, laboratory or medical facilities) in obtaining or retaining any business whatsoever.

10.2. Additional Representations and Warranties of Viridian. Viridian represents and warrants to Kissei as of the Effective Date as follows:

- 10.2.1 It has the right under the Viridian Technology to grant the licenses to Kissei as purported to be granted pursuant to this Agreement, and it has not granted any license or other right under the Viridian Technology that is inconsistent with the licenses granted to Kissei hereunder;
- 10.2.2 There is no pending or, to Viridian's Knowledge, threatened litigation, nor has Viridian received any written notice from any Third Party, asserting or alleging that the Exploitation of the Licensed Products prior to the Effective Date infringed or misappropriated the intellectual property rights of such Third Party; and
- 10.2.3 **Schedule 10.2.3** (Viridian Patent Rights) lists all Patent Rights in the Territory owned by Viridian that Cover the composition of matter or formulation of, or salt of or polymorph forms of, or method of using or manufacturing Licensed Products.
- 10.2.4 There are no legal claims, judgments, or settlements against or owed by Viridian or any of its Affiliates, or pending or, to Viridian's Knowledge, threatened, legal claims or litigation, in each case, arising from or alleging antitrust, anti-competition, or Anti-Corruption Law violations.

10.3. Additional Representations and Warranties of Kissei. Kissei represents and warrants to Viridian as of the Effective Date as follows:

- 10.3.1 Kissei and its Affiliates are not, and have never been, Debarred/Excluded.
- 10.3.2 Kissei has sufficient financial wherewithal to (a) perform all of its obligations pursuant to this Agreement, and (b) meet all of its obligations that come due in the ordinary course of business.
- 10.3.3 Kissei has, or will obtain, sufficient technical, clinical, and regulatory expertise to perform all of its obligations pursuant to this Agreement, including its obligations relating to Development, Manufacturing, Commercialization, and obtaining Regulatory Approvals.
- 10.3.4 There are no legal claims, judgments, or settlements against or owed by Kissei or any of its Affiliates, or pending or, to Kissei's Knowledge, threatened, legal claims or litigation, in each case, relating to antitrust, anti-competition, or Anti-Corruption Law violations.

10.4. Covenants of Each Party.

- 10.4.1 In the course of performing its obligations or exercising its rights under this Agreement, each Party will comply with all Applicable Law, including, as applicable, GxP standards, and Kissei will not employ or engage, and if so employed and engaged, will thereafter terminate any Person who has been Debarred/Excluded, or is the subject of any proceedings that could result in such Person being Debarred/Excluded.
- 10.4.2 Each Party will ensure that the records and documents that such Party provides to the other Party electronically under this Agreement are transmitted over secure systems that include adequate encryption safeguards to prevent unauthorized access and maintain data security.

10.4.3 Kissei will only engage Clinical Trial sites under a Territory Development Plan, which sites must conduct all Clinical Trials in compliance with Applicable Law, including GCP and the GCP Guidelines and that are approved by the applicable Regulatory Authority in the Territory in which such Clinical Trial site is located.

10.4.4 Notwithstanding any provision to the contrary set forth in this Agreement, each Party agrees as follows:

- (a) It will not, in the performance of this Agreement, perform any actions that are prohibited by Anti-Corruption Laws that may be applicable to such Party;
- (b) It will not, in the performance of this Agreement, directly or indirectly, make any payment, or offer or transfer anything of value, or agree or promise to make any payment or offer or transfer anything of value, to a government official or government employee, to any political party or any candidate for political office or to any other Third Party with the purpose of influencing decisions related to either Party or its business in a manner that would violate Anti-Corruption Laws;
- (c) It will, on an annual basis upon request by the other Party, verify in writing that to the best of such Party's knowledge, there have been no violations of Anti-Corruption Laws by such Party or persons employed by or subcontractors used by such Party in the performance of the Agreement, or will provide details of any exception to the foregoing; and
- (d) It will maintain records (financial and otherwise) and supporting documentation related to the subject matter of the Agreement in order to document or verify compliance with the provisions of this Section 10.4.3 (Covenants of Each Party), and upon request of the other Party, up to once per year and upon reasonable advance notice in writing, will provide a Third Party auditor mutually acceptable to the Parties with access to such records for purposes of verifying compliance with the provisions of this Section 10.4.3 (Covenants of Each Party). Acceptance of a proposed Third Party auditor may not be unreasonably withheld by either Party. [***], and that any auditing activities may not unduly interfere with the normal business operations of Party subject to such auditing activities. The audited Party may require the Third Party auditor to enter into a reasonable confidentiality agreement in connection with such an audit.

10.5. NO OTHER WARRANTIES. EXCEPT AS EXPRESSLY STATED IN THIS Article 10 (REPRESENTATIONS, WARRANTIES, AND COVENANTS), (A) NO REPRESENTATION, CONDITION, OR WARRANTY WHATSOEVER IS MADE OR GIVEN BY OR ON BEHALF OF VIRIDIAN OR KISSEI AND (B) ALL OTHER CONDITIONS AND WARRANTIES WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE ARE EXPRESSLY EXCLUDED, INCLUDING ANY CONDITIONS AND WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE, OR NON-INFRINGEMENT. ANY INFORMATION PROVIDED BY VIRIDIAN, KISSEI, OR THEIR RESPECTIVE AFFILIATES IS MADE AVAILABLE ON AN "AS IS" BASIS WITHOUT WARRANTY WITH RESPECT TO COMPLETENESS, COMPLIANCE WITH REGULATORY STANDARDS OR REGULATIONS, OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER KIND OF WARRANTY WHETHER EXPRESS OR IMPLIED.

Article 11 INDEMNIFICATION

11.1. By Kissei. Kissei will indemnify and hold harmless Viridian, its Affiliates, and their respective directors, officers, employees, successors, heirs and assigns, and agents (individually and collectively, the "**Viridian Indemnitees**") from and against all Losses incurred in connection with any Third Party Claims to the extent arising from or relating to (a) the Exploitation of the Licensed Products by or on behalf of Kissei or any of its Affiliates, or Sublicensees, or

Subcontractors, including product liability and intellectual property claims arising from such Exploitation, (b) the labeling of the Licensed Products by or on behalf of Kissei or any of its Affiliates, Sublicensees, or Subcontractors, including Approved Labeling, (c) the negligence or willful misconduct of Kissei or any of its Affiliates, Sublicensees, or Subcontractors, (d) Kissei's breach of any of its representations, warranties, covenants, or obligations set forth in or entered into pursuant to this Agreement, (e) the failure of Kissei or any of its Affiliates, Sublicensees, or Subcontractors to abide by any Applicable Law, or (f) any claim or demand from any employee or contractor of Kissei or its Affiliate who is an inventor of any Joint Collaboration Technology with respect to the ownership thereof, in each case of clauses (a) through (f) above, except to the extent such Third Party Claims arise out of a Viridian Indemnitee's gross negligence or willful misconduct, defects caused by Viridian, breach of this Agreement, failure to abide by any Applicable Law, or to the extent otherwise indemnifiable by Viridian under Section 11.2 (By Viridian).

- 11.2. By Viridian.** Viridian will indemnify and hold harmless Kissei, its Affiliates, and their respective directors, officers, employees, successors, heirs and assigns, and agents (individually and collectively, the "**Kissei Indemnitees**") from and against all Losses incurred in connection with any Third Party Claims to the extent arising from or relating to (a) the Exploitation of the Licensed Products, by or on behalf of Viridian or any of its Affiliates, licensees (not including Kissei or its Affiliates, Sublicensees, or its Subcontractors), including product liability and intellectual property claims arising from such Exploitation, and including such Exploitation after the effective date of termination of this Agreement, (b) the negligence or willful misconduct of Viridian or any of its Affiliates, licensees (not including Kissei or its Affiliates, Sublicensees, or its Subcontractors), Sublicensees, or Subcontractors, (c) Viridian's breach of any of its representations, warranties, covenants, or obligations set forth in or entered into pursuant to this Agreement, or (d) the failure of Viridian or any of its Affiliates, licensees (not including Kissei or its Affiliates, Sublicensees, or Subcontractors), Sublicensees, or Subcontractors to abide by any Applicable Law, in each case of clauses (a) through (d) above, except to the extent such Third Party Claims arise out of any of a Kissei Indemnitee's gross negligence or willful misconduct, defects caused by Kissei, breach of this Agreement or failure to abide by any Applicable Law, or to the extent otherwise indemnifiable by Kissei under Section 11.1 (By Kissei).
- 11.3. Indemnification Procedure.** If either Party is seeking indemnification under Section 11.1 (By Kissei) or Section 11.2 (By Viridian) (the "**Indemnified Party**"), then it will inform the other Party (the "**Indemnifying Party**") of the Third Party Claim giving rise to such indemnification obligations within [***] days after receiving written notice of the Third Party Claim; *provided* that the failure or delay by an Indemnified Party to give such notice of a Third Party Claim will not affect the Indemnifying Party's indemnification obligations hereunder except to the extent the Indemnifying Party will have been actually and materially prejudiced as a result of such failure or delay to give notice. The Indemnifying Party will have the right to assume the defense of any such Third Party Claim for which it is obligated to indemnify the Indemnified Party. The Indemnified Party will reasonably cooperate with the Indemnifying Party and the Indemnifying Party's insurer as the Indemnifying Party may reasonably request, and at the Indemnifying Party's cost and expense. The Indemnified Party will have the right to participate, at its own expense and with counsel of its choice, in the defense of any Third Party that has been assumed by the Indemnifying Party. Neither Party will have the obligation to indemnify the other Party in connection with any settlement made without the Indemnifying Party's prior written consent, which consent will not be unreasonably withheld, conditioned, or delayed. The Indemnifying Party will not admit liability of the Indemnified Party without the Indemnified Party's prior written consent, which consent will not be unreasonably withheld, conditioned, or delayed.
- 11.4. Insurance.** Kissei will procure and maintain during the Term of this Agreement and until the later of: (a) [***] years after termination or expiration of this Agreement, or (b) the date that all statutes of limitation covering claims or suits that may be instituted for personal injury based on the sale or use of the Licensed Products have expired, commercial general liability insurance from a minimum of [***] rated insurance company or insurer reasonably acceptable to Viridian, including contractual liability and product liability or clinical trials, if applicable, with coverage limits of not less than \$[***] per occurrence and \$[***] in the aggregate. Such policies will name

Viridian and its Affiliates as additional insureds and provide a waiver of subrogation in favor of Viridian and its Affiliates. Such insurance policies will be primary and non-contributing with respect to any other similar insurance policies available to Viridian or its Affiliates. [***]. Kissei will provide Viridian with evidence of such insurance promptly following execution by both Parties of this Agreement, upon Viridian's request, and prior to expiration of any one coverage. Kissei will provide Viridian with written notice at least [***] days prior to the cancellation or non-renewal of, or material changes in, such insurance. Such insurance will not be construed to create a limit of Kissei's liability with respect to its indemnification obligations under this Article 11 (Indemnification).

