

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

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2024

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File No. 001-36483

**VIRIDIAN THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

Delaware

47-1187261

(State or other jurisdiction of incorporation or organization)

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

221 Crescent Street, Suite 103A, Waltham, MA 02453

(Address, including zip code, of principal executive offices)

(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

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

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 November 7, 2024, there were 79,212,747 shares of the registrant's common stock outstanding.

**VIRIDIAN THERAPEUTICS, INC.**  
**INDEX**

**PART I. FINANCIAL INFORMATION**

<a href="#"><u>Item 1. Financial Statements</u></a>	<a href="#"><u>7</u></a>
<a href="#"><u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u></a>	<a href="#"><u>38</u></a>
<a href="#"><u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u></a>	<a href="#"><u>50</u></a>
<a href="#"><u>Item 4. Controls and Procedures</u></a>	<a href="#"><u>50</u></a>

**PART II. OTHER INFORMATION**

<a href="#"><u>Item 1. Legal Proceedings</u></a>	<a href="#"><u>51</u></a>
<a href="#"><u>Item 1A. Risk Factors</u></a>	<a href="#"><u>51</u></a>
<a href="#"><u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u></a>	<a href="#"><u>98</u></a>
<a href="#"><u>Item 3. Defaults Upon Senior Securities</u></a>	<a href="#"><u>98</u></a>
<a href="#"><u>Item 4. Mine Safety Disclosures</u></a>	<a href="#"><u>98</u></a>
<a href="#"><u>Item 5. Other Information</u></a>	<a href="#"><u>98</u></a>
<a href="#"><u>Item 6. Exhibits</u></a>	<a href="#"><u>98</u></a>

**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;
- the timing and focus of our ongoing and future preclinical studies and clinical trials and the timing of reporting data from those studies and trials;
- 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;
- 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 our expectation to seek an accelerated approval pathway and special designations, such as orphan drug designation, 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 preclinical studies, clinical trials and commercialization;
- our plans regarding any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- our estimates regarding expenses, future revenue, capital requirements and our ability to obtain additional financing to fund our operations and complete further development and commercialization of our product candidates; and

- the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements.

Any forward-looking statements in this 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 raise additional capital when needed, we would be forced to delay, reduce, or eliminate our research and product development programs or future commercialization efforts.
- We have historically incurred losses, have a limited operating history on which to assess our business, and anticipate that we will continue to incur significant losses for the foreseeable future.
- Clinical trials are costly, time consuming, and inherently risky, and we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.
- Regulatory approval processes are lengthy, time consuming and inherently unpredictable. Failure to obtain regulatory approval for our product candidates would have a material adverse effect upon our business and business prospects.
- Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial viability of approved labeling, or result in significant negative consequences following marketing approval, if any.
- We are heavily dependent on the success of our product candidates, which are in clinical development. Some of our product candidates have produced results only in non-clinical settings, or for other indications than those for which we contemplate conducting development and seeking U.S. Food and Drug Administration 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 preclinical studies and clinical trials may not be predictive of future clinical trial results.
- We may find it difficult to enroll and maintain patients or subjects in our clinical trials, in part due to the limited number of patients or subjects who have the diseases for which our product candidates are being studied or the availability of competing therapies and clinical trials. We cannot predict if we will have difficulty enrolling and maintaining patients or subjects in our future clinical trials. Difficulty in enrolling and maintaining patients or subjects could delay or prevent clinical trials of our product candidates.
- We rely on third parties to conduct our preclinical 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)  
(unaudited)

	September 30, 2024	December 31, 2023
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 200,317	\$ 102,827
Short-term investments	552,923	374,543
Prepaid expenses and other current assets	14,103	9,006
Unbilled revenue - related party	14	102
Total current assets	767,357	486,478
Property and equipment, net	1,290	1,672
Operating lease right-of-use asset	2,400	1,670
Other assets	853	604
Total assets	<u>\$ 771,900</u>	<u>\$ 490,424</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 6,338	\$ 2,239
Accrued liabilities and other (including related party of \$ 3,725 and \$ 374 as of September 30, 2024 and December 31, 2023, respectively)	34,738	24,108
Current portion of deferred revenue - related party	288	288
Total current liabilities	41,364	26,635
Long-term debt	20,523	20,205
Deferred revenue - related party	356	573
Other liabilities	2,161	989
Total liabilities	<u>64,404</u>	<u>48,402</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, series A non-voting convertible preferred stock, \$ 0.01 par value; 435,000 shares authorized; 134,864 and 172,435 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	61,188	78,235
Preferred stock, series B non-voting convertible preferred stock, \$ 0.01 par value; 500,000 shares authorized; 145,160 and 143,522 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	127,697	128,281
Common stock, \$ 0.01 par value; 200,000,000 shares authorized; 79,181,445 and 53,986,112 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	792	540
Additional paid-in capital	1,433,019	960,536
Accumulated other comprehensive gain	932	338
Accumulated deficit	( 916,132 )	( 725,908 )
Total stockholders' equity	<u>707,496</u>	<u>442,022</u>
Total liabilities and stockholders' equity	<u>\$ 771,900</u>	<u>\$ 490,424</u>

See accompanying notes to these 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		Nine Months Ended	
	September 30,	2024	September 30,	2024
<b>Revenue:</b>				
Collaboration revenue - related party	\$ 86	\$ 72	\$ 230	\$ 242
<b>Operating expenses:</b>				
Research and development (including related party expenses of \$ 7,725 and \$ 10,937 during the three and nine months ended September 30, 2024, respectively, and \$ 1,099 and \$ 6,521 during the three and nine months ended September 30, 2023, respectively.)	69,158	30,385	166,294	121,208
General and administrative	14,408	20,911	45,499	62,006
<b>Total operating expenses</b>	<b>\$ 83,566</b>	<b>\$ 51,296</b>	<b>\$ 211,793</b>	<b>\$ 183,214</b>
Loss from operations	( 83,480 )	( 51,224 )	( 211,563 )	( 182,972 )
<b>Other income (expense):</b>				
Interest and other income	7,795	4,164	23,527	13,029
Interest and other expense	( 1,004 )	( 600 )	( 2,188 )	( 931 )
Other income, net	6,791	3,564	21,339	12,098
<b>Net loss</b>	<b>\$ ( 76,689 )</b>	<b>\$ ( 47,660 )</b>	<b>\$ ( 190,224 )</b>	<b>\$ ( 170,874 )</b>
<b>Net loss per share, basic and diluted</b>	<b>\$ ( 1.15 )</b>	<b>\$ ( 1.09 )</b>	<b>\$ ( 2.98 )</b>	<b>\$ ( 3.97 )</b>
Weighted-average shares used to compute basic and diluted net loss per share	66,420,063	43,654,577	63,800,798	43,057,658
<b>Comprehensive loss:</b>				
Net loss	\$ ( 76,689 )	\$ ( 47,660 )	\$ ( 190,224 )	\$ ( 170,874 )
Other comprehensive gain:				
Change in unrealized gain on investments	1,475	109	594	326
<b>Total other comprehensive gain</b>	<b>1,475</b>	<b>109</b>	<b>594</b>	<b>326</b>
<b>Total comprehensive loss</b>	<b>\$ ( 75,214 )</b>	<b>\$ ( 47,551 )</b>	<b>\$ ( 189,630 )</b>	<b>\$ ( 170,548 )</b>

*See accompanying notes to these condensed consolidated financial statements.*

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

	Preferred Stock				Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)		Total Stockholders' Equity		
	Series A		Series B		Shares	Amount		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	157,435	\$ 71,429	143,522	\$ 128,281	63,798,536	\$ 638	\$ 1,156,999	\$ (367)	\$ 774,450	\$ 582,530		
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	157,435	\$ 71,429	143,522	\$ 128,281	63,879,675	\$ 639	\$ 1,168,975	\$ (543)	\$ 839,443	\$ 529,338		
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	134,864	\$ 61,188	145,160	\$ 127,697	79,181,445	\$ 792	\$ 1,433,019	\$ 932	\$ 916,132	\$ 707,496		

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

	Preferred Stock				Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity				
	Series A		Series B											
	Shares	Amount	Shares	Amount	Shares	Amount								
Balance as of December 31, 2022			56,677			741,067			488,174	(				
	188,381	\$ 85,470	51,210	\$	41,305,947	\$ 414	\$	\$ (390)	\$ )	\$ 395,064				
Issuance of common stock upon the conversion of convertible preferred stock	(15,946)	(7,235)	—	—	1,063,118	10	7,225	—	—	—				
Issuance of common stock upon exercises of warrants	—	—	—	—	57,553	1	945	—	—	946				
Issuance of common stock for exercises of stock options	—	—	—	—	612,846	6	6,932	—	—	6,938				
Issuance of common stock for cash under employee stock purchase plan	—	—	—	—	15,854	—	320	—	—	320				
Share-based compensation expense	—	—	—	—	—	—	15,216	—	—	15,216				
Change in unrealized gain on investments	—	—	—	—	—	—	—	216	—	216				
Net loss	—	—	—	—	—	—	—	—	(68,151)	(68,151)				
Balance as of March 31, 2023			56,677			771,705			556,325	(				
	172,435	\$ 78,235	51,210	\$	43,055,318	\$ 431	\$	\$ (174)	\$ )	\$ 350,549				
Issuance of common stock under license agreement	—	—	—	—	204,843	2	4,998	—	—	5,000				
Issuance of common stock upon exercises of warrants	—	—	—	—	56,666	1	934	—	—	935				
Issuance of common stock for exercises of stock options	—	—	—	—	245,381	2	2,131	—	—	2,133				
Share-based compensation expense	—	—	—	—	—	—	12,302	—	—	12,302				
Change in unrealized gain on investments	—	—	—	—	—	—	—	1	—	1				
Net loss	—	—	—	—	—	—	—	—	(55,063)	(55,063)				
Balance as of June 30, 2023			56,677			792,070			611,388	(				
	172,435	\$ 78,235	51,210	\$	43,562,208	\$ 436	\$	\$ (173)	\$ )	\$ 315,857				
Issuance of common stock under license agreement	—	—	—	—	39,059	—	693	—	—	693				
Issuance of common stock for exercises of stock options	—	—	—	—	84,360	1	710	—	—	711				
Issuance of common stock for cash under employee stock purchase plan					15,362	—	260	—	—	260				
Share-based compensation expense	—	—	—	—	—	—	13,606	—	—	13,606				
Change in unrealized gain on investments	—	—	—	—	—	—	—	109	—	109				
Net loss	—	—	—	—	—	—	—	—	(47,660)	(47,660)				
Balance as of September 30, 2023			56,677			807,339			659,048	(				
	172,435	\$ 78,235	51,210	\$	43,700,989	\$ 437	\$	\$ (64)	\$ )	\$ 283,576				

See accompanying notes to these condensed consolidated financial statements.

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

	<b>Nine Months Ended September 30,</b>	
	<b>2024</b>	<b>2023</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (190,224)	\$ (170,874)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Share-based compensation expense	33,175	41,124
Issuance of common stock under license agreement	—	5,693
Non-cash interest expense and amortization of debt issuance costs	318	194
Depreciation and amortization	417	372
Accretion and amortization of premiums and discounts on available-for-sale securities	(12,448)	(8,423)
Non-cash lease expense	188	59
Net loss on extinguishment of debt	—	181
Fees paid directly to creditor related to extinguishment of debt	—	514
Net loss on disposal of equipment	449	—
Other non-cash items	—	31
<b>Changes in operating assets and liabilities:</b>		
Prepaid expenses and other assets	(5,344)	(4,489)
Unbilled revenue - related party	88	—
Deferred revenue - related party	(216)	(216)
Accounts payable	3,850	(10,524)
Accrued and other liabilities	10,760	188
Net cash used in operating activities	<u>(158,987)</u>	<u>(146,170)</u>
<b>Cash flows from investing activities:</b>		
Purchases of short-term investments	(513,289)	(135,385)
Proceeds from maturities of short-term investments	347,950	211,694
Purchase of property and equipment	(397)	(850)
Net cash (used in) provided by investing activities	<u>(165,736)</u>	<u>75,459</u>
<b>Cash flows from financing activities:</b>		
Proceeds from the issuance of common stock, pursuant to January 2024 Public Offering, September 2024 Public Offering and September 2022 ATM Agreement	420,014	—
Payments of issuance costs associated with the sale of common stock	(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 long-term debt, net of costs	—	15,000
Payment of debt extinguishment costs	—	(514)
Proceeds from the issuance of common stock upon the exercise of warrants	—	1,881
Proceeds from the issuance of common stock upon the exercise of stock options	2,157	9,782
Proceeds from the issuance of common stock for cash under employee stock purchase plan	673	580
Net cash provided by financing activities	<u>422,213</u>	<u>26,729</u>

[Table of Contents](#)

Net increase (decrease) in cash and cash equivalents	97,490		( 43,982 )
Cash and cash equivalents at beginning of period	102,827		155,579
Cash and cash equivalents at end of period	\$ 200,317	\$ 111,597	
Supplemental disclosure of cash flow information			
Cash paid for interest	\$ 1,367	\$ 434	
Supplemental disclosure of non-cash investing and financing activities			
Conversion of preferred stock to common stock	\$ 41,132	\$ 7,235	
Unpaid common stock issuance costs included in accounts payable and accrued liabilities	\$ 370	\$ —	
Purchase of property and equipment in accounts payable and accrued liabilities	\$ 88	\$ 25	
Extinguishment of long-term debt	\$ —	\$ 4,707	
Issuance of long-term debt	\$ —	\$ 5,000	

*See accompanying notes to these condensed consolidated financial statements.*

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

**1. DESCRIPTION OF BUSINESS**

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

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

***Liquidity***

The accompanying condensed consolidated financial statements have been prepared on a basis that assumes the Company is a going concern and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from any uncertainty related to its ability to continue as a going concern. The Company has funded its operations to date principally through proceeds received from the sale of the Company's common stock, its Series A Preferred Stock, Series B Preferred Stock, and other equity securities, debt financings, license fees, and reimbursements received under collaboration agreements. Since its inception and through September 30, 2024, the Company has generated an accumulated deficit of \$ 916.1 million. The Company expects to continue to generate operating losses for the foreseeable future.

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

As of September 30, 2024, the Company had approximately \$ 753.2 million in cash, cash equivalents, and short-term investments. In addition, the Company also has access to additional undrawn funds under the Hercules Loan and Security Agreement Amended Term Loan, as further described in Note 5. *Debt*. As of the issuance date of these condensed consolidated financial statements, the Company expects that its current resources will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next twelve months from the issuance date of these financial statements.

The Company will require additional capital in order to continue to finance its operations. The amount and timing of future funding requirements will depend on many factors, including the pace and results of the Company's clinical development efforts, timing of market research and other professional and consulting

activities to prepare for commercial activities, equity financings, entering into license and collaboration agreements, and issuing debt or other financing vehicles. The Company's ability to secure additional capital is dependent upon a number of factors, some of which are outside of the Company's control, including success in developing its product candidates, operational performance, and market conditions, including those resulting from the current inflationary and broader macroeconomic environment.

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

## **2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

### ***Basis of Presentation***

The accompanying 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").

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, 2024, are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2024, or any other future period.

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, 2023, filed with the U.S. Securities and Exchange Commission on February 27, 2024. 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.

### ***Risk and Uncertainties – 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, the Company is unable to quantify the potential effects of this economic instability on its future operations.

### **Going Concern**

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

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

### **Use of Estimates**

The Company's 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 condensed consolidated financial statements include, but are not limited to, the accrual for clinical trial costs, including manufacturing activities, and other outsourced research and development expenses, and the valuation of share-based awards. Although these estimates are based on the Company's knowledge of current events and actions it may take in the future, actual results may ultimately differ from these estimates and assumptions.

### **Revenue Recognition**

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

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

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

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

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

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

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

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

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

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

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

***Research and Development***

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

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

***Clinical Trial and Preclinical Study Accruals***

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

***Share-Based Compensation***

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

### **Cash and Cash Equivalents**

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

### **Investments**

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

Unrealized gains and losses are reported as a component of stockholders' equity until their disposition. Realized gains and losses are included as a component of other income (expense), net based on the specific identification method. The securities are subject to a periodic impairment review. An impairment charge would occur when a decline in the fair value of the investments below the cost basis is judged to be other-than-temporary.

### **Fair Value Measurements**

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

- Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2 inputs utilize observable inputs other than Level 1 prices, such as quoted prices, for similar assets or liabilities, quoted market prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities.
- Level 3 inputs are unobservable data points for the asset or liability and include situations where there is little, if any, market activity for the asset or liability.

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

### **Concentrations of Credit Risk**

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

### **Property and Equipment**

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

### **Operating Lease Right-of-Use Assets and Liabilities**

The Company determines if an arrangement is, or contains, a lease at contract inception and during modifications or renewal of existing leases. Operating lease assets represent the Company's right to use an underlying asset for the lease term and operating lease liabilities represent the Company's obligation to make lease payments arising from the lease. The Company has recorded operating lease assets and liabilities pursuant to the guidance in ASU No. 2016-02, *Leases (Topic 842)*, and subsequent amendments to the initial guidance: ASU No. 2017-13, ASU No. 2018-10, and ASU No. 2018-11 (collectively, "ASC 842"). These operating lease assets and liabilities are recognized at the commencement date of the lease based upon the present value of lease payments over the lease term. The 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 6, *Commitments and Contingencies - Lease Obligations* for additional information related to the Company's operating leases.

### **Debt and Debt Issuance Costs**

Debt issuance costs and expenses paid by the Company to its lenders are presented on the consolidated balance sheet as a direct deduction from the related debt liability rather than capitalized as an asset in accordance with ASU No. 2015-03, *Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*. Debt issuance costs represent legal and other direct costs incurred in connection with the Company's Term Loan (as defined in Note 5, *Debt*). These costs are amortized as a non-cash component of interest expense using the effective interest method over the term of the loan.

### **Convertible Preferred Stock**

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

### **Impairment of Long-Lived Assets**

The Company assesses the carrying amount of its property and equipment whenever events or changes in circumstances indicate the carrying amount of such assets may not be recoverable. No impairment charges were recorded during the nine months ended September 30, 2024 and 2023.

### **Net Loss per Share**

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period without consideration of common stock equivalents. Since the

Company was in a loss position for all periods presented, diluted net loss per share is the same as basic net loss per share for all periods, as the inclusion of all potential common shares outstanding is antidilutive.

#### **Comprehensive Loss**

Comprehensive loss is comprised of net loss and adjustments for the change in unrealized gains and losses on investments. Unrealized accumulated comprehensive gains or losses are reflected as a separate component in the condensed consolidated statements of changes in 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, 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 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, 2024 and 2023.

#### **Warrants**

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

#### **Segment Information**

The Company operates in one operating segment and, accordingly, no segment disclosures have been presented herein. 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.

**Recent Accounting Pronouncements – To Be Adopted**

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

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Report Segment Disclosures ("ASU 2023-07"). ASU 2023-07 requires enhanced disclosures about significant segment expenses, enhanced interim disclosure requirements, clarifies circumstances in which an entity can disclose multiple segment measures of profit or loss, provides new segment disclosure requirements for entities with a single reportable segment, and contains other disclosure requirements. ASU 2023-07 is effective for the Company's annual reporting period beginning after December 15, 2023, and subsequent interim periods, with early adoption permitted. ASU 2023-07 requires retrospective application to all prior periods presented in the financial statements. The Company is currently evaluating the effect that adoption of ASU 2023-07 will have on its consolidated financial statements.

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

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

### 3. INVESTMENTS AND FAIR VALUE MEASUREMENTS

#### *Investments*

The Company's investments consisted of the following as of September 30, 2024 and December 31, 2023:

(in thousands)	Amortized Cost	Gross Unrealized		Gross Unrealized		Fair Value
		Gains	Losses	Gains	Losses	
<b>September 30, 2024</b>						
Money market funds	\$ 183,690	\$ —	\$ —	\$ —	\$ 183,690	
U.S. treasury securities	231,010	252	( 52 )			231,210
U.S. corporate paper and bonds	311,036	779	( 50 )			311,765
International corporate bond holdings	9,945	3	( 102 )			9,948
Total	<u>\$ 735,681</u>	<u>\$ 1,034</u>	<u>\$ ( 102 )</u>			<u>\$ 736,613</u>
<b>December 31, 2023</b>						
Money market funds	\$ 77,724	\$ 7	\$ —			77,731
U.S. treasury securities	148,423	255	( 5 )			148,673
U.S. corporate paper and bonds	227,463	142	( 85 )			227,520
International corporate bond holdings	9,304	24	( 90 )			9,328
Total	<u>\$ 462,914</u>	<u>\$ 428</u>	<u>\$ ( 90 )</u>			<u>\$ 463,252</u>

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

As of September 30, 2024, 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, 2024 and 2023. The Company did not have any sales of short-term investments during the three and nine months ended September 30, 2024 and 2023. The contractual maturity dates of all of the Company's investments are 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:

[Table of Contents](#)

(in thousands)	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total	
<b>September 30, 2024</b>					
<b>Cash equivalents:</b>					
Money market funds	\$ 183,690	\$ —	\$ —	\$ 183,690	
<b>Short-term investments:</b>					
U.S. treasury securities	—	231,210	—	231,210	
U.S. corporate paper and bonds	—	311,765	—	311,765	
International corporate bond holdings	—	9,948	—	9,948	
Total cash equivalents and short-term investments	\$ 183,690	\$ 552,923	\$ —	\$ 736,613	
<b>December 31, 2023</b>					
<b>Cash equivalents:</b>					
Money market funds	\$ 77,731	\$ —	\$ —	\$ 77,731	
U.S. corporate paper and bonds	—	10,978	—	10,978	
<b>Short-term investments:</b>					
U.S. treasury securities	—	148,673	—	148,673	
U.S. corporate paper and bonds	—	216,542	—	216,542	
International corporate bond holdings	—	9,328	—	9,328	
Total cash equivalents and short-term investments	\$ 77,731	\$ 385,521	\$ —	\$ 463,252	

#### 4. ACCRUED LIABILITIES AND OTHER

Accrued liabilities consisted of the following:

	September 30, 2024	December 31, 2023
	(in thousands)	
Accrued outsourced clinical trials and preclinical studies	\$ 21,676	\$ 10,724
Accrued employee compensation and related taxes	10,011	10,513
Operating lease liability, short-term	589	843
Accrued legal fees and expenses	846	399
Accrued other professional service fees	762	473
Value of liability-classified stock purchase warrants	100	100
Accrued interest payable	149	154
Other accrued liabilities	605	902
<b>Total accrued liabilities</b>	<b>\$ 34,738</b>	<b>\$ 24,108</b>

#### 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, available to the Company through June 15, 2023. Upon signing the Hercules Loan and Security Agreement, the Company drew an initial principal amount of \$ 5.0 million (the "initial draw"). The Company incurred debt issuance costs of \$ 0.2 million in connection with the Term Loan and paid to the Lenders a facility fee of \$ 0.1 million, as well as \$ 0.1 million of other expenses incurred by the Lenders and reimbursed by the Company ("Lender Expenses") in connection with the initial draw. The debt issuance costs and the Lender Expenses were being amortized as additional interest expense over the term of the loan.