Article 12 INTELLECTUAL PROPERTY

12.1. Inventions.

- 12.1.1 **Ownership.** As between the Parties, (a) Viridian will solely own all (i) Viridian Technology and all [***] Technology, (ii) Viridian Manufacturing Technology, and (iii) Viridian Generated Data, (b) Kissei will solely own all (i) Kissei Technology and (ii) Kissei Generated Data, and (c) each Party will own [***] all Joint Collaboration Technology, without a duty of accounting or an obligation to seek consent from the other Party for the exploitation or license of the Joint Collaboration Technology (subject to the licenses granted to the other Party under this Agreement). Kissei will promptly disclose to Viridian in writing, and will cause its Affiliates to disclose, the discovery, development, invention, or creation of any Collaboration Know-How. Collaboration Know-How that [***], is the "**Licensed Product Technology**." Kissei hereby assigns to Viridian all of Kissei's rights, title, and interests in and to all Licensed Product Technology, and Viridian hereby accepts such assignment. [***]. Kissei will take (and cause its Affiliates and their respective employees, agents, and Subcontractors to take) such further actions reasonably requested by Viridian to evidence such assignment and to assist Viridian in obtaining Patent Rights and other intellectual property protection for such Licensed Product Technology and all intellectual property rights therein, including executing further assignments, consents, releases, and other commercially reasonable documentation and providing good faith testimony by affidavit, declaration, in-person, or other proper means in support of any effort by Viridian to establish, perfect, defend, or enforce its rights in any Licensed Product Technology through prosecution of governmental filings, regulatory proceedings, litigation, and other means. Kissei will obligate its Affiliates and Subcontractors to assign all Licensed Product Technology to Kissei (or directly to Viridian) so that Kissei can comply with its obligations under this Section 12.1.1 (Ownership), and Kissei will promptly obtain any such assignment. To the extent Kissei is unable to assign any Licensed Product Technology to Viridian due to restrictions under Applicable Law, Kissei will, and hereby does, grant to Viridian and its Affiliates an irrevocable, perpetual, fully-paid-up, royalty-free exclusive license consistent in all ways with ownership under such Licensed Product Technology for use in all fields worldwide and without further obligation or liability to Kissei.
- 12.1.2 **Employee Assignment.** Kissei and its Affiliates performing activities or exercising rights under this Agreement will enter into with each of their respective employees legally binding and sufficient agreements or employment policies. Without limiting the generality of the foregoing, Kissei and its Affiliates will enter into an agreement or employment policy with each of its employees performing activities under this Agreement that (a) compels prompt disclosure to Kissei of all Collaboration Know-How and Collaboration Patent Rights developed, invented, or filed (as applicable) by such employee during any performance under this Agreement; (b) automatically assigns to Kissei all Collaboration Technology and requires each employee to execute all documents and take such other actions as may be necessary to effectuate such assignment; and (c) includes a waiver of pre-emption rights under any Applicable Law in the Territory.

12.2. CREATE Act. Notwithstanding any provision to the contrary set forth in this Agreement, Kissei may not invoke the Cooperative Research and Technology Enhancement Act, 35 U.S.C. § 102(c) (the “**CREATE Act**”) when exercising its rights under this Agreement without the prior written approval of Viridian. If Kissei intends to invoke the CREATE Act, then it will notify Viridian and if agreed by the Parties, Viridian will cooperate and coordinate its activities with Kissei with respect to any filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a “joint research agreement” as defined in the CREATE Act.

12.3. Patent Prosecution.

12.3.1 Viridian Responsibilities.

- (a) **Right to Prosecute.** As between the Parties, Viridian will have the first right, in its sole discretion, to control the Patent Prosecution of all applications and registrations included in the [***] (such Patent Rights described in the preceding clauses (i) and (ii), the “**Viridian Prosecution Patent Rights**”). In addition, as between the Parties, Viridian will have the sole right, in its sole discretion to control the Patent Prosecution of [***]. Kissei will obtain any necessary assignment documents for Viridian with respect to the Patent Prosecution of Viridian Prosecution Patent Rights, will render all signatures that will be necessary for such patent filings, and will assist Viridian in all other reasonable ways that are necessary for the issuance of Viridian Prosecution Patent Rights as well as for the Patent Prosecution of Viridian Prosecution Patent Rights. [***].
- (b) **Abandonment.** If Viridian decides that it is no longer interested in the Patent Prosecution of a particular Viridian Prosecution Patent Right [***] during the Term, [***]. With respect to a Viridian Prosecution Patent Right that [***].
- (c) **Review and Consult.** The prosecuting Party will keep the non-prosecuting Party [***]. In addition, the prosecuting Party will [***]. The prosecuting Party will [***].

12.3.2 Kissei Responsibilities.

- (a) **Right to Prosecute.** As between the Parties, Kissei will have the right to control the Patent Prosecution of [***] (the “**Kissei Prosecution Patent Rights**”) throughout the world. [***].
- (b) **Review and Consult.** Kissei will keep Viridian reasonably informed regarding the Patent Prosecution of the Kissei Prosecution Patent Rights. In addition, Kissei will provide Viridian with [***].
- (c) **Abandonment.** If Kissei decides that it is no longer interested in continuing the Patent Prosecution of a particular Kissei Prosecution Patent Right during the Term, [***].

12.4. Patent Enforcement.

12.4.1 Notice. Each Party will notify the other within [***] days after becoming aware of any alleged or threatened infringement by a Third Party product in the Territory in the Field [***], and, in each case, [***] of such Patent Rights (collectively “**Product Infringement**”). Kissei will also notify Viridian within [***] days after becoming aware of any alleged or threatened infringement by a Third Party product [***] in the Territory or outside of the Territory, [***] of any such Patent Rights (an “**Ex-Territory Infringement**”). [***].

12.4.2 Enforcement Rights.

- (a) **Viridian First Right.** Viridian will have the first right, but not obligation, to bring and control any legal action to enforce the [***] Patent Rights [***] Patent Rights [***]. Prior to commencing any such action, Viridian will [***]. Viridian will also [***]. Viridian will [***]. Viridian will [***]. Viridian will [***] proposed settlement of any such action of enforcement of such [***] Patent Rights instituted by Viridian and [***]: (i) [***]; (ii) [***]; or (iii) [***]. Kissei will have the right, but not the obligation, to be separately represented in connection with such action at its sole option and at its own cost and expense.
- (b) **Kissei [***] Rights.** [***], then, [***], Kissei will [***]. Prior to commencing any such action, [***]. Kissei will also [***]. Kissei will [***]. Kissei will [***]. Kissei will [***] proposed settlement of any such action of enforcement of such [***] Patent Rights instituted by Kissei and will not, [***], enter into any settlement that would: (A) [***]; (B) [***]; or (C) [***].
- (c) **Viridian Sole Right.** In addition, as between the Parties, Viridian will have the sole right, in its sole discretion to bring and control the enforcement of [***] Patent Rights.

12.4.3 **Cooperation.** At the request of the Party bringing an action related to infringement of any [***] Patent Right, [***] Patent Right, [***] Patent Right, or [***] Patent Right in accordance with this Section 12.4 (Patent Enforcement) (a) in the Territory or (b) outside the Territory with respect to any Patent Right within the Licensed Product Technology, in each case ((a) and (b)), the other Party will provide reasonable assistance reasonably requested by the enforcing Party in connection therewith, including by executing reasonably appropriate documents, cooperating in discovery, and joining as a party to the action if required by Applicable Law to pursue such action. [***]. Viridian will [***]. In connection with an action related to Product Infringement, the Party bringing the action will not enter into any settlement [***].

12.4.4 **Recoveries.** Any recoveries resulting from an enforcement action relating to a claim of Product Infringement in the Territory will be [***]. Any such recoveries [***]. [***].

12.5. Infringement of Third Party Rights.

12.5.1 **Notice.** If a Licensed Product used or sold by Kissei or its Affiliates or Sublicensees becomes the subject of a Third Party's claim or assertion of infringement of a Patent Right or other rights in the Territory that are owned or controlled by such Third Party, then Kissei will promptly notify Viridian within [***] Business Days after receipt of such claim or assertion and will include in such notice a copy of any summons or complaint (or the equivalent thereof) received regarding the foregoing. Thereafter, the Parties will promptly meet [***].

12.5.2 **Defense.** Viridian will [***] such settlement, consent to judgment, or other voluntary final disposition would (a) [***], (b) [***], or (c) [***]. [***] will have the right, but not the obligation, to be separately represented in such defense action at its sole option and at its own cost and expense. [***].

12.6. **Patent Term Extensions.** With respect to any system for extending the term of Patent Rights in the Territory established by any applicable Regulatory Authority during the Term that is similar to the patent term extension system in the U.S., Viridian will be solely responsible for making all decisions regarding patent term extensions in the Field in the Territory, including supplementary protection certificates and any other extensions that are now or become available in the future, that are applicable to Viridian Patent Rights licensed hereunder and that become available directly as a result of the Regulatory Approval of the Licensed Product in the Territory; [***].

12.7. Product Trademarks.

- 12.7.1 **Global Brand Elements.** Kissei acknowledges that Viridian may decide to develop and adopt certain distinctive colors, logos, images, symbols, and trademarks to be used in connection with the Commercialization of the Licensed Product on a global basis (such branding elements, collectively, the “**Global Brand Elements**”).
- 12.7.2 **Product Marks in the Territory.** Viridian will have the right to brand the Licensed Products in the Territory using trademarks, logos, and trade names that it determines appropriate for the Licensed Products in the Territory, and that are consistent with Viridian’s Global Brand Elements (the “**Product Marks**”). Notwithstanding the foregoing, Kissei will have the right to develop and apply for local language versions of the Product Marks in the Territory that are consistent with the Global Brand Elements [***] (the “**Local Marks**”). Kissei will not use any trademarks in connection with the Exploitation of the Licensed Products other than the Product Marks and Local Marks [***].
- 12.7.3 **Ownership.** During the Term, Viridian will be the sole and exclusive owner of all [***]. To the extent Kissei acquires any rights, title, or interests in or to any [***], Kissei will, and hereby does, assign the same to Viridian. Viridian will and hereby does grant Kissei the exclusive right to use [***] solely to Commercialize the Licensed Products in the Territory without any additional consideration by Kissei to Viridian. Viridian will register and maintain [***] in the Territory that it determines reasonably necessary in Viridian’s name, at Viridian’s cost and expense. Kissei will register and maintain [***], and at Kissei’s cost and expense. On a Licensed Product-by-Licensed Product basis, [***]. Notwithstanding any provision to the contrary set forth in this Agreement, including the expiration of this Agreement, [***].
- 12.7.4 **Use and Quality.** Viridian will properly manage the Product Marks, Local Marks, and Global Brand Elements. Kissei agrees that it and its Affiliates and Sublicensees will Commercialize each of the Licensed Products in the Territory in a manner consistent with the Global Brand Elements and will: (a) ensure that the Licensed Products that are sold bearing the Product Marks and Global Brand Elements are of a high quality consistent with industry standards for global pharmaceutical and biologic therapeutic products; (b) ensure that each use of the Global Brand Elements and Product Marks by Kissei and its Affiliates and Sublicensees is accompanied by an acknowledgment that such Global Brand Elements and Product Marks are [***]; (c) not use such Global Brand Elements or Product Marks in a way that might materially prejudice their distinctiveness or validity or the goodwill of Viridian therein and includes the trademark registration symbol ® or ™ as appropriate; (d) not use any trademarks or trade names so resembling any of such Global Brand Elements or Product Marks as to be likely to cause confusion or deception; and (e) place and display the Global Brand Elements and the Product Marks on and in connection with the Licensed Products in a way that [***].

12.7.5

Article 13 TERM AND TERMINATION

13.1. Term. This Agreement will be effective as of the Effective Date, and will continue on the Licensed Products in effect until the expiration of the last to expire Royalty Term applicable to the Licensed Products and satisfaction of all other payment obligations (but, excluding the obligation to pay a [***] Royalty) (the “**Term**”).