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

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

recognized a loss on debt extinguishment of \$ 0.2 million in August 2023 related to unamortized debt discount and debt issuance costs.

Under the Hercules Amendment, the Lenders provided the Company access to an increased term loan with an aggregate principal amount of up to \$ 150.0 million, in four tranches (collectively the "Amended Term Loan"), consisting of (1) an initial tranche of \$ 50.0 million, \$ 5.0 million of which was drawn at closing of the Hercules Loan and Security Agreement in April 2022, \$ 15.0 million of which was drawn at closing of the Hercules Amendment in August 2023, \$ 5.0 million of which was available through December 15, 2023, and \$ 25.0 million of which is available from July 1, 2024 through December 15, 2024; (2) a second tranche of \$ 20.0 million, subject to achievement of certain regulatory milestones, available through February 15, 2025; (3) a third tranche of \$ 20.0 million, subject to achievement of certain regulatory milestones, available through March 31, 2025; and (4) a fourth tranche of \$ 60.0 million subject to approval by the Lenders' investment committee(s), available through June 15, 2025. The milestones for the second and third tranches have not yet been achieved. The obligations of the Borrower under the Hercules Amendment agreement are secured by substantially all of the assets of the Borrower, excluding the Borrower's intellectual property. The Amended Term Loan has a maturity date of October 1, 2026.

The Amended Term Loan bears interest at a floating per annum rate equal to the greater of (i) 7.45 % and (ii) 4.2 % above the Prime Rate (as defined therein), provided that the Term Loan interest rate shall not exceed a per annum rate of 8.95 %. Interest is payable monthly in arrears on the first day of each month. The interest rate as of September 30, 2024 was 8.95 %.

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

The total cost of all items (cash interest, the amortization/accretion of the debt issuance costs and the end-of-term fee) is being recognized as interest expense using an effective interest rate of approximately 9.3 %. The Company recorded interest expense of \$ 0.5 million and \$ 1.7 million during the three and nine months ended September 30, 2024, and \$ 0.4 million and \$ 0.8 million during the three and nine months ended September 30, 2023, respectively.

The following table summarizes the components of the Term Loan, on the Company's condensed consolidated balance sheet at September 30, 2024:

	September 30, 2024	
	(in thousands)	
Gross term loan proceeds	\$	20,000
Accrued end-of-term fee		523
<b>Total debt</b>	<b>\$</b>	<b>20,523</b>
Less: current portion of long-term debt		—
<b>Long-term debt, net</b>	<b>\$</b>	<b>20,523</b>

The carrying value of the Term Loan approximates its fair value. Future principal payments, which exclude the end of term fee, in connection with the Hercules Loan and Security Agreement as of September 30, 2024 are as follows (in thousands):

**Fiscal Year**

Fiscal Year	\$	—
2024 (remainder)	\$	—
2025		4,441
2026		15,559
<b>Total</b>	<b>\$</b>	<b>20,000</b>

## 6. COLLABORATION AGREEMENTS

### ***License Agreement with Zenas BioPharma***

In October 2020, the Company became party to a license agreement with Zenas BioPharma (Cayman) Limited ("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 Accounting Standards Codification, Topic 808, *Collaborative Arrangements* ("ASC 808"). While this arrangement is in the scope of ASC 808, the Company applied ASC 606 to account for certain aspects of this arrangement. The Company applied ASC 606 for certain activities within the arrangement associated with the Company's transfer of a good or service (i.e., a unit of account) that is part of the Company's ongoing major or central operations. The Company allocated the transaction price based on the relative estimated standalone selling prices of each performance obligation or, in the case of certain variable consideration, to one or more performance obligations. Research and development activities are priced generally at cost. The Company's license of goods and services to Zenas BioPharma during the contract term was determined to be a single performance obligation satisfied over time. The Company will recognize the transaction price from the license agreement over the Company's estimated period to complete its activities.

At the inception of the arrangement, the Company evaluated whether the milestones were considered probable of being reached and estimated the amount to be included in the transaction price using the most likely amount

method. As it was not probable that a significant revenue reversal would not occur, none of the associated milestone payments were included in the transaction price at contract inception. For the sales-based royalties included in the arrangement, the license was deemed to be the predominant item to which the royalties relate. The Company will recognize royalty revenues at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). During the 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. During the three and nine months ended September 30, 2023, the Company recognized \$ 0.1 million and \$ 0.2 million, respectively, of collaboration revenue related to the Zenas Agreements.

In January 2024, the Company entered into a letter agreement with Zenas BioPharma (the "Zenas Letter Agreement") pursuant to which Zenas BioPharma agreed to support the Company's THRIVE-2 and STRIVE trials by initiating and managing the studies in China. Under the Zenas Letter Agreement, the Company agreed to reimburse costs incurred by Zenas BioPharma, including a full-time equivalent rate for services rendered. In connection with the execution of the Zenas Letter Agreement, the Company made an initial payment of \$ 1.5 million, which was recorded as research and development expense during the nine months ended September 30, 2024 as services were performed.

The Zenas Agreements are considered related party transactions because Fairmount Funds Management LLC ("Fairmount") beneficially owns more than 5 % of the Company's common stock and is also a 5 % or greater stockholder of Zenas BioPharma and has a seat on Zenas BioPharma's board of directors.

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

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

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

\$ 2.3 million (the "First Amendment Payment"), which was recorded as research and development expense during the three months ended December 31, 2022. The non-refundable upfront fee and the First Amendment Payment are separate from any development costs or cost advance paid or owing with respect to the specified program.

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

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

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 bases upon the achievement of specified clinical or regulatory milestones, with total milestone payments under all programs not to exceed \$ 40.0 million. Additionally, if the Company develops a product utilizing certain intellectual property rights granted to it under the Amended Paragon License Agreement, the Company is obligated to pay Paragon potential additional future development milestone payments of up to \$ 3.1 million and commercial milestone payments of up to \$ 17.0 million with respect to such product. If the Company successfully commercializes any product candidate subject to the Amended Paragon License Agreement, it is responsible for royalty payments equal to a percentage in the mid-single digits of such product's net sales.

During the 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 Research Agreement and Amended Paragon License Agreement (collectively, the "Paragon Agreements"). During the three and nine months ended September 30, 2023, the Company recorded \$ 1.1 million and \$ 6.5 million, respectively, in research and development costs related to the Paragon Agreements.

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.

## 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. In December 2021, the Company paid a \$ 2.5 million milestone payment to ImmunoGen upon the submission of an investigational new drug ("IND") application for veligrotug with the FDA. In May 2022, the Company paid a \$ 3.0 million milestone payment to ImmunoGen related to the first patient dosed in the clinical trial for veligrotug. In December 2022, the Company recorded \$ 10.0 million as research and development expense related to a milestone owed to ImmunoGen related to the first patient dosed in a pivotal clinical trial for veligrotug, amount which was paid in January 2023. Additionally, if the Company successfully commercializes any product candidate subject to the ImmunoGen License Agreement, it is responsible for royalty payments equal to a percentage in the mid-single digits of net sales and commercial milestone payments of up to \$ 95.0 million. The Company is obligated to make any such royalty payments on a product-by-product and country-by-country basis from the first commercial sale of a specified product in each country until the later of (i) the expiration of the last patent claim subject to the ImmunoGen License Agreement in such country, (ii) the expiration of any applicable regulatory exclusivity obtained for each product in such country, or (iii) the 12th anniversary of the date of the first commercial sale of such product in such country. On February 12, 2024, AbbVie Inc. acquired ImmunoGen. The terms of the ImmunoGen License Agreement did not change as a result of this acquisition.

### ***Development and License Agreement with Enable Injections***

In January 2023, the Company entered into a Development and License Agreement (the "Enable License Agreement") with Enable Injections, Inc. ("Enable"), under which Enable granted the Company an exclusive, royalty-bearing, sublicensable, non-transferrable license to (i) develop, commercialize, seek marketing approval for and otherwise use and exploit certain products, and (ii) make and have made such product solely for such permitted uses. Pursuant to the terms of the Enable License Agreement, the Company granted Enable a non-exclusive, royalty-free, non-sublicensable, non-transferable license. In consideration for the rights granted by Enable, the Company paid Enable an initial, non-creditable, non-refundable license fee of \$ 15.0 million in January 2023. This amount is included in research and development expense during the nine months ended September 30, 2023 in the accompanying condensed consolidated statement of operations and comprehensive loss.

The Company is obligated to make certain future milestone payments of up to \$ 45.0 million upon the achievement of specified development, clinical and regulatory milestones. Additionally, if the Company is successful in commercializing any product candidate subject to the Enable License Agreement, the Company is obligated to make certain commercial milestone payments of up to \$ 150.0 million and royalty payments equal to a percentage in the mid-single digits.

### ***Contingent Value Rights Agreement***

In accordance with the merger agreement with miRagen Therapeutics, Inc. ("miRagen"), on November 4, 2020, the Company entered into a contingent value rights agreement (the "CVR Agreement"), pursuant to which each holder of the Company's common stock as of November 6, 2020, other than former stockholders of the private entity Viridian Therapeutics, Inc. (which merged with miRagen), received one contingent value right (a "CVR") for each share of Company common stock held by such holder on that date. Under the CVR Agreement, holders

of CVRs would have been entitled to receive a portion of the net proceeds for any dispositions of certain legacy miRagen assets consummated through December 31, 2021. As of December 31, 2021, the disposition period had expired. There were no dispositions of any such legacy assets prior to that time and, accordingly, there will be no payments made under the CVR Agreement. The CVR Agreement expires on November 4, 2025.