13.2. Termination.

- 13.2.1 **Termination by Kissei for Convenience.** Kissei may terminate this Agreement in its entirety by providing a written notice of termination to Viridian that includes an effective date of termination of at least (a) 12 months after the date of such notice if Kissei delivers such notice before Kissei receives Regulatory Approval for a Licensed Product in the Territory or (b) 18 months after the date of such notice if Kissei provides such notice after Kissei receives Regulatory Approval for a Licensed Product in the Territory.
- 13.2.2 **Termination for Material Breach.** If either Party believes in good faith that the other is in material breach of any of its material obligations hereunder, then the non-breaching Party may deliver notice of such breach to the other Party stating the cause and proposed remedy (“**Breach Notification**”). For any breach arising from a failure to make a payment set forth in this Agreement, the allegedly breaching Party will have 15 days from the receipt of the applicable Breach Notification to dispute or cure such breach. For all breaches other than a failure to make a payment as set forth in this Agreement, the allegedly breaching Party will have 60 days from the date of the Breach Notification to dispute or cure such breach. If the Party receiving notice of breach fails to cure, or fails to dispute, that breach within the applicable period set forth above, then the Party originally delivering the Breach Notification may terminate this Agreement effective on written notice of termination to the other Party. The Parties stipulate and agree that a material breach of Kissei’s diligence obligations set forth under Section 2.6 (Exclusivity Covenants), Section 4.1 (Development Diligence and Responsibilities), or Section 7.1 (Commercialization Diligence and Responsibilities), or of Kissei’s payment obligations set forth under Article 8 (Payments), will each be considered a material breach of a material obligation under this Agreement for purposes of this Section 13.2.2 (Termination for Material Breach).
- 13.2.3 **Termination for Patent Challenge.** Except to the extent unenforceable under Applicable Law, Viridian may terminate this Agreement by providing written notice of termination to Kissei if Kissei or its Affiliates or Sublicensees (individually or in association with any Person) contests or assists a Third Party in contesting the scope, validity, or enforceability of any Viridian Patent Right or any foreign counterpart thereof anywhere in the world in any court, tribunal, arbitration proceeding, or other proceeding, including the U.S. Patent and Trademark Office and the U.S. International Trade Commission (a “**Patent Challenge**”). In the event of such a Patent Challenge, Viridian will [***]. As used herein, a Patent Challenge includes: (a) filing an action under 28 U.S.C. §§ 2201-2202 seeking a declaration of invalidity or unenforceability of any such Patent Right; (b) filing, or joining in, a petition under 35 U.S.C. § 311 to institute *inter partes* review of any such Patent Right; (c) filing, or joining in, a petition under 35 U.S.C. § 321 to institute post-grant review of any such Patent Right or any portion thereof; (d) filing or commencing any opposition, nullity, or similar proceedings challenging the validity of any such Patent Right in the Territory; or (e) any foreign equivalent of clauses (a), (b), (c), or (d).
- 13.2.4 **Termination for Cessation of Development and Commercialization.** If Kissei and its Affiliates do not conduct any material Development or Commercialization activities with respect to at least one Licensed Product for a continuous period of longer than [***], then Viridian may, at its election, terminate this Agreement in its entirety upon 60 days’ prior written notice to Kissei.
- 13.2.5 **Termination for Insolvency.** Each Party will have the right to terminate this Agreement upon delivery of written notice to the other Party if (a) such other Party files in any court or agency pursuant to any statute or regulation of any jurisdiction a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of such other Party or its assets, (b) such other Party is served with an involuntary petition against it in any insolvency proceeding and such involuntary petition has not been stayed or dismissed within 60 days of its filing, or (c) such other Party makes an assignment of substantially all of its assets for the benefit of its creditors.

13.2.6 **Full Force and Effect During Notice Period.** Except for Section 2.6 (Exclusivity Covenants) and Kissei's diligence obligations under Section 4.1 (Development Diligence and Responsibilities) and Section 7.1 (Commercialization Diligence and Responsibilities), this Agreement will remain in full force and effect until the expiration of the applicable termination notice period.

13.3. Effects of Termination. Upon the termination of this Agreement:

13.3.1 **Licenses.** As of the effective date of termination of this Agreement, all licenses and all other rights granted by Viridian to Kissei under the Viridian Technology and the Viridian Manufacturing Technology will terminate and all sublicenses granted to Subcontractors engaged by Kissei will also terminate. In addition, upon the termination of this Agreement, Viridian will have, and Kissei hereby grants to Viridian, effective upon such termination, a worldwide, exclusive, fully-paid, royalty-free, perpetual, irrevocable, and sublicensable (through multiple tiers) license under the Kissei Technology Controlled by Kissei as of the effective date of such termination solely to Exploit the Licensed Products. Notwithstanding any provision to the contrary set forth in the preceding sentence, as between the Parties, Kissei will have the sole right to use the Kissei Collaboration Technology to Exploit any products other than Licensed Products. In addition, Kissei will assign to Viridian any Third Party IP Agreement pursuant to which Kissei then Controls any Kissei Technology, if permitted under such Third Party IP Agreement (and will use reasonable efforts to seek any consent required from the applicable Third Party in connection with such an assignment). If such Third Party IP Agreement cannot be assigned to Viridian, then upon Viridian's reasonable request, Kissei will maintain such Third Party IP Agreement and Viridian will pay to the applicable Third Party 100% of all payments due to the applicable Third Party under any such Third Party IP Agreement in consideration of the sublicense to Viridian and Viridian's Exploitation of such Kissei Identified Rights. If Kissei is unable to assign the Third Party IP Agreement pursuant to which Kissei acquired rights to any Kissei Identified Rights and is unable to sublicense any Kissei Identified Rights to Viridian pursuant to this Section 13.3.1 (Licenses) without the consent of the Third Party, then Kissei will, upon request from Viridian, use reasonable efforts to procure such licenses with respect to the Licensed Products on behalf of Viridian to the extent that it is able to do so, and Viridian will pay such fees and agree to be bound by the terms agreed between Kissei and the Third Party licensor.

13.3.2 **Cessation of Exploitation.** In the event this Agreement is terminated by Viridian pursuant to Section 13.2.2 (Termination for Material Breach) or Section 13.2.5 (Termination for Insolvency) or by Kissei pursuant to Section 13.2.1 (Termination by Kissei for Convenience), except as expressly provided in this Agreement, Kissei will, and will cause its Affiliates, Sublicensees, and Subcontractors to, cease all Development, Manufacture, and Commercialization of the Licensed Antibody and Licensed Products.

13.3.3 **Appointment as Exclusive Distributor.** If Kissei is Commercializing the Licensed Products in the Territory as of the effective date of termination, then, at Viridian's election (in its sole discretion) in the Territory, until such time as all Regulatory Approvals with respect to the Licensed Products in the Territory have been assigned and transferred to Viridian, either (a) Kissei will appoint Viridian or its designee as its exclusive distributor of the Licensed Products in the Territory and grant Viridian or its designee the right to appoint sub-distributors, to the extent not prohibited by any written agreement between Kissei or any of its Affiliates and a Third Party; *provided* that Viridian will purchase any and all salable inventory of the Licensed Products held by Kissei or its Affiliates as of the effective date of termination with respect to the Licensed Products at a price equal to the price paid by Kissei to Viridian for such inventory (if Manufactured by Viridian) or at Kissei's Full Manufacturing Cost (if Manufactured by Kissei), or (b) Kissei will have the continued right to sell the Licensed Products in the Territory from its inventory; *provided, however,* that Kissei's obligations under this Agreement with respect to the Licensed Products that Kissei sells, including the

obligation to remit Royalty Payments to Viridian hereunder, will continue in full force and effect during such period.

- 13.3.4 **Regulatory Submissions and Regulatory Approvals.** Kissei will and hereby does, and will cause its Affiliates and Sublicensees to, (a) no later than [***] days after the effective date of termination of this Agreement, assign and transfer to Viridian or its designee all of Kissei's rights, title, and interests in and to all Regulatory Submissions and Regulatory Approvals for the Licensed Products then owned or Controlled by Kissei or any of its Affiliates or Sublicensees, and (b) to the extent assignment pursuant to clause (a) is delayed or is not permitted by the applicable Regulatory Authority, permit Viridian to cross-reference and rely upon any Regulatory Submissions and Regulatory Approvals filed by Kissei or any of its Affiliates or Sublicensees with respect to the Licensed Products. Kissei will take all steps necessary to transfer ownership of all such assigned Regulatory Submissions and Regulatory Approvals to Viridian, including submitting to each applicable Regulatory Authority a letter or other necessary documentation (with a copy to Viridian) notifying such Regulatory Authority of the transfer of such ownership of each Regulatory Submission and Regulatory Approval. In addition, upon Viridian's written request, Kissei will, at its cost and expense, provide to Viridian copies of all substantive related documentation, including non-clinical, preclinical, and clinical data that are held by or reasonably available to Kissei or its Affiliates or Sublicensees. The Parties will discuss and establish appropriate arrangements with respect to safety data exchange; *provided* that Viridian will assume all safety and safety database activities with respect to the Licensed Products no later than [***] days after the effective date of termination of this Agreement.
- 13.3.5 **Assignment and Disclosure.** To the extent requested by Viridian following the date that a Party provides notice of termination of this Agreement, Kissei will promptly upon request (and in any event within [***] days after the effective date of termination):
- (a) provide to Viridian for its review unredacted copies of all clinical trial agreements, manufacturing and supply agreements, distribution agreements (to the extent assignable and not cancelled), and confidentiality and other agreements, in each case, relating to the Licensed Products and that are [***] for the Exploitation of the Licensed Products, and, following such review, upon Viridian's request, assign and transfer to Viridian or its designee all of Kissei's rights, title, and interests in and to any such agreements. If such agreement is not assignable, the Kissei will cooperate with Viridian in all reasonable respects to secure the consent of the applicable Third Party to such assignment or to cause such Third Party to enter into a separate agreement with Viridian on terms substantially similar to those granted to Kissei;
 - (b) disclose to Viridian or its designee all data, information, documents, records, and materials related to the Licensed Products that are controlled by Kissei or that Kissei is able to obtain using reasonable efforts, and that embody the foregoing; and
 - (c) assign and transfer to Viridian or its designee all of Kissei's rights, title, and interests in and to any promotional materials, training materials, medical education materials, Packaging and Labeling, and all other literature or other information related to the Licensed Products and copyrights and any registrations for the foregoing.
- 13.3.6 **Assignment Costs.** Unless this Agreement is terminated by Kissei pursuant to Section 13.2.2 (Termination for Material Breach), Kissei will bear the costs and expenses associated with the assignments set forth in Section 13.3.5 (Assignment and Disclosure). To the extent that any agreement or other asset described in Section 13.3.5 (Assignment and Disclosure) is not assignable by Kissei, then such agreement or other asset will not be assigned, and upon the request of Viridian, Kissei will use reasonable efforts to take such

steps as may be necessary to allow Viridian to obtain and to enjoy the benefits of such agreement or other asset, without additional payment therefor, in the form of a license or other right to the extent Kissei has the right and ability to do so. For clarity, Viridian will have the right to request that Kissei take any or all of the foregoing actions in whole or in part, or with respect to all or any portion of the assets set forth in Section 13.3.5 (Assignment and Disclosure).