**Exclusive License and Collaboration Agreement**

In May 2023, the Company and a third-party collaborator entered into an Exclusive License and Collaboration Agreement to collaborate and conduct certain IND-enabling activities with respect to the licensed compound and licensed product. Under the terms of the agreement, the Company was granted an exclusive, royalty-bearing, worldwide license to develop, manufacture, and commercialize certain licensed compounds and licensed products in the field (the "License"). In consideration for the rights granted by the License, the Company initially issued 204,843 shares of its common stock to certain stockholders of the third-party. The shares were valued at \$ 5.0 million and recorded as research and development expense during the three months ended June 30, 2023. On July 24, 2023, the Company issued 39,059 additional shares of its common stock to certain stockholders of the third-party and recorded the related \$ 0.7 million expense as research and development expenses during three months ended September 30, 2023. Additionally, upon the date when the Company decides to pursue certain studies for the licensed compound under the agreement, the Company shall issue the third-party collaborator the equivalent of \$ 10.0 million in shares of its common stock. The Company is also obligated to make certain future milestones of up to \$ 45.0 million upon the achievement of certain development milestones. Remaining development milestone payments shall be payable in cash. If the Company is successful in commercializing products related to the licensed compound, the Company is 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.

**Lease Obligations**

*Colorado-based Office and Lab Space*

The Company is party to a multi-year, non-cancelable lease agreement for its Colorado-based office and lab space (the "Colorado Lease"). The Colorado Lease includes rent escalation clauses through the lease term and a Company option to extend the lease term for up to three terms of three years each. Minimum base lease payments under the Colorado Lease, including the impact of tenant improvement allowances, are recognized on a straight-line basis over the full term of the lease. The lease term was amended in March 2021 to extend the lease maturity date to December 31, 2024. Upon adoption of ASC 842 and upon subsequent modification of the lease in 2020 and in March 2021, the Company recognized a right-of-use asset and corresponding lease liability for the Colorado Lease of approximately \$ 1.6 million by calculating the present value of lease payments, discounted at 6 %, the Company's estimated incremental borrowing rate, over the 12 months expected remaining term.

In September 2024, the Company entered into a new, multi-year lease agreement for its Colorado-based office and lab space (the "New Colorado Lease"). Under ASC 842, the New Colorado Lease was treated as a lease modification representing an extension of the lease term for a reduced portion of the space currently in use under the existing Colorado Lease. As of the effective date, the Company recorded a \$ 0.3 million increase in the right-of-use asset and corresponding lease liability for the extension of the lease term. The remaining space under the Colorado Lease will terminate 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.

*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 and April 2024, the "Massachusetts Lease"). The Massachusetts Lease includes rent escalation clauses throughout the lease term. Minimum base lease payments under the Massachusetts Lease are recognized on a straight-line basis over the full term of the Massachusetts Lease. Upon initial assumption of the Massachusetts Lease in October 2020, the Company recognized a right-of-use asset and corresponding lease liability of \$ 0.1 million by calculating the present value of lease payments, discounted at 6 %, the Company's estimated incremental borrowing rate, over the expected remaining term.

In April 2024, the Company entered into a Fourth Amendment of the Massachusetts Lease (the "Fourth Amendment"). The Fourth Amendment makes certain modifications to the Massachusetts Lease, including (i) securing 10,427 square feet of office space in a new building suite (the "New Premises"), (ii) the termination of the 10,956 square feet of leased space under the existing Massachusetts Lease (the "Original Premises"), and (iii) the extension of the expiration date of the leased space to five years from the delivery of the New Premises. The Massachusetts Lease provides for annual base rent of approximately \$ 0.5 million during the lease term. The Company is also obligated to pay the landlord certain costs, taxes and operating expenses. Under the Fourth Amendment, the Massachusetts Lease will expire in July 2029. The Company has the option to extend the lease term for an additional period of three years upon notice to the landlord.

The Company recorded a new right-of-use asset of \$ 1.6 million and corresponding lease liability of \$ 1.9 million for the New Premises and simultaneously derecognized the right-of-use asset of \$ 1.1 million and corresponding lease liability of \$ 1.2 million for the Original Premises on the lease commencement date in April 2024.

In September 2024, the Company entered into a Fifth Amendment of the Massachusetts Lease (the "Fifth Amendment") to lease an additional 2,788 square feet of office space in the same building. The Fifth Amendment provides for additional annual base rent of approximately \$ 0.1 million for the additional office space and includes annual base rent escalation clauses during the lease term. The Fifth Amendment was treated as a lease modification accounted for as a separate contract and the Company recorded a new right-of-use asset and corresponding lease liability of approximately \$ 0.5 million related to the Fifth Amendment on the lease commencement date.

Future lease payments under noncancelable leases as of September 30, 2024 are as follows:

	(in thousands)
2024 (remainder)	273
2025	723
2026	748
2027	613
2028	627
2029	370
<b>Total future minimum lease payments</b>	<b>3,354</b>
<b>Less: imputed interest</b>	<b>( 603 )</b>
<b>Total</b>	<b>\$ 2,751</b>

As of September 30, 2024, the Company's operating lease obligations were reflected as short-term operating lease liabilities of \$ 0.6 million within accrued liabilities and \$ 2.2 million of long-term lease obligations as other liabilities in the Company's condensed consolidated balance sheets.

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, which was included in operating expense in the 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 \$ 0.6 million for the three and nine months ended September 30, 2023.

The Company is also required to pay for certain costs, taxes, and operating expenses related to both the Colorado Lease and Massachusetts Lease, which were \$ 0.1 million and \$ 0.3 million for the three and nine months ended September 30, 2024 and 2023, respectively. The operating expenses are incurred separately and were not included in the present value of lease payments.

## **8. CAPITAL STOCK**

### ***Common Stock***

Under the Company's second restated certificate of incorporation, the Company is authorized to issue 205,000,000 shares of its stock, of which 200,000,000 shares have been designated as common stock and 5,000,000 shares have been designated as preferred stock, both with a par value of \$ 0.01 per share. The number of authorized shares of common stock may be increased or decreased by the affirmative vote of the holders of a majority of the Company's stock who are entitled to vote. Each share of common stock is entitled to one vote. The holders of common stock are entitled to receive dividends when and as declared or paid by its board of directors.

### ***Common Stock Sales Agreements - Jefferies LLC***

In September 2022, the Company entered into an Open Market Sale Agreement <sup>SM</sup> (the "September 2022 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 \$ 175.0 million from time to time at prices and on terms to be determined by market conditions at the time of offering, with Jefferies acting as its sales agent. Jefferies will receive a commission of 3.0 % of the gross proceeds of any shares of common stock sold under the September 2022 ATM Agreement. No shares were sold under the September 2022 ATM Agreement during the three months ended September 30, 2024 and 2023. During the nine months ended September 30, 2024, the Company sold 1,561,570 shares under the September 2022 ATM Agreement with Jefferies 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. No shares were sold under the September 2022 ATM Agreement during the nine months ended September 30, 2023.

### ***Private Placements***

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

### ***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 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.

#### **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 preferred stock, at its discretion, in one or more classes or series and to fix the powers, preferences and rights, and the qualifications, limitations, or restrictions thereof, including dividend rights, conversion rights, voting rights, terms of redemption, and liquidation preferences, without further vote or action by the Company's stockholders.

##### *Series A Preferred Stock*

Holders of Series A Preferred Stock are entitled to receive dividends on shares of Series A 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 Preferred Stock does not have voting rights. However, as long as any shares of Series A 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 Preferred Stock, (i) alter or change adversely the powers, preferences or rights given to the Series A 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 Preferred Stock, (iv) increase the number of authorized shares of Series A Preferred Stock, (v) at any time while at least 30 % of the originally issued Series A 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 Preferred Stock does not have a preference upon any liquidation, dissolution, or winding-up of the Company. Each share of Series A 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 Preferred Stock is prohibited from converting shares of Series A 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, 2024 and December 31, 2023, there were 134,864 and 172,435 shares of Series A Preferred Stock outstanding, respectively. During the nine months ended September 30, 2024, 37,571 shares of Series A Preferred Stock were converted into 2,504,855 shares of common stock.

##### *Series B Preferred Stock*

Each share of Series B Preferred Stock is convertible into 66.67 shares of common stock, subject to certain limitations, including that a holder of Series B Preferred Stock is prohibited from converting shares of Series B 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 4.9 % and 19.9 %) 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 Preferred Stock are set forth in the Certificate of Designation filed in September 2021.

Holders of Series B Preferred Stock are entitled to receive dividends on shares of Series B 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 Preferred Stock does not have voting rights. However, as long as any shares of Series B 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 Preferred Stock, (i) alter or change adversely the powers, preferences or rights given to the Series B 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 Preferred Stock. The Series B Preferred Stock does not have a preference upon any liquidation, dissolution, or winding-up of the Company.

As of September 30, 2024 and December 31, 2023, there were 145,160 and 143,522 shares of Series B Preferred Stock outstanding, respectively. During the nine months ended September 30, 2024, 18,362 of Series B Preferred Stock were converted into 1,224,193 shares of common stock.

## 9. WARRANTS

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

	Number of Underlying Shares (1)			Remaining Contractual Life at September 30, 2024 (No. Years)
	September 30, 2024	December 31, 2023	Weighted-Average Exercise Price at September 30, 2024	
<b>Liability-classified warrants</b>				
Issued April 2017	781	781	\$ 127.95	0.58
<b>Equity-classified warrants</b>				
Acquired October 2020	29,446	29,446	\$ 0.02	5.98
Issued February 2020 (2)	218,050	218,050	\$ 14.44	0.37
Issued November 2017	1,606	1,606	\$ 0.69	0.12
Subtotal	249,102	249,102	\$ 15.15	
<b>Total warrants</b>	<b>249,883</b>	<b>249,883</b>	<b>\$ 15.51</b>	

(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.

[Table of Contents](#)

A summary of the Company's warrant activity during the nine months ended September 30, 2024 is as follows:

	Common Stock Warrants	
	Number	Weighted Average Exercise Price
Outstanding at December 31, 2023	249,883	\$ 15.51
Exercised	—	\$ —
Outstanding at September 30, 2024	249,883	\$ 15.51

## 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. The 2016 Plan will terminate on April 19, 2034.

As of September 30, 2024, the Company had the following balances by plan:

	Restricted Stock Units Outstanding	Stock Options Outstanding	Shares Available for Issuance
Inducement Awards	—	5,663,625	—
2020 Plan	—	125,396	—
2016 Plan	514,540	5,563,042	4,639,444
2008 Plan	—	24	—
<b>Total</b>	<b>514,540</b>	<b>11,352,087</b>	<b>4,639,444</b>

### *Restricted Stock Units*

RSUs granted under the Equity Incentive Plans and the Inducement Awards generally vest annually over a 4-year period and are settled in shares of the Company's common stock.