- 13.3.7 **Regulatory Transfer Support.** In furtherance of the assignment of Regulatory Submissions and Regulatory Approvals and other data pursuant to Section 13.3.4 (Regulatory Submissions and Regulatory Approvals) and Section 13.3.5 (Assignment and Disclosure), Kissei will appoint Viridian as Kissei's or its Affiliate's agent for all Licensed Product-related matters involving Regulatory Authorities until all Regulatory Approvals, Regulatory Submissions, and other governmental or regulatory filings that are not then in Viridian's or its Affiliate's name have been assigned to Viridian or its designee. In the event of failure to obtain such assignment, Kissei hereby consents and grants to Viridian the right to access and reference (without any further action required on the part of Kissei, whose authorization to file this consent with any Regulatory Authority is hereby granted) any such item with respect to the Licensed Products.
- 13.3.8 **Know-How Transfer Support.** In furtherance of the assignment of Know-How pursuant to Section 13.3.5 (Assignment and Disclosure), Kissei will, for a period of [***] months from the effective date of termination of this Agreement, provide such consultation or other assistance as Viridian may reasonably request to assist Viridian in becoming familiar with such Know-How in order for Viridian to undertake further Exploitation of the Licensed Products.
- 13.3.9 **Inventory.** At Viridian's election and request, unless Viridian elects to grant to Kissei the continued right to sell the Licensed Products in the Territory from its inventory pursuant to clause (b) of Section 13.3.3 (Appointment as Exclusive Distributor), Kissei will either (a) transfer to Viridian or its designee some or all inventory of, or (b) destroy, in each case ((a) and (b)), the Licensed Products (including all final product, bulk drug substance, intermediates, works-in-process, formulation materials, reference standards, drug product clinical reserve samples, packaged retention samples, and the like) then in the possession or Control of Kissei, its Affiliates or Sublicensees. In the event that Viridian elects to proceed under clause (a), then Viridian will pay Kissei a price equal to the price paid by Kissei to Viridian for such transferred Licensed Product (if Manufactured by Viridian) or at Kissei's Full Manufacturing Cost (if Manufactured by Kissei).
- 13.3.10 **Wind Down and Transition.** Kissei will be responsible, at its own cost and expense, for the wind-down of Kissei's and its Affiliates' and its Sublicensees' Exploitation of the Licensed Products. Kissei will, and will cause its Affiliates and Sublicensees to, reasonably cooperate with Viridian to facilitate orderly transition of the Exploitation of the Licensed Products to Viridian or its designee, including (a) assigning or amending as appropriate, upon request of Viridian, any agreements or arrangements with Third Party vendors (including distributors) to Exploit the Licensed Products or, to the extent any such Third Party agreement or arrangement is not assignable to Viridian, reasonably cooperating with Viridian to arrange to continue to provide such services for a reasonable time after termination of this Agreement with respect to the Licensed Products; and (b) to the extent that Kissei or its Affiliate is performing any activities described in the foregoing clause (a), reasonably cooperating with Viridian to transfer such activities to Viridian or its designee and continuing to perform such activities on Viridian's behalf for a reasonable time after termination of this Agreement with respect to the Licensed Products until such transfer is completed.
- 13.3.11 **Ongoing Clinical Trials.**

- (a) **Transfer to Viridian.** If, as of the effective date of termination of this Agreement, Kissei or its Affiliates are conducting any Clinical Trials for the Licensed Products, then, at Viridian's election on a Clinical Trial-by-Clinical Trial basis, Kissei will fully cooperate, and will ensure that its Affiliates fully cooperate, with Viridian to either transfer the conduct of such Clinical Trial to Viridian or its designees or to continue to conduct such Clinical Trial in accordance with Applicable Law and ethical standards. If Viridian so elects, then Kissei will continue to conduct such Clinical Trial, at Viridian's cost, to enable such transfer to be completed without interruption of any such Clinical Trial (including the assignment of all related Regulatory Submissions and investigator and other agreements related to such Clinical Trials). Kissei will provide such knowledge transfer and other training to Viridian or its designated Affiliate or Third Party as reasonably necessary for Viridian or such designated Affiliate or Third Party to continue such Clinical Trial for the Licensed Products.
- (b) **Wind-Down.** If Viridian does not elect to assume control of, or for Kissei to complete the conduct of, any such Clinical Trials for the Licensed Products, then Kissei will, in accordance with accepted pharmaceutical industry norms and ethical practices, wind-down the conduct of any such Clinical Trial in an orderly manner. Kissei will be responsible for any costs and expenses associated with such wind-down.

13.3.12 **Return of Confidential Information.** At the Disclosing Party's election, the Receiving Party will return (at Disclosing Party's expense) or destroy all tangible materials comprising, bearing, or containing any Confidential Information of the Disclosing Party relating to the Licensed Products that are in the Receiving Party's or its Affiliates' or Sublicensees' possession or control and provide written certification of such destruction (except to the extent any information is the Confidential Information of both Parties or to the extent that the Receiving Party has the continuing right to use the Confidential Information under this Agreement); *provided* that the Receiving Party may retain one copy of such Confidential Information for its legal archives. Notwithstanding any provision to the contrary set forth in this Agreement, the Receiving Party will not be required to destroy electronic files containing such Confidential Information that are made in the ordinary course of its business information back-up procedures pursuant to its electronic record retention and destruction practices that apply to its own general electronic files and information.

13.3.13 **Further Assistance.** Kissei will provide any other assistance or take any other actions, in each case, reasonably requested by Viridian as necessary to transfer to Viridian the Exploitation of the Licensed Products, and will execute all documents as may be reasonably requested by Viridian in order to give effect to this Section 13.3 (Effects of Termination).

13.3.14 **Termination by Kissei for Material Breach.** Notwithstanding any provision to the contrary set forth in this Article 13 (Term and Termination), if Kissei terminates this Agreement pursuant to Section 13.2.2 (Termination for Material Breach) due to Viridian's material breach, then Viridian will be responsible for the reasonable out-of-pocket costs incurred by Kissei directly in connection with the performance of the activities set forth in this Section 13.3 (Effects of Termination). Kissei will invoice Viridian each Calendar Quarter for the foregoing costs incurred by or on behalf of Kissei in such Calendar Quarter, and Viridian will pay all undisputed invoiced amounts within [***] days after the date of any such invoice.

13.4. [***]

13.5. **Survival.** Expiration or termination of this Agreement will not relieve the Parties of any obligation accruing prior to such expiration or termination. Without limiting the foregoing, the following provisions of this Agreement will survive the expiration or termination of this

Agreement: Article 1 (Definitions), Section 2.3 (License Grant to Viridian), Section 4.7 (Development Records) (for the period of time set forth therein), Section 6.7 (Supply Following Expiration) (for the period of time set forth therein), Section 8.1 (Upfront Payment) (solely to the extent the Upfront Payment is not paid by Kissei to Viridian prior to the effective date of termination), the last sentence of Section 8.3.2 (Royalty Term) (solely in the case of expiration), Section 8.3.5 ([***] Royalty) (solely in the case of expiration), Section 8.4 (Payments to Third Parties), Section 8.5 (Other Amounts Payable) through Section 8.12 (Taxes) (inclusive) (in each case, solely with respect to payments that were accrued prior to expiration or termination), Section 9.1 (for the period of time set forth therein), Section 9.8 (Residual Knowledge), Article 11 (Indemnification), the last two sentences of Section 12.7.3 (Ownership) (solely in the case of expiration), Section 13.3 (Effects of Termination), this Section 13.5 (Survival), Section 13.6 (Cumulative Remedies; Termination Not Sole Remedy), Article 14 (Dispute Resolution), and Article 15 (Miscellaneous), and any regulatory obligations contained herein that are required by Applicable Law of either Party or both Parties by an applicable regulatory authority.

- 13.6. Cumulative Remedies; Termination Not Sole Remedy.** No remedy referred to in this Agreement is intended to be exclusive, but each will be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under Applicable Law. Without limiting the generality of the foregoing, termination is not the sole remedy under this Agreement and, whether or not termination is effected and notwithstanding any provision to the contrary set forth in this Agreement, all other remedies will remain available except as expressly set forth herein.

Article 14 DISPUTE RESOLUTION

- 14.1. General.** The Parties recognize that a dispute may arise relating to this Agreement (a “**Dispute**”). Except as otherwise expressly set forth in this Agreement, any Dispute, including Disputes that may involve the Affiliates of any Party, will be resolved in accordance with this Article 14 (Dispute Resolution).
- 14.2. Negotiation; Escalation.** The Parties will negotiate in good faith and use reasonable efforts to settle any Dispute under this Agreement, other than [***]. Any Dispute as to the breach, enforcement, interpretation, or validity of this Agreement will be referred to the Executive Officers for attempted resolution. If the Executive Officers are unable to resolve such Dispute within [***] days after such Dispute is referred to them, then, upon the written request of either Party to the other Party, other than a Dispute relating to the scope, validity, enforceability, or infringement of any Patent Rights or trademark rights (which will be submitted for resolution to a court of competent jurisdiction in the Territory), the Dispute will be subject to arbitration in accordance with Section 14.3 (Arbitration).
- 14.3. Arbitration.** If any Dispute that was subject to Section 14.2 (Negotiation; Escalation) remains [***]days after such Dispute is referred to the Executive Officers, then either Party may at any time after such [***] day period submit such Dispute to be settled by arbitration administered by the [***]. The arbitration will be conducted before an arbitral tribunal composed of three arbitrators, all of whom will have previous judicial experience and experience with the life sciences industry, appointed by agreement of the Parties in accordance with [***]. If, at the time of the arbitration, the Parties agree in writing to submit the Dispute to a single arbitrator, said single arbitrator will be appointed by agreement of the parties, or, failing such agreement, [***]. Unless otherwise agreed by the Parties, all such arbitration proceedings [***]; *provided* that proceedings may be conducted by telephone conference call with the consent of the Parties and the arbitrator(s). All arbitration proceedings will be conducted in the English language. The arbitrator(s) will have no authority to award punitive damages. The allocation of expenses of the arbitration, including reasonable attorney’s fees, will be determined by the arbitrator(s), or, in the absence of such determination, each Party will pay its own expenses. All arbitration proceedings must be completed within [***] days of the notice of commencement of arbitration proceedings. The Parties hereby agree that the arbitrator(s) have authority to issue rulings and orders regarding all procedural and evidentiary matters that the arbitrator(s) deem reasonable and necessary with or

without petition therefore by the Parties as well as the final ruling and judgment. Rulings will be issued by written order summarizing the arbitration proceedings no more than [***] days after the final submissions of the Parties. All rulings by the arbitrator(s) will be final and binding on the Parties. The provisions of this Section 14.3 (Arbitration) may be enforced and judgment on the award (including without limitation equitable remedies) granted in any arbitration hereunder may be entered in any court having jurisdiction over the award or any of the Parties or any of their respective assets.

- 14.4. Injunctive Relief.** Notwithstanding the foregoing, in the event of an actual or threatened breach hereunder, the aggrieved Party may seek equitable relief (including restraining orders, specific performance or other injunctive relief) in any court or other forum, without first submitting to the dispute resolution procedures set forth in Section 14.2 (Negotiation; Escalation) pending a decision by the arbitral tribunal in accordance with Section 14.3 (Arbitration).
- 14.5. WAIVER OF RIGHT TO JURY TRIAL.** IN CONNECTION WITH THE PARTIES' RIGHTS UNDER SECTION 14.3 (ARBITRATION), EACH PARTY, TO THE EXTENT PERMITTED BY APPLICABLE LAWS, KNOWINGLY, VOLUNTARILY, AND INTENTIONALLY WAIVES ITS RIGHT TO A TRIAL BY JURY IN ANY ACTION OR OTHER LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT AND THE TRANSACTIONS IT CONTEMPLATES. THIS WAIVER APPLIES TO ANY ACTION OR LEGAL PROCEEDING, WHETHER SOUNDING IN CONTRACT, TORT, OR OTHERWISE.
- 14.6. Confidentiality.** Any and all activities conducted under this Article 14 (Dispute Resolution), including any and all non public proceedings and decisions under Section 14.3 (Arbitration), will be the Confidential Information of each of the Parties, and will be subject to the terms of Article 9 (Confidentiality; Publication).