A summary of RSU activity is as follows:

[Table of Contents](#)

	RSUs	Weighted-Average Date Fair Value
Nonvested, December 31, 2023	804,947	\$ 15.82
Granted	5,428	\$ 18.85
Vested	( 19,115 )	\$ 35.40
Forfeited	( 276,720 )	\$ 16.33
Nonvested, September 30, 2024	<u><u>514,540</u></u>	<u><u>\$ 14.85</u></u>

**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	Remaining Contractual Term (years)	Weighted-Average Remaining Contractual Term (years)		Aggregate Intrinsic Value (in thousands)
				Weighted-Average Exercise Price	Remaining Contractual Term (years)	
Outstanding as of December 31, 2023	11,533,484	\$ 19.68	8.50	<u><u>\$ 54,772</u></u>	<u><u>8.50</u></u>	<u><u>\$ 54,772</u></u>
Granted	2,996,156	\$ 15.08				
Exercised	( 232,006 )	\$ 9.31				
Forfeited or expired	( 2,945,547 )	\$ 22.58				
Outstanding as of September 30, 2024	<u><u>11,352,087</u></u>	<u><u>\$ 17.93</u></u>	<u><u>8.05</u></u>	<u><u>\$ 68,434</u></u>	<u><u>8.05</u></u>	<u><u>\$ 68,434</u></u>
Vested and expected to vest as of September 30, 2024	<u><u>11,352,087</u></u>	<u><u>\$ 17.93</u></u>	<u><u>8.05</u></u>	<u><u>\$ 68,434</u></u>	<u><u>8.05</u></u>	<u><u>\$ 68,434</u></u>
Exercisable as of September 30, 2024	<u><u>3,324,526</u></u>	<u><u>\$ 21.66</u></u>	<u><u>5.39</u></u>	<u><u>\$ 9,890</u></u>	<u><u>5.39</u></u>	<u><u>\$ 9,890</u></u>
Vested as of September 30, 2024	<u><u>3,324,526</u></u>	<u><u>\$ 21.66</u></u>	<u><u>5.39</u></u>	<u><u>\$ 9,890</u></u>	<u><u>5.39</u></u>	<u><u>\$ 9,890</u></u>

**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, 2024 and 2023 was \$ 10.83 and \$ 23.19 , respectively. The fair value was determined by the Black-Scholes option pricing model using the following weighted-average assumptions:

	Nine Months Ended September 30,	
	2024	2023
Expected term, in years	5.11	5.57
Expected volatility	88.8 %	90.8 %
Risk-free interest rate	4.3 %	3.8 %
Expected dividend yield	— %	— %
Weighted average exercise price	\$ 15.08	\$ 31.07

**Employee Stock Purchase Plan**

The 2016 Employee Stock Purchase Plan ("ESPP") allows qualified employees to purchase shares of common stock at a price equal to 85 % of the lower of: (i) the closing price at the beginning of the offering period or (ii) the closing price at the end of the offering period. As of September 30, 2024, the Company had 1,187,109 shares available for issuance, and 102,426 cumulative shares had been issued under the ESPP.

**Share-Based Compensation Expense**

Share-based compensation related to all equity awards issued pursuant to the Equity Incentive Plans, the Inducement Awards, and for estimated shares to be issued under the ESPP for the purchase periods active during each respective period is included in the condensed consolidated statements of operations and comprehensive loss as follows:

	Three Months Ended September 30,		Nine Months Ended September 30, 2024	
	2024	2023	2024	2023
	(in thousands)		(in thousands)	
Research and development	\$ 4,673	\$ 4,003	\$ 17,142	\$ 11,671
General and administrative	4,047	9,603	16,033	29,453
<b>Total share-based compensation expense</b>	<b>\$ 8,720</b>	<b>\$ 13,606</b>	<b>\$ 33,175</b>	<b>\$ 41,124</b>

During the nine months ended September 30, 2024, the Company recorded an additional \$ 4.6 million in share-based compensation related to the acceleration of vesting for former executive officers, an amount which includes \$ 0.3 million related to the modification of the terms of options outstanding at the time of termination for one executive which would have otherwise forfeited. The Company also recorded \$ 2.0 million in share-based compensation related to the accounting for a modification of the equity awards to extend the post-termination exercise period of certain vested stock options for a former executive.

During the nine months ended September 30, 2023, the Company recorded an additional \$ 9.1 million in share-based compensation related to the acceleration of vesting for former executive officers, an amount which includes \$ 1.6 million related to the modification of the terms of options outstanding at the time of termination for one executive which would have otherwise forfeited.

As of September 30, 2024, the Company had \$ 87.1 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 2.95 years. As of September 30, 2024, the Company had \$ 5.9 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 3.03 years.

## 11. NET LOSS PER SHARE

Basic net loss per share is computed by dividing the net loss available to common stockholders by the weighted-average number of common stock outstanding. Diluted net loss per share is computed similarly to basic net loss per share except that the denominator is increased to include the number of additional shares of common stock that would have been outstanding if the potential shares of common stock had been issued and if the additional shares of common stock were dilutive. Diluted net loss per share is the same as basic net loss per share of common stock, as the effects of potentially dilutive securities are antidilutive.

Potentially dilutive securities include the following:

	September 30,	
	2024	2023
Series A Preferred Stock (as converted to shares of common stock)	8,991,383	11,496,241
Series B Preferred Stock (as converted to shares of common stock)	9,677,817	3,414,171
Options to purchase common stock	11,352,087	8,261,261
Warrants to purchase common stock	249,883	249,883
Restricted stock units	514,540	338,875
<b>Total</b>	<b>30,785,710</b>	<b>23,760,431</b>

## **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 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, 2023 included in our Annual Report on Form 10-K filed with the SEC on February 27, 2024 ("2023 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, including antibodies, 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 for TED, development of anti-neonatal Fc receptor therapies, and nonclinical and clinical development for indications in rare and autoimmune diseases.

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

We have first prioritized the development of 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® (tepotumumab), which is an intravenously administered monoclonal antibody that targets IGF-1R. Tepezza® is marketed in the United States by Horizon Therapeutics plc (“Horizon”), which was acquired by Amgen Inc. (“Amgen”) in October 2023.

The results from clinical trials of tepotumumab conducted by Horizon provide strong clinical validation linking the targeting of IGF-1R to clinical benefit in patients with TED. However, clinical trials evaluating tepotumumab 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 tepotumumab’s features, including dosing schedule, route of administration, and safety profile.

We are developing two product candidates, veligrotug (formerly known as VRDN-001) for intravenous 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* preclinical data, we showed that veligrotug is a potentially differentiated full antagonist of IGF-1R, compared to tepotumumab’s incomplete antagonism of IGF-1R. We also 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 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. 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 SAEs. Veligrotug additionally showed a rapid onset of action, with the majority (53%) of veligrotug-treated patients achieving a proptosis response after just one infusion, or three weeks after start of therapy. We completed enrollment of THRIVE-2 in July 2024, and expect to announce topline data for this study by the end of 2024. 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 tepotumumab, the currently marketed IGF-1R inhibitor. In addition, to meet the 300 patient standard safety database requirements for the veligrotug biologics license application (“BLA”), we are actively enrolling patients into our STRIVE clinical trial. 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). We are also enrolling patients in the open label extension study for non-responding patients in THRIVE and THRIVE-2. We anticipate filing a BLA for veligrotug in the second half of 2025.

In addition to our veligrotug IV program, in December 2023 we selected VRDN-003 as our subcutaneous product candidate for pivotal development in TED following positive data in a phase 1 clinical trial in healthy volunteers. 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. VRDN-003 has the same binding domain as veligrotug, and was engineered to have a longer half-

## [Table of Contents](#)

life. VRDN-003 is designed to be a low-volume, self-administered, infrequently dosed subcutaneous IGF-1R for TED, which we plan to launch commercially with an auto-injector.

The VRDN-003 phase 1 clinical study showed VRDN-003 to have a prolonged half-life of 40 to 50 days, which is four to five times that of veligrotug. Because of the healthy volunteer data and the similarities between the veligrotug and VRDN-003 antibodies, we expect VRDN-003 to have similar clinical responses at the exposure levels of veligrotug that led to robust clinical activity in its clinical trials to date in TED. Further, pharmacokinetic modeling of VRDN-003 based on the healthy volunteer data predicted that exposure levels of VRDN-003 could be achieved that are equivalent to exposure levels of veligrotug that produced clinically meaningful results with multiple dosing regimens of VRDN-003, i.e., subcutaneous injection every two, four, or eight weeks. We are advancing our VRDN-003 program, including the initiation of two global phase 3 clinical trials for VRDN-003 in August 2024: REVEAL-1 and REVEAL-2 in active and chronic TED, respectively. Both studies will evaluate subcutaneous VRDN-003 administered every four weeks or every eight weeks and will assess outcomes versus placebo. We also anticipate that the program will include a safety study to complete a 300 patient standard safety database (to include patients from the REVEAL-1 and REVEAL-2 trials), and we expect that it will also include the required development to have an auto-injector device available at the time of commercial launch, if approved. We anticipate topline data for REVEAL-1 and REVEAL-2 in the first half of 2026, and we anticipate submitting a BLA for VRDN-003 for the treatment of TED by the end of 2026.

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

VRDN-006 is a FcRn-targeting Fc fragment, and in non-human primate studies, demonstrated specificity for blocking FcRn-IgG interactions while not showing decreases in albumin or increases in LDL levels, which are known potential side effects associated with certain full-length anti-FcRn monoclonal antibodies. In our head-to-head non-human primate 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 plan to file an IND for VRDN-006 by the end of 2024 and expect healthy volunteer data for VRDN-006 in the second half of 2025. VRDN-008 is a novel, potential first-in-class FcRn inhibitor that aims to pair IgG suppression with extended half-life technology, potentially enabling deeper and more durable suppression of IgG than existing anti-FcRn therapies. Both molecules are designed to be convenient, self-administered, subcutaneous products.

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

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

### **Research and Development Expenses**

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

- employee-related expenses, including salaries, severance, retention, benefits, insurance, and share-based compensation expense;
- expenses incurred under agreements with 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 preclinical materials, including costs incurred under agreements with contract manufacturing organizations ("CMOs");
- costs associated with non-clinical 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 preclinical 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, preclinical data, competition, manufacturability, and commercial viability of our product candidates.

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

#### **General and Administrative Expenses**

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

#### **Other Income, net**

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

#### **Critical Accounting Policies and Estimates**

There were no changes to our critical accounting policies as disclosed in our 2023 Annual Report on Form 10-K during the nine months ended September 30, 2024. Our significant accounting policies are disclosed in Note 2. *Summary of Significant Accounting Policies* to our 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, 2024 and 2023.

	Three Months Ended September 30,			Increase (Decrease)
	2024		2023	
	(in thousands)			
Collaboration revenue - related party	\$ 86	\$ 72	\$ 14	
Research and development expenses	69,158	30,385	38,773	
General and administrative expenses	14,408	20,911	(6,503)	
Other income, net	6,791	3,564	3,227	

#### **Revenue**

Revenue for both the three months ended September 30, 2024 and 2023 was attributable to our collaboration agreement with Zenas BioPharma.