Article 15 MISCELLANEOUS

15.1. Assignment.

- 15.1.1 **General.** Neither Party may assign this Agreement or the licenses granted hereunder without the other Party's prior written consent unless such assignment is to (a) a Third Party successor or purchaser of all or substantially all of the assets or businesses of such Party to which this Agreement relates, whether pursuant to a sale of assets, merger, or other transaction, or (b) an Affiliate of such Party. Any other assignment of this Agreement by a Party requires the prior written consent of the other Party. Any assignment of this Agreement in violation of this Section 15.1.1 (General) will be null, void, and of no legal effect. This Agreement will be binding on and will inure to the benefit of the permitted successors and assigns of the Parties.
- 15.1.2 **Securitization Transaction.** Notwithstanding any provision to the contrary in Section 15.1.1 (General) or elsewhere in this Agreement, Viridian may assign to a Third Party its right to receive the Milestone Payments and the Royalty Payments (such assignment, a "**Securitization Transaction**"). In connection with a contemplated Securitization Transaction and after the closing of any such Securitization Transaction, Viridian may disclose to such Third Party the Royalty Reports contemplated under Section 8.3.4 (Royalty Reports and Payments), without the prior written consent of Kissei, to the extent reasonably necessary to enable such Third Party to evaluate the Securitization Transaction opportunity (*provided* that such Third Party is under obligations of confidentiality and non-use with respect to Confidential Information included in such reports and plans that are no less protective or restrictive than the terms of Article 9 (Confidentiality; Publication) (but of duration customary in confidentiality agreements entered into for a similar purpose)), and to enable such Third Party to exercise its rights with respect to such Securitization Transaction, as applicable. As part of any consummated Securitization Transaction, subject to the terms of this Section 15.1.2

(Securitization Transaction), Viridian may assign, without the prior written consent of Kissei, its right to receive the Royalty Reports and to conduct audits under, respectively, Section 8.3.4 (Royalty Reports and Payments) and Section 8.11 (Financial Records and Audits) to the counterparty in such Securitization Transaction, and to allow such counterparty to exercise its rights under such sections.

- 15.2. LIMITATION OF LIABILITY.** NEITHER PARTY WILL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES OR ANY LOSS OF PROFIT, IN EACH CASE, ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT IN CONNECTION WITH THIS AGREEMENT, IN EACH CASE, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 15.12 (LIMITATION OF LIABILITY) IS INTENDED TO OR WILL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 11.1 (BY KISSEI) OR SECTION 11.2 (BY VIRIDIAN), MISAPPROPRIATION OR INFRINGEMENT OF INTELLECTUAL PROPERTY OWNED OR CONTROLLED BY SUCH PARTY, KISSEI'S BREACH OF ITS OBLIGATIONS UNDER SECTION 2.6 (EXCLUSIVITY COVENANTS) OR SECTION 8.1 (UPFRONT PAYMENT), OR EITHER PARTY'S BREACH OF Article 9 (CONFIDENTIALITY; PUBLICATION).
- 15.3. Force Majeure.** Neither Party will be held liable or responsible to the other Party or be deemed to have breached this Agreement for failure or delay in fulfilling or performing any obligation of this Agreement (other than failures to make payments as and when due under this Agreement) if and to the extent that such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, hurricanes, embargoes, shortages, epidemics, pandemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts, or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), acts of God, changes in law or regulation, or acts, omissions, or delays in acting by any Governmental Authority (a "**Force Majeure**"). The non-performing Party will notify the other Party of such Force Majeure within [***] days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect, and either Party may terminate this Agreement in the event of any such Force Majeure that lasts beyond [***] days after receipt of such notice. The non-performing Party will use reasonable efforts to remedy its inability to perform.
- 15.4. Severability.** If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality, and enforceability of the remaining provisions contained herein will not in any way be affected or impaired thereby, then unless the absence of the invalidated provisions adversely affects the substantive rights of the Parties. The Parties will in such an instance use their best efforts to replace the invalid, illegal or unenforceable provisions with valid, legal, and enforceable provisions that, insofar as practical, implement the purposes of this Agreement.
- 15.5. Notices.** All notices that are required or permitted hereunder will be in writing and sufficient if delivered by internationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, and in each case, addressed as follows (with a courtesy copy sent by email, which will not constitute notice):

If to Viridian:

Viridian Therapeutics, Inc.
221 Crescent Street, Suite 103A
Waltham, MA 02453
USA
Attention: Chief Legal Officer
Email: [***]

With a copy (which will not constitute notice) to:

Ropes & Gray LLP
800 Boylston Street; Prudential Tower
Boston, MA 02199
Attention: [***]
Email: [***]

If to Kissei:

(1) Until August 24, 2025;
Kissei Pharmaceutical Co., Ltd.
1-8-9 Nihonbashi, Muromachi
Chuo-Ku
Tokyo 103-0022
Japan
Attention: [***]
Email: [***]

(2) From August 25, 2025;
Kissei Pharmaceutical Co., Ltd.
3-1-3, Koishikawa
Bunkyo-ku
Tokyo 112-0002
Japan
Attention: [***]
Email: [***]

With a copy (which will not constitute notice) to:

Kissei Pharmaceutical Co., Ltd.
19-48, Yoshino
Matsumoto City
Nagano Prefecture 399-8710
Japan
Attention: [***]
Email: [***]

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice will be deemed to have been given: (a) on the day after dispatch if sent by internationally-recognized overnight courier; or (b) on the fifth day after dispatch if sent by registered or certified mail, postage prepaid, return receipt requested.

15.6. Governing Law. This Agreement, and all claims or causes of action (whether in contract, tort or statute) that may be based upon, arise out of or relate to this Agreement, or the negotiation, execution or performance of this Agreement or the breach thereof (including any claim or cause of action based upon, arising out of or related to any representation or warranty made in or in connection with this Agreement or as an inducement to enter into this Agreement), will be governed by, and enforced in accordance with, the internal laws of the State of New York,

including its statutes of limitations without giving effect to the conflicts of law provisions thereunder.

- 15.7. Entire Agreement; Amendments.** This Agreement, together with the Schedules hereto, contains the entire understanding of the Parties with respect to the collaboration and the licenses granted hereunder. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect to the collaboration and the licenses granted hereunder are superseded by the terms of this Agreement. The Schedules to this Agreement are incorporated herein by reference and will be deemed a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of each Party. The foregoing will not be interpreted as a waiver of any remedies available to either Party or its Affiliates as a result of any breach, prior to the Effective Date, by the other Party or its Affiliates of such Party's or its Affiliate's obligations pursuant to the Confidentiality Agreement.
- 15.8. Headings.** The captions to the several Articles, Sections and subsections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections of this Agreement.
- 15.9. Independent Contractors.** It is expressly agreed that Viridian and Kissei will be independent contractors and that the relationship between the two Parties will not constitute a partnership, joint venture or agency. Neither Viridian nor Kissei will have the authority to make any statements, representations, or commitments of any kind, or to take any action that is binding on the other Party without the prior written consent of the other Party.
- 15.10. Performance by Affiliates.** Notwithstanding any provision to the contrary set forth in this Agreement, either Party will have the right to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any Affiliate. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance.
- 15.11. Waiver.** Any waiver of any provision of this Agreement will be effective only if in writing and signed by Viridian and Kissei. No express or implied waiver by a Party of any default under this Agreement will be a waiver of a future or subsequent default. The failure or delay of any Party in exercising any rights under this Agreement will not constitute a waiver of any such right, and any single or partial exercise of any particular right by any Party will not exhaust the same or constitute a waiver of any other right provided in this Agreement.
- 15.12. Waiver of Rule of Construction.** Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement will be construed against the drafting Party will not apply.
- 15.13. Business Day Requirements.** If any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a Business Day, then such notice or other action or omission will be deemed to be required to be taken on the next occurring Business Day.
- 15.14. Further Actions.** Each Party agrees to execute, acknowledge, and deliver such further instruments, and to do all such other acts, as necessary or appropriate in order to carry out the purposes and intent of this Agreement.
- 15.15. Construction.** Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa), (b) the words "include," "includes," and "including" will be deemed to be followed by the phrase "without limitation" or "but not limited to," (c) the word "will" will be construed to have the same meaning and effect as the word "shall," (d) any definition of or reference to any agreement, instrument, or other

document herein will be construed as referring to such agreement, instrument, or other document as from time to time amended, supplemented, or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person will be construed to include the person's successors and assigns, (f) the words "herein," "hereof," and "hereunder" and words of similar import, will each be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Articles, Sections, Schedules, or Exhibits will be construed to refer to Articles, Sections, Schedules, or Exhibits of this Agreement, and references to this Agreement include all Schedules hereto, (h) the word "notice" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent," "approve," or the like will require that such agreement, consent, or approval be specific and in writing, whether by written agreement, letter, approved minutes, or otherwise (but excluding e-mail and instant messaging), (j) references to any specific law, rule or regulation, or Section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, and (k) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or."

15.16. Language; Translations. This Agreement is in the English language only, which language will be controlling in all respects, and all versions hereof in any other language will be for accommodation only and will not be binding upon the Parties. All communications and notices to be made or given by one Party to the other pursuant to this Agreement, and any dispute proceeding related to or arising hereunder, will be in the English language. If there is a discrepancy between any translation of this Agreement and any non-English translation of this Agreement, this Agreement will prevail. Kissei will provide all information, data, documents, and other materials to be provided to Viridian under this Agreement in English. If the original version of any such information, data, documents, or other materials are in a language other than English, then Kissei will provide a translated version in English. [***]. Except as otherwise provided in this Agreement, each Party will bear all costs and expenses of any translations that such Party prepares in accordance with this Section 15.16 (Language; Translations).

15.17. Counterparts. This Agreement may be executed in counterparts, all of which taken together will be regarded as one and the same instrument. Counterparts may be delivered via electronic mail, including Adobe™ Portable Document Format (PDF) or any electronic signature complying with the U.S. Federal ESIGN Act of 2000, and any counterpart so delivered will be deemed to be original signatures, will be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Agreement.

[Remainder of the Page Intentionally Left Blank; Signature Page Follows]

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Collaboration and License Agreement to be executed by their respective duly authorized representatives as of the Effective Date.

Viridian Therapeutics, Inc.

By: /s/ Steve Mahoney

Name: Steve Mahoney

Title: President and Chief Executive Officer

Kissei Pharmaceutical Co., Ltd.

By: /s/ Mutsuo Kanzawa

Name: Mutsuo Kanzawa

Title: Chairman and Chief Executive Officer

SIXTH AMENDMENT TO LEASE

This **SIXTH AMENDMENT TO LEASE** (this "**Amendment**") is made as of the 8th day of September, 2025 (the "**Effective Date**") by and between **WATCH CITY VENTURES MT LLC**, a Massachusetts limited liability company, having an address at c/o Berkeley Investments, Inc., 125 High Street, Suite 531, Boston, Massachusetts 02110 ("**Landlord**"), and **VIRIDIAN THERAPEUTICS, INC.**, a Delaware corporation, having an address at 221 Crescent Street, Suite 103A, Waltham, Massachusetts 02453 ("**Tenant**"), as successor in interest to Viridian, LLC, a Massachusetts limited liability company ("**Viridian LLC**").

REFERENCE is made to a certain Lease, dated January 13, 2020 by and between Landlord and Viridian LLC as Tenant's predecessor in interest, pursuant to that certain Assignment and Consent Agreement entered into between the Landlord, Tenant and Viridian, LLC, dated September 27, 2020, as amended by that certain First Amendment to Lease dated July 6, 2021, as further amended by that certain Second Amendment to Lease dated April 13, 2022, as further amended by that certain Third Amendment to Lease dated July 29, 2022, as further amended by that certain Fourth Amendment to Lease dated April __, 2024, and as further amended by that certain Fifth Amendment to Lease dated September 19, 2024 (as amended, the "**Lease**") for certain premises consisting of (a) approximately 10,427 rentable square feet on the first (1st) floor of Buildings #18 and #19, as shown as Suite 103A on the plan attached to the Lease as Exhibit A-1.4, and (b) approximately 2,788 rentable square feet on the first (1st) floor of Building #20, as shown as Suite 103B on the plan attached to the Lease as Exhibit A-1.5 (the "**Original Premises**").

WHEREAS, Tenant desires to exercise its right of first refusal to lease an additional approximately 5,240 rentable square feet consisting of (a) approximately 2,737 rentable square feet located on the first (1st) floor of Building #4 , and shown as Suite 110 on the plan attached hereto as **Exhibit A-1.7** (the "**Suite 110 Premises**"), and (b) approximately 2,503 rentable square feet located on the first (1st) floor of Building #4, and shown as Suite #111 on the plan attached hereto as **Exhibit A-1.7** (the "**Suite 111 Premises**" and together with the Suit 110 Premises, sometimes referred to herein as the "**New Premises**");

WHEREAS, the rent commencement date for the New Premises shall be the later to occur of (a) delivery of the New Premises to Tenant, and (b) September 15, 2025 (the "**New Premises Rent Commencement Date**");

WHEREAS, Tenant has agreed to accept the Suite 110 Premises and the Suite 111 Premises in its current "as is" condition, and Landlord shall not be obligated to construct any improvements on behalf of Tenant or to alter, remodel, improve, renovate, repair or decorate the Suite 110 Premises, the Suite 111 Premises, the Building, or any part thereof, or to provide any allowance for such purposes;

WHEREAS, Tenant has requested and Landlord has agreed to grant to Tenant an ongoing right of first refusal solely with respect to space, consisting of approximately 7,035 rentable square feet consisting of (a) approximately 1,408 rentable square feet located on the first (1st) floor of Building #21 (the "**Suite 104 Premises**"), (b) approximately 3,342 rentable square feet located on the first (1st) floor of Buildings #21 and #25 (the "**Suite 107 Premises**"), and (c) approximately 2,285 rentable square feet located on the first (1st) floor of Buildings #24 and 25 (the "**Suite 108 Premises**"), all as shown on the plan attached hereto as **Exhibit A-1.8** (the "**ROFR Expansion Premises**"), subject to the rights of the current tenant, Earnix, Inc. (and any affiliate and successors or assigns of any of them) to renew or extend

its lease with respect to all or any portion of the ROFR Expansion Premises, and further subject to the pre-existing expansion rights of Devoted Health (and any affiliate and successor or assigns of any of them) to lease all or any portion of the ROFR Expansion Premises, and further subject to the pre-existing rights of any other tenants or occupants at the Watch Factory complex, and all in accordance with the terms of this Amendment; and

WHEREAS, Landlord and Tenant desire to amend the Lease to (i) add the New Premises to the Premises, (ii) adjust the Base Rent, (iii) adjust the number of parking spaces available to Tenant, (iv) adjust Tenant’s Proportionate Share, and (v) provide Tenant with an ongoing right of first refusal with respect to the ROFR Expansion Premises, all in accordance with the terms and provisions as hereinafter set forth.

NOW, THEREFORE, in consideration of Tenant's agreement to pay additional Base Rent as hereinafter set forth, for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and for the mutual promises hereinafter set forth, Landlord and Tenant agree to amend the Lease, effective as of the Effective Date, as follows:

1. Capitalized terms used herein and not otherwise defined shall have the meaning ascribed thereto in the Lease.
2. The following definitions shall be added to Article 1 (Definitions) of the Lease:

Suite 110 Premises: approximately 2,737 rentable square feet located on the first (1st) floor of Building #4, and shown as Suite 110 on the plan attached hereto as **Exhibit A-1.7**.

Suite 110 Premises Commencement Date (“S110PCD”): The Suite 110 Premises Delivery Date. See Section 2.1.6 below.

Suite 110 Premises Rent Commencement Date (“S110PRCD”): The later to occur of (a) the Suite 110 Premises Delivery Date, or (b) September 15, 2025.

Suite 110 Premises Base Rent:

| <u>Period</u> | <u>RSF Paying Rent On</u> | <u>Base Rent</u> | <u>Yearly Base Rent</u> | <u>Monthly Base Rent</u> |
|----------------------|--------------------------------------|-----------------------------|------------------------------------|-------------------------------------|
| S110PRCD – 7/31/2026 | \$2,737 | \$41.00/RSF | \$112,217.00 | \$9,351.42 |
| 8/1/2026 – 7/31/2027 | \$2,737 | \$42.00/RSF | \$114,954.00 | \$9,579.50 |
| 8/1/2027 – 7/31/2028 | \$2,737 | \$43.00/RSF | \$117,691.00 | \$9,807.58 |
| 8/1/2028 – 7/31/2029 | \$2,737 | \$44.00/RSF | \$120,428.00 | \$10,035.67 |

Suite 110 Premises Term: The period commencing on the Suite 110 Premises Commencement Date and ending at 11:59 P.M. on the Termination Date, unless sooner terminated or extended as provided in this Lease.

Suite 111 Premises: approximately 2,503 rentable square feet located on the first (1st) floor of Building #4, and shown as Suite #111 on the plan attached hereto as **Exhibit A-1.7**.

Suite 111 Premises Commencement Date (“S111PCD”): The Suite 111 Premises Delivery Date. See Section 2.1.7 below.

Suite 111 Premises Rent Commencement Date (“S111PRCD”): The later to occur of (a) the Suite 111 Premises Delivery Date, or (b) September 15, 2025.

Suite 111 Premises Base Rent:

| Period | RSF Paying Rent On | Base Rent | Yearly Base Rent | Monthly Base Rent |
|----------------------|-------------------------------|----------------------|-----------------------------|------------------------------|
| S111PRCD – 7/31/2026 | \$2,503 | \$41.00/RSF | \$102,623.00 | \$8,551.92 |
| 8/1/2026 – 7/31/2027 | \$2,503 | \$42.00/RSF | \$105,126.00 | \$8,760.50 |
| 8/1/2027 – 7/31/2028 | \$2,503 | \$43.00/RSF | \$107,629.00 | \$8,969.08 |
| 8/1/2028 – 7/31/2029 | \$2,503 | \$44.00/RSF | \$110,132.00 | \$9,177.67 |

Suite 111 Premises Term: The period commencing on the Suite 111 Premises Commencement Date and ending at 11:59 P.M. on the Termination Date, unless sooner terminated or extended as provided in this Lease.

Termination Date: July 31, 2029.

3. The first sentence of the definition of “Additional Rent” appearing in Article 1 (Definitions) of the Lease is hereby deleted and replaced with the following:

“(a) with respect to the Suite 103A Premises and the Suite 103B Premises, Tenant’s Proportionate Share (as defined below) of the cost of any (i) reasonable and customary operating expenses for the Buildings, the Common Areas and the Property (as defined below) as reasonably determined by Landlord (including, without limitation, gas, heat, air conditioning, electricity, water, sewer, cleaning, trash collection, snow removal and sanding, and insurance, as applicable) (the “**Operating Expenses**”) in excess of the Operating Expenses for Calendar Year 2024; and (ii) real estate taxes for the Property (as defined below) and the Buildings in excess of the real estate taxes imposed against the Property and the Buildings for Fiscal Year 2024 (July 1, 2023 – June 30, 2024); and (b) with respect to the Suite 110 Premises and the Suite 111 Premises, Tenant’s Proportionate Share (as defined below) of the cost of any (i) Operating Expenses in excess of the Operating Expenses for Calendar Year 2026; and (ii) real estate taxes for the Property (as defined below) and the Buildings in excess of the real estate taxes imposed against the Property and the Buildings for Fiscal Year 2026 (July 1, 2025 – June 30, 2026).”

4. The following definitions set forth in Article 1 (Definitions) of the Lease shall be deleted in their entirety and replaced as follows:

Lease Year: With respect to the Suite 103A Premises, the first “Lease Year” shall be the period commencing on the Suite 103A Premises Commencement Date and ending on the last day of the calendar month in which the first anniversary of the Suite 103A Premises Rent Commencement Date occurs if the Suite 103A Premises Rent Commencement Date is other than the first day of a calendar month. If the Suite 103A Premises Rent Commencement Date is the first day of a calendar month, then the first “Lease Year” with respect to the Suite 103A Premises shall be the period commencing on the Suite 103A Premises Commencement Date and ending on the day (last of the calendar month) immediately prior to the first (1st) anniversary of the Suite 103A Premises Rent Commencement Date. With respect to the Suite 103B Premises, the first “Lease Year” shall be the period commencing on the Suite 103B Premises Commencement Date and ending on the last day of the calendar month in which the first anniversary of the Suite 103B Premises Rent Commencement Date occurs if the Suite 103B Premises Rent Commencement Date is other than the first day of a calendar month. If the Suite 103B Premises Rent Commencement Date is the first day of a calendar month, then the first “Lease Year” with respect to the Suite 103B Premises shall be the period commencing on the Suite 103B Premises Commencement Date and ending on the day (last of the calendar month) immediately prior to the first (1st) anniversary of the Suite 103B Premises Rent Commencement Date. With respect to the Suite 110 Premises, the first “Lease Year” shall be the period commencing on the Suite 110 Premises Commencement Date and ending on July 31, 2026. With respect to the Suite 111 Premises, the first “Lease Year” shall be the period commencing on the Suite 111 Premises Commencement Date and ending on July 31, 2026, it being the intention of the parties that the first “Lease Year” with respect to both the Suite 110 Premises and the Suite 111 Premises, be co-terminus. In either case of the Suite 103A Premises, the Suite 103B Premises, the Suite 110 Premises, or the Suite 111 Premises, each succeeding twelve (12) month period thereafter, as the case may be, shall be a Lease Year, with the final Lease Year of each of the Suite 103A Premises, the Suite 103B Premises, the Suite 110 Premises, or the Suite 111 Premises, all ending on the Termination Date.

Parking: From and after the date hereof, Tenant shall have the non-exclusive right, in common with Landlord and others, to use and occupy during the remainder of the Term up to sixty-one (61) parking spaces in the parking lots serving the Buildings as shown on **Exhibit A-2**, attached hereto, (“**Parking Facilities**”), all at no additional fee or cost, but subject to the reasonable rules and regulations established by Landlord from time to time of uniform application to all users, and of which Tenant has received prior notice. Landlord reserves the right in its sole discretion, from time to time, to modify, reconfigure, or relocate the Parking Facilities within reasonable proximity to the Parking Facilities as shown on **Exhibit A-2** attached hereto.

Tenant’s Proportionate Share: (a) with respect to the Suite 103A Premises during the Suite 103A Premises Term, Six and Forty-Four One Hundredths percent (6.44%), (b) with respect to the Suite 103B Premises during the Suite 103B Premises Term, One and Seventy-Two One Hundredths percent (1.72%), (c) with respect to the Suite 110 Premises during the Suite 110 Premises Term, One and Sixty-Nine One Hundredths percent (1.69%), and (d) with respect to the Suite 111 Premises during the Suite 111 Premises Term, One and Fifty-Five One Hundredths percent (1.55%), which percentages have been determined by dividing the total number of rentable square feet in the Suite 103A Premises, Suite 103B Premises, the Suite 110 Premises, and the Suite 111 Premises respectively, by the Total Building Rentable Square Footage (161,790) and multiplying the resulting quotient by one hundred (100).

Term: (a) with respect to the Suite 103A Premises, the period commencing on the Suite 103A Premises Commencement Date and ending at 11:59 p.m. on the Termination Date, (b) with respect to the Suite 103B Premises, the period commencing on the Suite 103B Premises Commencement Date and ending at 11:59 p.m. on the Termination Date, (c) with respect to the Suite 110 Premises, the period commencing on the Suite 110 Premises Commencement Date and ending at 11:59 p.m. on the Termination Date, and (d) with respect to the Suite 111 Premises, the period commencing on the Suite 111 Premises Commencement Date and ending at 11:59 p.m. on the Termination Date, it being the intention of the parties that the Term with respect to the Suite 103A Premises, the Suite 103B Premises, the Suite 110 Premises, and the Suite 111 Premises, be co-terminus.