#### **Research and Development Expenses**

Research and development expenses were \$69.2 million during the three months ended September 30, 2024, compared to \$30.4 million during the three months ended September 30, 2023. The \$38.8 million increase in research and development expenses is primarily attributable to the following:

- \$17.4 million increase in clinical trial costs mainly due to expenses associated with our ongoing THRIVE and THRIVE-2 clinical trials;
- \$10.6 million increase in chemistry, manufacturing and controls costs to support our ongoing and planned clinical trials;
- \$3.3 million increase in milestone, license and option fees due to the \$4.0 million upfront payment to Paragon for an exclusive license agreement during the three months ended September 30, 2024;
- \$4.3 million increase in preclinical research costs to advance our FcRn inhibitor portfolio; and
- \$2.9 million increase in personnel related costs, due primarily to increased headcount to support our ongoing research and development efforts, including share-based compensation and other employee compensation and recruiting costs.

We expect our research and development expenses to increase as we continue to advance our clinical and preclinical programs.

**General and Administrative Expenses**

General and administrative expenses were \$14.4 million during the three months ended September 30, 2024, compared to \$20.9 million during the three months ended September 30, 2023. The \$6.5 million decrease in general and administrative expenses is primarily attributable to a \$7.1 million decrease in personnel-related costs, primarily due to a decrease in headcount and a decrease in share-based compensation and other employee compensation and recruiting costs. This decrease is partially offset by a \$0.7 million increase in market research and other professional services fees.

**Other Income, net**

Other income, net was \$6.8 million during the three months ended September 30, 2024 compared to \$3.6 million during the three months ended September 30, 2023. Other income, net for the three months ended September 30, 2024 is comprised of \$7.5 million of interest income earned on short-term investments, \$0.2 million gain on investment as well as \$0.1 million of sub-lease income, offset by \$0.5 million in interest expense related to our Hercules Loan and Security Agreement and \$0.4 million loss on disposal of equipment. Other income, net for the three months ended September 30, 2023 is comprised of \$4.1 million of interest income earned on short-term investments as well as \$0.1 million of sub-lease income, partially offset by \$0.4 million in interest expense related to our Hercules Loan and Security Agreement and a \$0.2 million loss on debt extinguishment related to the Hercules Amendment. The increase in interest income, as compared to prior year, is primarily attributable to higher average short-term investment balances during the three months ended September 30, 2024 as compared to the three months ended September 30, 2023.

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

	Nine Months Ended September 30,			Increase (Decrease)
	2024		2023	
	(in thousands)			
Collaboration revenue - related party	\$ 230	\$ 242	\$ (12)	
Research and development expenses	166,294	121,208	45,086	
General and administrative expenses	45,499	62,006	(16,507)	
Other income, net	21,339	12,098	9,241	

**Revenue**

Revenue for both the nine months ended September 30, 2024 and 2023 was attributable to our collaboration agreement with Zenas BioPharma.

Research and development expenses were \$166.3 million during the nine months ended September 30, 2024, compared to \$121.2 million during the nine months ended September 30, 2023. The \$45.1 million increase in research and development expenses is primarily attributable to the following:

- \$37.6 million increase in clinical trial costs mainly due to expenses associated with our ongoing THRIVE and THRIVE-2 clinical trials;
- \$8.5 million increase in chemistry, manufacturing and controls costs to support our ongoing and planned clinical trials;

- \$4.2 million increase in severance costs primarily related to separation agreements with former executive officers, including a \$3.2 million increase in share-based compensation related to the acceleration of stock option vesting during the nine months ended September 30, 2024;
- \$8.1 million increase in personnel related costs, due primarily to increase in headcount to support our ongoing research and development efforts, including increased share-based compensation and other employee compensation and recruiting costs;
- \$2.4 million increase in professional service fees for consultants and contractors to support ongoing programs; and
- \$0.9 million increase in preclinical research costs to advance our FcRn inhibitor portfolio.

These increases are partially offset by a \$16.7 million decrease in milestone, license and option fees as a result of the \$15.0 million upfront payment for development of subcutaneous delivery systems and the \$5.7 million upfront payment for an exclusive license and collaboration agreement incurred during the nine months ended September 30, 2023, offset by the \$4.0 million upfront payment to Paragon for an exclusive license agreement during the nine months ended September 30, 2024.

We expect our research and development expenses to increase as we continue to advance our clinical and preclinical programs.

#### ***General and Administrative Expenses***

General and administrative expenses were \$45.5 million during the nine months ended September 30, 2024, compared to \$62.0 million during the nine months ended September 30, 2023. The \$16.5 million decrease in general and administrative expenses is primarily attributable to the following:

- \$8.2 million decrease in severance costs primarily related to separation agreements with former executive officers, including a \$5.7 million decrease in share-based compensation related to the modification and acceleration of stock option vesting for former executives. Share-based compensation costs for the nine months ended September 30, 2024 included \$3.4 million in costs related to the modification and acceleration of vesting for former executive officers as compared to \$9.1 million for the nine months ended September 30, 2023; and
- \$8.8 million decrease in personnel-related costs, primarily due to a decrease in headcount and a decrease in share-based compensation and other employee compensation and recruiting costs.

These decreases were partially offset by a \$0.9 million increase in consulting and other professional services fees.

#### ***Other Income, net***

Other income, net was \$21.3 million during the nine months ended September 30, 2024 compared to \$12.1 million during the nine months ended September 30, 2023. Other income, net for the nine months ended September 30, 2024 is comprised of \$23.1 million of interest income earned on cash equivalents and short-term investments, \$0.2 million gain on investment as well as \$0.3 million of sub-lease income, offset by \$1.7 million in interest expense related to our Hercules Loan and Security Agreement and \$0.4 million loss on disposal of equipment. Other income, net for the nine months ended September 30, 2023 is comprised of \$12.8 million of interest income earned on cash equivalents and short-term investments as well as \$0.2 million of sub-lease income, partially offset by \$0.8 million in interest expense related to our Hercules Loan and Security Agreement and a \$0.2 million loss on debt extinguishment related to the Hercules Amendment. The increase in

interest income, as compared to prior year, is primarily attributable to higher average cash equivalent and short-term investment balances during the nine months ended September 30, 2024 as compared to the nine months ended September 30, 2023.

### **Liquidity and Capital Resources**

We have funded our operations to date principally through proceeds received from the sale of our common stock, our Series A Preferred Stock, our Series B Preferred Stock and other equity securities, debt financings, license fees, and reimbursements received under collaboration agreements. As of September 30, 2024, we had \$753.2 million in cash, cash equivalents, and short-term investments. We expect that our current cash, cash equivalents and short-term investments will be sufficient to fund our operations, including our clinical development plan described above, into the second half of 2027. In addition, as of September 30, 2024, the Company has access to additional undrawn funds under the Hercules Amended Term Loan, as described below.

We have no products approved for commercial sale and have not generated any revenue from product sales. Since our inception and through September 30, 2024, we have generated an accumulated deficit of \$916.1 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.

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

Our commitments primarily consist of obligations under our collaboration, development, and license agreements. Under these agreements, we are required to make milestone payments upon successful completion of certain regulatory and sales milestones. The payment obligations under the license agreements are contingent upon future events such as our achievement of specified development, regulatory and commercial milestones and we will be required to make development milestone payments and royalty payments in connection with the sale of products developed under these agreements. As of September 30, 2024, we were unable to estimate the timing or likelihood of achieving the milestones or making future product sales. For additional information regarding our agreements, see Note 6 and Note 7 to our condensed consolidated financial statements included elsewhere in this report.

Our operating lease obligations primarily consist of lease payments on our lab and office facilities in Boulder, Colorado and our office space in Waltham, Massachusetts. For additional information regarding our lease obligations, see Note 7 to our condensed consolidated financial statements included elsewhere in this report.

Additionally, we have entered into agreements with third-party contract manufacturers for the manufacture and processing of certain of our product candidates for clinical testing purposes, and we have entered and will enter into other contracts in the normal course of business with contract research organizations for clinical trials and

other vendors for other services and products for operating purposes. These agreements generally provide for termination or cancellation with appropriate notice, other than for costs already incurred. We expect to enter into additional clinical development, contract research, clinical and commercial manufacturing, supplier and collaborative research agreements in the future, which may require upfront payments and long-term commitments of capital resources.

If we raise additional funds through the issuance of debt, the obligations related to such debt could be senior to rights of holders of our capital stock and could contain covenants that may restrict our operations. Should additional capital not be available to us in the near term, or not be available on acceptable terms, we may be unable to realize value from our assets and discharge our liabilities in the normal course of business, which may, among other alternatives, cause us to further delay, substantially reduce, or discontinue operational activities to conserve our cash resources.

***Loan and Security Agreement with Hercules Capital, Inc.***

On April 1, 2022, we entered into a loan and security agreement (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 Capital, Inc. ("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 through June 15, 2023.

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

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

Under the Hercules Amendment, the Lenders provided the Company access to an increased term loan with an aggregate principal amount of up to \$150 million, in four tranches (collectively the "Amended Term Loan"), consisting of (1) an initial tranche of \$50.0 million, \$5.0 million of which was drawn at closing of the Hercules Loan and Security Agreement in April 2022, \$15.0 million of which was drawn at closing of the Hercules Amendment in August 2023, \$5.0 million of which was available through December 15, 2023, and \$25.0 million available from July 1, 2024 through December 15, 2024; (2) a second tranche of \$20.0 million, subject to achievement of certain regulatory milestones, available through February 15, 2025; (3) a third tranche of \$20.0 million, subject to achievement of certain regulatory milestones, available through March 31, 2025; and (4) a fourth tranche of \$60.0 million subject to approval by the Lenders' investment committee(s), available through June 15, 2025. The milestones for the second and third tranches have not yet been achieved. The obligations of the Borrower under the Hercules Amendment agreement are secured by substantially all of the assets of the Borrower, excluding the Borrower's intellectual property. The Amended Term Loan has a maturity date of October 1, 2026.

The Amended Term Loan bears interest at a floating per annum rate equal to the greater of (i) 7.45% and (ii) 4.2% above the Prime Rate (as defined therein), provided that the Term Loan interest rate shall not exceed a per

annum rate of 8.95%. Interest is payable monthly in arrears on the first day of each month. The interest rate as of September 30, 2024 was 8.95%.

Per the terms of the Hercules Amendment, we were originally obligated to make interest-only payments through April 1, 2025. Upon achievement of certain development milestones related to our topline results for our phase 3 THRIVE trial in September 2024, the interest-only period was extended to October 1, 2025. If additional development milestones are met, the interest-only period will be 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.

#### **Public Offerings**

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

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

#### **Private Placements**

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

#### **ATM Agreement**

In September 2022, we entered into an Open Market Sale Agreement <sup>SM</sup> (the "September 2022 ATM Agreement") with Jefferies pursuant to which we may offer and sell shares of our common stock having an aggregate offering price of up to \$175.0 million from time to time at prices and on terms to be determined by market conditions at the time of offering, with Jefferies acting as the sales agent. Jefferies will receive a commission of 3.0% of the gross proceeds of any shares of common stock sold under the September 2022 ATM Agreement. During the year ended December 31, 2023, the Company sold 684,298 shares under the September 2022 ATM Agreement with Jefferies at a weighted average price of \$22.30 per share, for aggregate net proceeds of approximately \$14.8 million, including commissions to Jefferies as a sales agent. During the nine months ended September 30, 2024, we sold 1,561,570 shares under the September 2022 ATM Agreement with Jefferies 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. During the three months ended September 30, 2024, there were no sales under the September 2022 ATM Agreement.