5. The following shall be added as new Section 2.1.6 and new Section 2.1.7:

2.1.6 Suite 110 Premises: Landlord hereby leases to Tenant the Suite 110 Premises for the Suite 110 Premises Term, subject to the terms and conditions set forth herein. For the purposes of this Lease, the “**Suite 110 Premises Delivery Date**” shall be deemed to have occurred on the later to occur of (a) the full execution and delivery of this Amendment, and (b) the date Landlord has made the Suite 110 Premises available to Tenant.

2.1.7 Suite 111 Premises: Landlord hereby leases to Tenant the Suite 111 Premises for the Suite 111 Premises Term, subject to the terms and conditions set forth herein. For the purposes of this Lease, the “**Suite 111 Premises Delivery Date**” shall be deemed to have occurred on the later to occur of (a) the full execution and delivery of this Amendment, and (b) the date Landlord has made the Suite 111 Premises available to Tenant.

6. The following shall be added as new Section 2.2.6 and new Section 2.2.7:

2.2.6 Acceptance of Suite 110 Premises. Tenant acknowledges and agrees that Tenant is accepting the Suite 110 Premises in its “as is” condition and Landlord shall not be obligated to construct any improvements on behalf of Tenant; *provided however*, Landlord shall deliver the Suite 110 Premises to Tenant free of other occupants and personal property and in broom clean condition with all systems serving the Building and Suite 110 Premises in good working condition. Landlord has no obligation and has made no promises to alter, remodel, improve, renovate, repair or decorate the Suite 110 Premises, the Building, or any part thereof, or to provide any allowance for such purposes, and that no representations respecting the condition of the Suite 110 Premises or the Building have been made by Landlord to Tenant (except as otherwise specifically set forth herein). Notwithstanding the foregoing, Landlord and Tenant shall reasonably agree on a date from and after the Suite 110 Premises Commencement Date by which Landlord shall remove any existing furniture located with the Suite 110 Premises.

2.2.7 Acceptance of Suite 111 Premises. Tenant acknowledges and agrees that Tenant is accepting the Suite 111 Premises in its “as is” condition and Landlord shall not be obligated to construct any improvements on behalf of Tenant; *provided however*, Landlord shall deliver the Suite 111 Premises to Tenant free of other occupants and personal property and in broom clean condition with all systems serving the Building and Suite 111 Premises in good working condition. Landlord has no obligation and has made no promises to alter, remodel, improve, renovate, repair or decorate the Suite 111 Premises, the Building, or any part thereof, or to provide any allowance for such purposes, and that no representations respecting the condition of

the Suite 111 Premises or the Building have been made by Landlord to Tenant (except as otherwise specifically set forth herein). Notwithstanding the foregoing, Landlord and Tenant shall reasonably agree on a date from and after the Suite 111 Premises Commencement Date by which Landlord shall remove any existing furniture located with the Suite 111 Premises.

7. Section 2.7 shall be deleted in its entirety and replaced with the following:

2.7. Expansion; Right of First Refusal. Tenant shall have an on-going right, strictly in accordance with this Section 2.7, and subject to the rights of any of Landlord's other existing tenants in the Buildings, including without limitation, Earnix, Inc. (and any affiliate and successors or assigns of any of them) to renew or extend its existing lease (with or without Landlord's consent) with respect to all or any portion of the ROFR Expansion Premises, and further subject to the pre-existing expansion rights of Devoted Health (and any affiliate and successor or assigns of any of them) to lease all or any portion of the ROFR Expansion Premises, to the to lease (a) approximately 1,408 rentable square feet located on the first (1st) floor of Building #21 (the "**Suite 104 Premises**"), (b) approximately 3,342 rentable square feet located on the first (1st) floor of Buildings #21 and #25 (the "**Suite 107 Premises**"), and (c) approximately 2,285 rentable square feet located on the first (1st) floor of Buildings #24 and 25 (the "**Suite 108 Premises**"), and as shown on the plan attached hereto as **Exhibit A-1.8** (each suite individually and collectively, the "**ROFR Expansion Premises**") on the following terms and conditions: (i) Landlord shall notify Tenant in writing that Landlord has received a signed offer to lease the ROFR Expansion Premises which Landlord is prepared to accept and the basic terms and conditions of such offer ("**Landlord's ROFR Notice**"); (ii) Tenant shall be entitled to lease the ROFR Expansion Premises upon the same terms and conditions as contained in Landlord's ROFR Notice; (iii) there shall remain not less than twenty-four (24) months remaining in the unexpired initial Term of this Lease, or if there shall remain less than twenty-four (24) months remaining in the initial Term of this Lease, Landlord's ROFR Notice shall include Landlord's determination of Prevailing Market Rate (for the then existing Premises) in accordance with Section 2.6 above and Tenant's election to lease the ROFR Expansion Premises shall be conditioned upon Tenant exercising its option to extend the Term of this Lease for the Extended Term, pursuant to Section 2.6 hereof; (iv) Tenant shall have ten (10) business days from receipt of Landlord's ROFR Notice, time being of the essence, to notify Landlord in writing that Tenant elects to lease the ROFR Expansion Premises on such terms and conditions as are set forth in Landlord's ROFR Notice, and otherwise as set forth herein, or that Tenant disputes Landlord's calculation of Prevailing Market Rate, in which case Landlord and Tenant shall proceed with the appraisal procedure set forth in Section 2.6 above, and Tenant's failure to so timely notify Landlord shall be deemed a waiver of the right to lease the ROFR Expansion Premises in accordance with this Section 2.7 and Landlord shall be entitled to lease the ROFR Expansion Premises (or such applicable portion of the ROFR Expansion Premises included in Landlord's ROFR Notice) free and clear of any rights of Tenant; provided however, if Landlord subsequently reduces the economic terms set forth in Landlord's ROFR Notice by 10% or more, Landlord shall again offer the ROFR Expansion Premises to Tenant pursuant to the terms of this Section 2.7; (v) the ROFR Expansion Premises shall be leased in its then "as is" condition except as set forth in Landlord's ROFR Notice; (vi) Tenant may utilize any furniture located within the ROFR Expansion Premises until Tenant provides Landlord with a one-time written notice to Landlord within sixty (60) days of taking possession of the ROFR Expansion Premises, of Tenant's election to have Landlord remove such existing furniture, in which event Landlord shall promptly remove such furniture from the ROFR Expansion Premises at Landlord's sole cost and expense,

and (vii) within ten (10) business days of Tenant's receipt from Landlord of an amendment to this Lease solely reflecting Tenant's exercise of its option for the ROFR Expansion Premises and reflecting the modification of only the applicable terms of the Lease which relate to Tenant's exercise of its option for the ROFR Expansion Premises including, without limitation, the Base Rent and Additional Rent, time being of the essence, Tenant shall execute such amendment and return same to Landlord. Tenant's failure to timely comply with any of the above conditions, time being of the essence, shall be deemed Tenant's waiver of the rights contained in this Section 2.7 to lease such portion of the ROFR Expansion Premises included in Landlord's ROFR Notice), and thereafter Tenant shall have no further rights with respect to such portion of the ROFR Expansion Premises included in Landlord's ROFR Notice. At Landlord's option, Tenant's exercise of its option for the ROFR Expansion Premises shall be effective only if, at the time of Tenant's notice and through the date on which Landlord is to deliver the ROFR Expansion Premises to Tenant, there is no default under this Lease, or condition which would be a default with the passage of time and/or the giving of notice. Notwithstanding anything contained in this Section 2.7 to the contrary, (i) Tenant's right to lease the ROFR Expansion Premises, or any portion thereof, shall expire on the date which is nine (9) months prior to the expiration of the initial Term, unless Tenant has exercised its right to extend the Term of this Lease for the Extended Term in accordance with Section 2.6 hereof, (ii) in the event Tenant has exercised its right to extend the Term of this Lease for the Extended Term in accordance with Section 2.6 hereof, Tenant's right to lease the ROFR Expansion Premises, or any portion thereof, shall expire on the date which is twenty four (24) months prior to the expiration of the Extended Term. Upon Tenant's waiver or deemed waiver of its rights to lease any portion of the ROFR Expansion Premises, such portion shall be deemed removed from the ROFR Expansion Premises and Tenant shall have no further rights under this Section 2.7 with respect to such portion of ROFR Expansion Premises so removed.

8. Section 3.1 of the Lease is hereby deleted in its entirety and shall be replaced by the following:

3.1. Base Rent and Additional Rent. From and after (i) the Suite 103A Premises Rent Commencement Date with respect to the Suite 103A Premises, (ii) the Suite 103B Premises Rent Commencement Date with respect to the Suite 103B Premises, (iii) the Suite 110 Premises Rent Commencement Date with respect to the Suite 110 Premises, and (iv) the Suite 111 Premises Rent Commencement Date with respect to the Suite 111 Premises, Tenant agrees to pay the Suite 103A Base Rent, with respect to the Suite 103A Premises, the Suite 103B Base Rent, with respect to the Suite 103B Premises, the Suite 110 Base Rent, with respect to the Suite 110 Premises, the Suite 111 Base Rent, with respect to the Suite 111 Premises, and the Additional Rent in lawful money of the United States in advance on the first day of each and every calendar month during the Term of this Lease, at the Payment Address or at such other place as Landlord may from time to time designate by notice. Landlord may, from time to time, (but not more frequently than once for each calendar year) provide Tenant with an estimate of the Additional Rent for the coming year and such estimated Additional Rent shall be payable by Tenant to Landlord in accordance with the provisions of the preceding sentence in 12 equal monthly installments. The Suite 103A Premises Base Rent, the Suite 103B Premises Base Rent, the Suite 110 Premises Base Rent, the Suite 111 Premises Base Rent, and Additional Rent for any partial month shall be prorated on the basis of a 30 day month.

9. **Exhibit A-1.7** attached hereto showing the Suite 110 Premises and the Suite 111 Premises shall be added as new **Exhibit A-1.7** of the Lease.

10. **Exhibit A-1.8** attached hereto showing the ROFR Expansion Premises shall be added as new **Exhibit A-1.8** of the Lease.
11. Tenant and Landlord each represent and warrant to the other that it has not directly or indirectly dealt, with respect to the leasing of office space in the Building, including without limitation, the Suite 110 Premises, and the Suite 111 Premises with any broker or had its attention called to the Premises, Suite 110 Premises, the Suite 111 Premises or other space to let in the Building by anyone other than Newmark. Landlord assumes sole responsibility for compensating such brokers. Notwithstanding the foregoing, if Tenant fails to take occupancy of either the Suite 110 Premises or the Suite 111 Premises, due to Tenant's fault, Tenant shall reimburse Landlord for any amounts that Landlord has or will pay to any brokers.
12. From and after the S110PCD, all references appearing in the Lease to the Premises shall be amended and read hereafter to be references to the Original Premises, the Suite 110 Premises, and the Suite 111 Premises, unless specifically set forth in this Amendment to the contrary.
13. From and after the S110PCD, all references appearing in the Lease to the Rent shall be amended and read hereafter to include, without limitation, the Suite 110 Premises Base Rent.
14. From and after the S111PCD, all references appearing in the Lease to the Rent shall be amended and read hereafter to include, without limitation, the Suite 111 Premises Base Rent.
15. The Lease is hereby ratified and confirmed and, as modified by this Amendment, shall remain in full force and effect.
16. All references appearing in the Lease and in any related instruments shall be amended and read hereafter to be references to the Lease as amended by this Amendment.
17. This Amendment shall have the effect of an agreement under seal and shall be binding upon and inure to the benefit of the parties hereto and their respective heirs, executors, administrators, successors and assigns.
18. Except as otherwise specifically provided herein, all of the terms and conditions of the Lease shall remain in full force and effect for the extended Lease term and this Amendment is effective as of the date first set forth above.
19. This Amendment may be executed in multiple counterparts, each of which shall be deemed an original, and all of which shall constitute one and the same agreement. This Amendment (and any further amendments to the Lease and any other instruments relating to the transactions contemplated hereby, other than any instruments to be recorded, witnessed and/or notarized) may be electronically signed by the parties by the use of DocuSign, which will be treated as an original copy as though ink-signed by officers or other duly authorized representatives of such party. Ink-signed or electronically signed executed copies hereof may be delivered by telecopier or email and upon receipt will be deemed originals and binding upon the parties hereto.

[Remainder of Page Intentionally Blank. Signatures on the Following Page.]

EXECUTED under seal as of the date first set forth above.

LANDLORD: WATCH CITY VENTURES MT LLC,
a Massachusetts limited liability company

By: Berkeley Watch MM LLC, its Managing Member

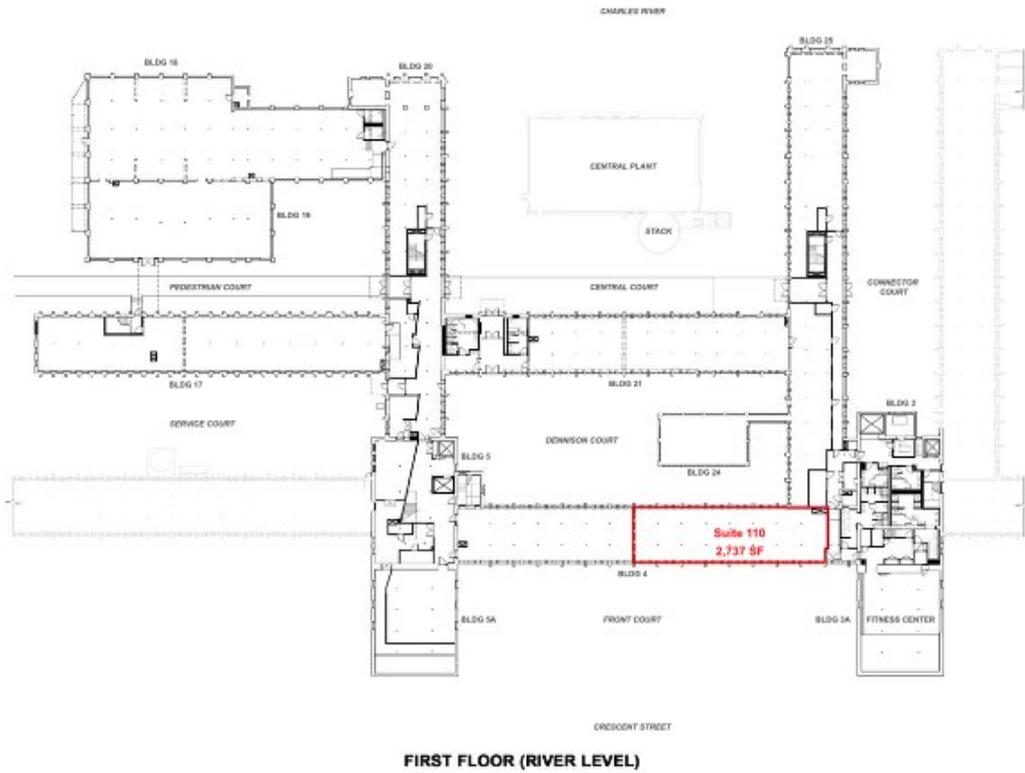
By: /s/ Young Park
Name: Young Park
Its: Authorized Signatory
(hereunto duly authorized)

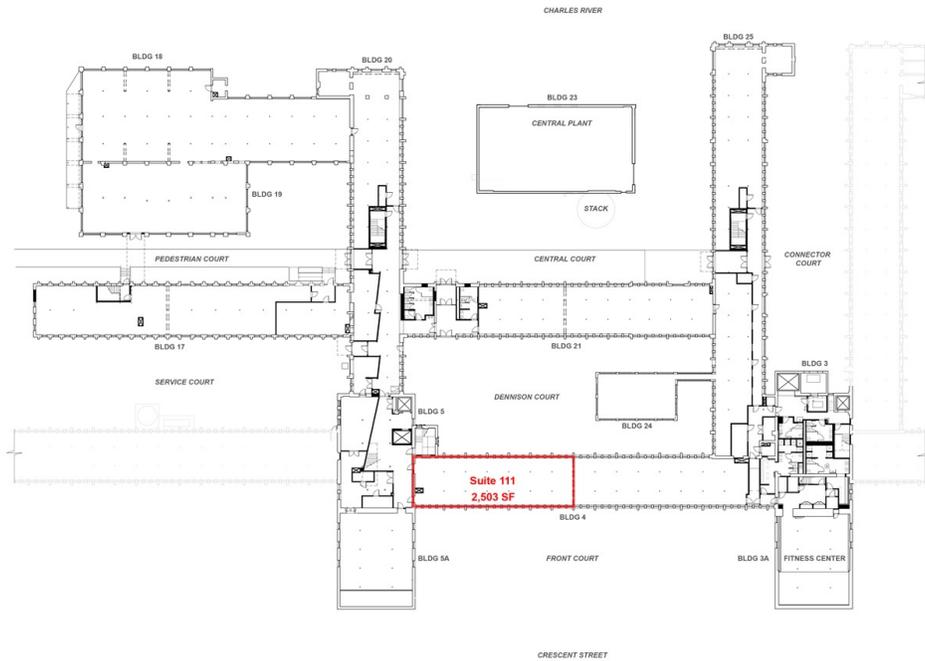
TENANT: VIRIDIAN THERAPEUTICS, INC.,
a Delaware corporation

By: /s/ Steve Mahoney
Name: Steve Mahoney
Title: CEO

By: /s/ Jennifer Tousignant
Name: Jennifer Tousignant
Title: Secretary

EXHIBIT A-1.7
PLAN SHOWING SUITE 110 PREMISES and SUITE 111 PREMISES



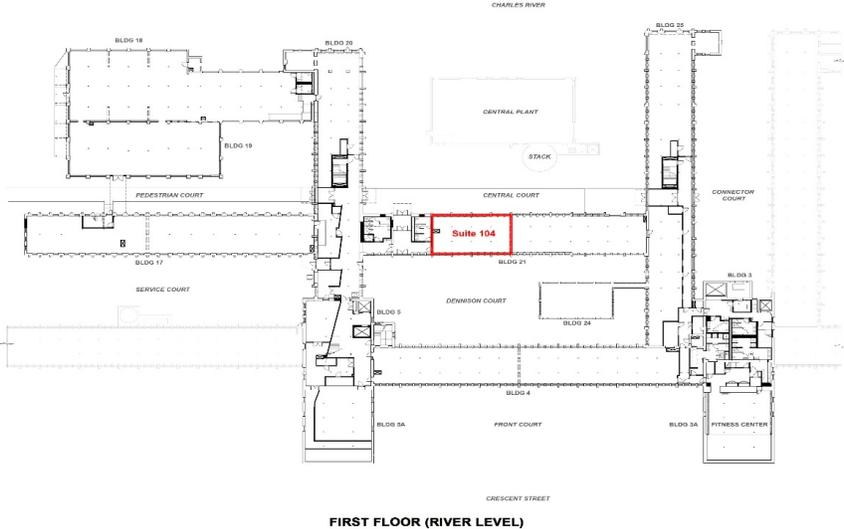


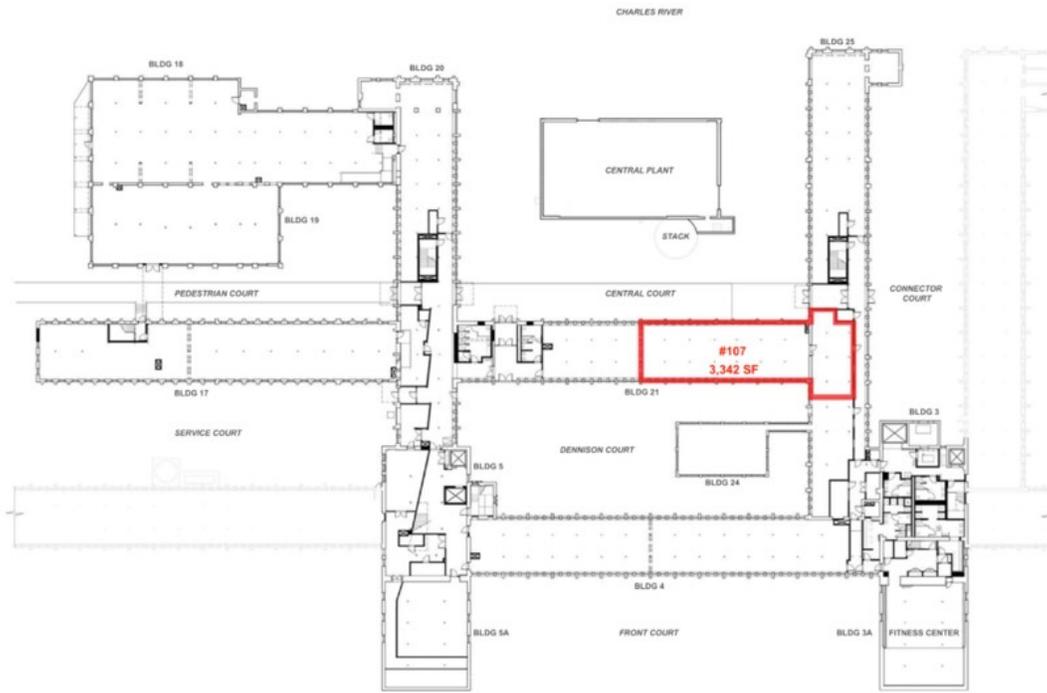
FIRST FLOOR (RIVER LEVEL)

EXHIBIT A-1.8

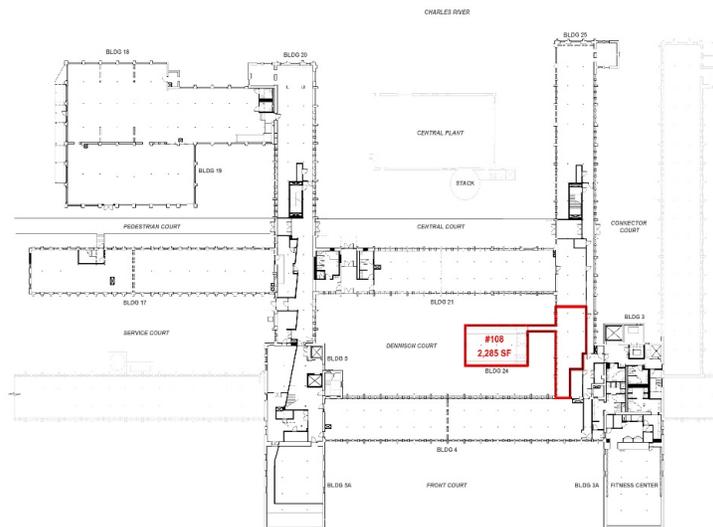
PLAN SHOWING ROFR EXPANSION PREMISES

Suite 104, Suite 107 and Suite 108





FIRST FLOOR (RIVER LEVEL)



FIRST FLOOR (RIVER LEVEL)

CERTIFICATION

I, Stephen Mahoney, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q, 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: November 5, 2025

By: /s/ Stephen Mahoney
Stephen Mahoney
President, Chief Executive Officer and Director
(Principal Executive Officer)

CERTIFICATION

I, Seth Harmon, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q, 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: November 5, 2025

By: /s/ Seth Harmon

Seth Harmon

Chief Financial Officer

(Principal Financial Officer; Principal Accounting Officer)

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 Quarterly Report on Form 10-Q of the Company for the quarterly period ended September 30, 2025, 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: November 5, 2025

/s/ Seth Harmon

Seth Harmon
Chief Financial Officer
(Principal Financial Officer; Principal Accounting Officer)

Date: November 5, 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.