Summarized cash flows for the nine months ended September 30, 2024 and 2023 are as follows:

	Nine Months Ended September 30,			Increase (Decrease)
	2024		2023	
	(in thousands)			
<b>Net cash provided by (used in):</b>				
Operating activities	\$ (158,987)	\$ (146,170)	\$ (12,817)	
Investing activities	(165,736)	75,459	(241,195)	
Financing activities	422,213	26,729	395,484	
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>\$ 97,490</b>	<b>\$ (43,982)</b>	<b>\$ 141,472</b>	

#### ***Operating Activities***

Net cash used in operating activities was \$159.0 million for the nine months ended September 30, 2024, and primarily consisted of our net loss of \$190.2 million, adjusted for non-cash items of \$22.1 million (primarily share-based compensation of \$33.2 million, offset by the 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.

Net cash used in operating activities was \$146.2 million for the nine months ended September 30, 2023, and primarily consisted of a net loss of \$170.9 million, adjusted for non-cash items of \$39.7 million (primarily share-based compensation of \$41.1 million) and changes in working capital of \$15.0 million. The change in working capital was primarily related to a net decrease of \$10.3 million in accounts payable and accrued and other liabilities and an increase of \$4.5 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 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 and \$0.4 million in purchases of property and equipment.

Net cash provided by investing activities was \$75.5 million during the nine months ended September 30, 2023, and consisted primarily of \$76.3 million in net maturities of short-term investments, offset by \$0.9 million in purchases of property and equipment.

### **Financing Activities**

Net cash provided by financing activities was \$422.2 million during the nine months ended September 30, 2024, and consisted of 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 and \$0.7 million in proceeds from the issuance of common stock under our employee stock purchase plan.

Net cash provided by financing activities was \$26.7 million during the nine months ended September 30, 2023, and consisted primarily of \$14.5 million in net proceeds from the Hercules Amendment, as well as \$9.8 million in proceeds from the exercise of stock options, \$1.9 million in proceeds from the exercise of warrants and \$0.6 million in proceeds from the issuance of common stock under our employee stock purchase plan.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

There were no material changes to our market risks in the nine months ended September 30, 2024, when compared to the disclosures in Item 7A of our 2023 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, 2024 and 2023, our net loss was \$190.2 million and \$170.9 million, respectively. As of September 30, 2024, we had an accumulated deficit of \$916.1 million and cash, cash equivalents, and short-term investments of \$753.2 million.

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

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

We have devoted substantially all of our financial resources to identify, acquire, and develop our product candidates, including conducting clinical trials and providing general and administrative support for our operations. To date, we have financed our operations primarily through the sale of equity securities, convertible promissory notes and the Hercules Loan and Security Agreement. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations, or grants. 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 preclinical studies or clinical trials for our product candidates;
- seek regulatory and marketing approvals 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, 2024, we had \$753.2 million of cash, cash equivalents, and short-term investments. We believe that our current cash, cash equivalents and short-term investments, will be sufficient to fund our operations, including our clinical development plan, into the second half of 2027. We will need to raise additional capital to continue to fund our operations and service our obligations in the future. If we are unable to raise additional capital when needed, we will not be able to continue as a going concern.

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

We do not currently have any products approved for sale and do not generate any revenue from product sales. Accordingly, we expect to rely primarily on equity and/or debt financings to fund our continued operations. Our ability to raise additional funds will depend, in part, on the success of our preclinical 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 assurance that sufficient funds will be available to us when required or on acceptable terms, if at all.

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

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

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

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

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

- completing research and development of our product candidates;
- obtaining regulatory and marketing approvals for our product candidates;
- manufacturing product candidates and establishing and maintaining supply and manufacturing relationships with third parties that are commercially feasible, meet regulatory requirements and our supply needs in sufficient quantities to meet market demand for our product candidates, if approved;
- establishing and maintaining a commercial supply chain for our product candidates in the countries or regions in which we obtain regulatory approval for them, including receipt and maintenance of necessary licenses, permits, or similar permissions, either directly or with a collaborator or distributor;
- marketing, launching, and commercializing product candidates for which we obtain regulatory and marketing approval, either directly or with a collaborator or distributor;
- gaining market acceptance of our product candidates as treatment options;
- addressing any competing products;
- developing, protecting and enforcing our intellectual property rights, including patents, trade secrets, and know-how;
- 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 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, 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, or declaring dividends.

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

To the extent that we raise additional capital through the sale of equity, including pursuant to any sales under our September 2022 ATM Agreement with Jefferies, convertible debt, or other securities convertible into equity, the ownership interest of our stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our stockholders. Any additional sales of our capital stock by us will dilute the ownership interest of our stockholders and may cause the price per share of our common stock to decrease. In addition, any exercise of outstanding warrants will dilute the ownership interest of our stockholders and may cause the price per share of our common stock to decrease.

Debt financing, including under our Hercules Loan and Security Agreement, may include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, making additional product acquisitions, or declaring dividends. If we raise additional funds through strategic collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates or future revenue streams or grant licenses on terms that are not favorable to us. 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, CMOs, and other contractors and consultants, could be subject to acts of war, earthquakes, power shortages, information technology and telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, governmental actions, medical pandemics or epidemics, such as the novel coronavirus, and other natural or man-made disasters or business interruptions, for which we are partly uninsured. In addition, we rely on our third-party research institution collaborators for conducting research and development of our product candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

**Risks Related to the Discovery and Development of Our Product Candidates**

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

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

- inability to generate satisfactory preclinical, 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 CMOs, 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 ("GCP"), current good laboratory practice ("GLP"), 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 and 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 are expecting that that the THRIVE and THRIVE-2 phase 3 clinical trials, together with a safety database comprising 300 treated patients, will support global health authority registration for 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. In August 2024, we initiated a pivotal program for VRDN-003. We may be required to take other additional steps in the course of development and regulatory interaction regarding our product candidates, including veligrotug and VRDN-003. Such additional steps may include, without limitation, initiating new trials, starting at an earlier phase of clinical trial, conducting bridging studies, enrolling more patients, amending trial protocols, or requiring us to assess additional parameters related to safety or efficacy. For example, we may make adjustments to the VRDN-003 clinical trial designs as a result of the veligrotug data. 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 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.

***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 preclinical 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.

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

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

Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical 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 preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA, supplementary BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the number of participants required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate or we may fail to recruit suitable participants for a trial;
- our third-party contractors may fail to comply with data quality and regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulatory authorities may believe that we have not sufficiently demonstrated our ability to manufacture our candidates to the requisite level of quality standards, including that such material is sufficiently comparable to material used in previous clinical trials, or they may fail to approve our manufacturing processes or facilities, or the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- regulatory authorities may conclude that on-site inspections and data audits have not sufficiently demonstrated the quality and integrity of the clinical trial conduct and of data submitted to regulatory authorities in support of our new product approvals and marketing applications;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- our product candidates may have undesirable side effects, toxicities or other unexpected characteristics, causing us or our investigators, regulatory authorities, institutional review boards or ethics committees to reject, suspend or terminate the clinical trials; and
- the approval policies or regulations of regulatory authorities may significantly change in a manner rendering our clinical data, biologic manufacturing process and other supporting information insufficient for approval.

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

successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our current or future product candidates.

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

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

We are or may develop our product candidates in areas with existing investigational and/or approved products where such products may have known risk profiles. Undesirable side effects caused by our product candidates, or other product candidates, including in the TED space, 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.

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 2023 Annual Report on Form 10-K.

***Our product development program may not uncover all possible adverse events that patients or subjects who take our product candidates may experience. The number of patients or subjects exposed to our product candidates and the average exposure time in the clinical development program may be inadequate to detect rare adverse events that may only be detected once the product is administered to more patients or subjects and for greater periods of time.***

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.

***We are heavily dependent on the success of our product candidates, 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.***

We have invested substantially all of our effort and financial resources to identify, acquire, and develop our portfolio of product candidates. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for and commercialize one or more product candidates. We currently generate no revenue from sales of any products, and we may never be able to develop or commercialize a product candidate. We continue to evaluate and pursue additional opportunities to expand our product pipeline, either by discovering novel antibodies or proteins internally, or by acquiring rights to existing antibodies or antibody sequences or proteins and protein sequences. Our goal is to build a sustainable portfolio of protein and antibody therapies.

We currently have a limited number of product candidates. There can be no assurance that the data that we may or may not develop for our product candidates in our planned indications will be sufficiently supportive to obtain regulatory approval.

We are not permitted to market or promote any of our product candidates before they receive regulatory approval from the FDA, EMA, or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

***Product development involves a lengthy and expensive process with an uncertain outcome, and results of earlier preclinical 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 preclinical 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 preclinical 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 preclinical and clinical data are often susceptible to varying interpretations and analyses. Third parties upon whom we rely may analyze data differently than others, or differently than we do. As a result, they or we may reach different conclusions regarding the results of our studies, including our clinical studies.

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

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

From time to time, we publish preliminary data from our clinical trials. On December 18, 2023, we reported clinical data from our phase 1 clinical study in healthy volunteers and announced the selection of VRDN-003 as our lead subcutaneous product candidate for TED. Based on the comparable pharmacology of VRDN-003 to veligrotug, we believe VRDN-003 has the potential to maintain the clinical response of veligrotug while significantly increasing patient convenience. However, we have just initiated clinical trials of VRDN-003 in patients with TED in August of 2024, and results of any clinical trials conducted in TED patients with VRDN-003 may not demonstrate safety or efficacy comparable to veligrotug or at all.

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

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

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

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

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

***We may find it difficult to enroll and maintain patients or subjects in our clinical trials, in part due to the limited number of patients or subjects who have the diseases for which our product candidates are being studied or the availability of competing therapies and clinical trials. We cannot predict if we will have difficulty enrolling and maintaining patients or subjects in our future clinical trials. Difficulty in enrolling and maintaining patients or subjects could delay or prevent clinical trials of our product candidates.***

Identifying and enrolling patients or subjects to participate in clinical trials of our product candidates is essential to our success. The timing of our clinical trials depends in part on the rate at which we can recruit patients or subjects to participate in clinical trials of our product candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment. Our current or future clinical trials may face increased competition for and difficulty recruiting eligible patients for enrollment, for example, as a result of additional therapies for TED being tested in clinical trials or the availability of approved therapies. In addition, our enrollment has been, and may in the future be, delayed due to supply chain delays and difficulties in site activation. Delays in enrollment may delay the generation of clinical data and the completion of our clinical trials.

The eligibility criteria of our clinical trials may further limit the available eligible trial participants, as we expect to require that patients or subjects have specific characteristics that we can measure or meet the criteria to assure their conditions are appropriate for inclusion in our clinical trials. We may not be able to identify, recruit, enroll and maintain a sufficient number of patients or subjects to complete our clinical trials in a timely manner because of the perceived risks and benefits of the product candidate under study, the availability and efficacy of competing therapies and clinical trials, the option for patients to choose alternate existing approved therapies and the willingness of physicians to participate in our planned clinical trials. Additional factors outside our control, such as pandemics or other public health crises, may also impact our ability to enroll patients in our planned clinical trials. If patients or subjects are unwilling or unable to participate in our clinical trials for any reason, the timeline for conducting trials and obtaining regulatory approval of our product candidates may be delayed.

If we experience delays in the completion of, or termination of, any clinical trials of our product candidates, the commercial prospects of our product candidates could be harmed, and our ability to generate product revenue from any of these product candidates could be delayed or prevented. In addition, any delays in completing our

clinical trials would likely increase our overall costs, impair product candidate development, and jeopardize our ability to obtain regulatory approval relative to our current plans. Any of these occurrences may harm our business, financial condition, and prospects significantly.

***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 in the United States, 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 Our Reliance on Third Parties**

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

to repeat clinical trials or add patients to ongoing clinical trials, which would be costly and delay the regulatory submission and/or approval process.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs in a timely manner or do so on commercially reasonable terms. In addition, our CROs may not prioritize our clinical trials relative to those of other customers, and any turnover in personnel or delays in the allocation of CRO employees by the CRO may negatively affect our clinical trials. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, our clinical trials may be delayed or terminated, and we may not be able to meet our current plans with respect to our product candidates. Additionally, regional disruptions, including natural disasters 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 preclinical 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 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 supply of our product candidates for clinical trials or commercialization, if approved.***

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 an autoinjector device in connection with our product candidate VRDN-003. 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 manufacturers WuXi Biologics and WuXi AppTec, 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 CMO 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 one CMO increases the risk that any problems or delays with that CMO 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 current good manufacturing practice 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 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 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 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 taking steps to build redundancy into our supply chain. 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) and 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 contract research, development and manufacturing organizations ("CDMOs") WuXi AppTec (Hong Kong) Limited and WuXi Biologics (Hong Kong) Limited (together, "WuXi") and other foreign CDMOs, to develop and manufacture our product candidates, and will likely continue to rely on them in the future. There has been increased governmental focus in the United States on the role of Chinese companies in the life sciences industry. This focus has included U.S. legislative proposals, such as the proposed BIOSECURE Act, which has been passed by the U.S. House of Representatives and is pending before the U.S. Senate. If enacted, the BIOSECURE Act would, among other things, prohibit U.S. federal agencies from entering into or renewing any contract with any entity that uses biotechnology equipment or services produced or provided by a "biotechnology company of concern" to perform that contract with the government. Although the proposed Act has not been enacted and thus is subject to change through the legislative process, a version of the Act passed by the U.S. House of Representatives defines a "biotechnology company of concern" to include WuXi Biologics and WuXi AppTec. If adopted, the BIOSECURE Act could cause us to seek to exit some or all of our arrangements with WuXi (or any other China-based service provider determined to be "biotechnology companies of concern") and accelerate the transition of these services to alternative companies or continue to engage redundant suppliers for the U.S. market. Additionally, the legislation could adversely impact WuXi's operations or financial position which, in turn, could impact their ability to perform under our agreements with it. Our reliance on Chinese-based contract research organizations, such as WuXi, may also cause us to face

additional risks due to geopolitical tensions between the U.S. and China and related legal and regulatory restrictions and requirements, including measures directly affecting WuXi.

In addition, these entities may be subject to other U.S. legislation, sanctions, investigations, regulations, trade restrictions, 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 has yet to 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, 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 or 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 CMOs, 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 CMO 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.

***We enter into various contracts in the normal course of our business in which we indemnify the other party to the contract. In the event we have to perform under these indemnification provisions, we could have a material adverse effect on our business, financial condition, and results of operations.***

In the normal course of business, we periodically enter into commercial, service, licensing, consulting, and other agreements that contain indemnification provisions. With respect to our research agreements, we typically indemnify the party and related parties from losses arising from claims relating to the products, processes, or services made, used, sold, or performed pursuant to the agreements for which we have secured licenses, and from claims arising from our or our sublicensees' exercise of rights under the agreement. With respect to future collaboration agreements, we may indemnify our collaborators from any third-party product liability claims that could result from the production, use, or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right by a third party. With respect to consultants, we indemnify them from claims arising from the good faith performance of their services.

Should our obligation under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage, our business, financial condition, and results of operations could be adversely affected. Similarly, if we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage or the indemnification obligation exceeds the applicable insurance coverage, and if the collaborator does not have other assets available to indemnify us, our business, financial condition, and results of operations could be adversely affected.

#### **Risks Related to Our Intellectual Property**

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

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

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

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

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

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

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

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

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

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

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

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

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

uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, or results of operations.

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

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

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

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

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

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, such as processes for which patents are difficult to enforce, other elements of our product candidate discovery and/or development processes that involve proprietary know-how, information, or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, and contractors. 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 patent rights of third parties. Numerous third-party U.S. and non-U.S. issued patents and pending applications exist in the area of our product candidates. From time to time, we may also monitor these patents and patent applications. We may in the future pursue available proceedings in the U.S. and foreign patent offices to challenge these patents and patent applications. In addition, or alternatively, we may consider whether to seek to negotiate a license of rights to technology covered by one or more of such third-party patents and patent applications. If any patents or patent applications cover our product candidates or technologies, we may not be free to manufacture or market our product candidates as planned, absent such a license, which may not be available to us on commercially reasonable terms, or at all.

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

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

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

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

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

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

We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license their patent rights to us. Even if we are able to license or acquire third-party intellectual property rights that are necessary for our product candidates, there can be no assurance that they will be available on favorable terms.

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

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

While we normally seek and gain the right to fully prosecute the patents relating to our product candidates, there may be times when the prosecution and maintenance of patent applications and patents relating to our product candidates are controlled by our licensors. In these instances, we normally seek a right to participate in such prosecution or maintenance, which is not always granted. If any of our licensors fail to appropriately follow our

instructions or consider our comments with regard to the prosecution and maintenance of patent protection for patents covering any of our product candidates, it may result in patent rights that do not or do not sufficiently cover products. If this happens, our ability to develop and commercialize those product candidates may be adversely affected, and we may not be able to prevent competitors from making, using, importing, and selling competing products. In addition, even where we now have the right to control patent prosecution of patents and patent applications, we have licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensors in effect from actions prior to us assuming control over patent prosecution.

***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 condition, results of operations and prospects.

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

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

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

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

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

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

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries, particularly some developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology and therapeutic products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally.

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

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

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

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

We believe that any of the product candidates we develop that is approved in the United States as a biological product under a BLA should qualify for the current 12-year period of exclusivity provided law. However, there is a risk that this exclusivity could be shortened in the future due to congressional action or otherwise, 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 rights in the United States 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 2023 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 Breakthrough Therapy designation for one or more of our product candidates from the FDA, but we might not receive such designation, and even if we do, such designation may not actually lead to a faster development or regulatory review or approval process.***

We may seek a breakthrough therapy designation from the FDA for some of our product candidates. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review, or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one of our product candidates is designated as a breakthrough therapy, the FDA may later decide that the product candidate no longer meets the conditions for designation and the designation may be rescinded. See “Business—Government Regulation—Expedited Development and Review Programs” in our 2023 Annual Report on Form 10-K.

***We may seek Fast Track designation for one or more of our product candidates, but we might not receive such designation, and even if we do, such designation 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. If we seek Fast Track designation for a product candidate, we may not receive it from the FDA. However, even if we receive Fast Track designation, Fast Track designation does not ensure that we will receive marketing approval in any particular timeframe or at all. We may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA’s priority review procedures. See “Business—Government Regulation—Expedited Development and Review Programs” in our 2023 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 sponsor’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.

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

If any of our product candidates are approved, we will be subject to ongoing regulatory requirements with respect to manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing clinical trials, and submission of safety, efficacy, and other post-approval information, including both federal and state requirements in the United States, and requirements of the EMA and comparable foreign regulatory authorities. See "Business—Government Regulation—Expedited Development and Review Programs" and "Business—Government Regulation—Regulation in the European Union" in our 2023 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 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 United States 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.

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

In the United States, there have been and continues to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA was passed, which was intended to substantially change the way healthcare is financed by both governmental and private insurers, and significantly impact the U.S. pharmaceutical industry. More recently, on August 16, 2022, President Biden signed into law the IRA, which, among other provisions, included several measures intended to lower the cost of prescription drugs and related healthcare reforms. See "Business—Health Reform" in our 2023 Annual Report on Form 10-K.

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

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

Our operations may be subject to various foreign, federal, and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and Physician Payments Sunshine Act, the European General Data Protection Regulation 2016/679, 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 2023 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.***

Regulation of personal data or 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 2023 Annual Report on Form 10-K.

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.

#### **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 currently have no commercial manufacturing relationships or marketing or sales organization. To successfully commercialize any products that may result from our development programs, we will 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. 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 SE ("Argenx"), Immunovant, Inc., Roche Holdings AG, Acelyrrin, Inc., Tourmaline Bio, Inc., Lassen Therapeutics and Sling Therapeutics, Inc. Other companies such as Kriya Therapeutics, Inc., Septerna and Crinetics Pharmaceuticals, Inc. among others, have earlier stage products in development which, if successfully developed, may impact the value of our product candidates over their lifecycle. If approved, veligrotug and VRDN-003 will also compete against generic medications, such as corticosteroids, and surgical procedures that are prescribed for the treatment of TED. We are also aware that the following companies, among others, may have anti-FcRn therapeutics marketed or in development: Argenx, UCB S.A., Janssen Pharmaceutical Companies of Johnson & Johnson, Immunovant, Inc. and AstraZeneca/Alexion Pharmaceuticals, 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-1L-6 and other mechanisms of action.

Our product candidates may demonstrate inferior efficacy and safety profiles as compared to currently approved drugs, or product candidates currently in development by our competitors. Our competitors may succeed in developing, acquiring, or licensing technologies and drug products that are more effective or less costly than our product candidates that we are currently developing or that we may develop, which could render our product

candidates obsolete and noncompetitive. Our competitors may also adopt a similar licensing and development strategy as ours with regard to the development of an existing anti-IGF-1R monoclonal antibody for the treatment of TED. If any competitor was able to effect this strategy in a more efficient manner, there may be less demand for our product candidates if any are approved.

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

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

Many of our competitors have materially greater name recognition and financial, manufacturing, marketing, research, and drug development resources than we do. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. For example, in October 2023, Amgen completed its acquisition of Horizon, which could have a significant impact on the competitive landscape for clinical trials and therapeutics for TED. Large pharmaceutical companies in particular have extensive expertise in preclinical and clinical testing and in obtaining regulatory approvals 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.

***The commercial success of any of our current or future product candidates will depend upon the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community.***

Even with the approvals from the FDA, EMA, and comparable foreign regulatory authorities, the commercial success of our products will depend in part on the healthcare providers, patients, and third-party payors accepting our product candidates as medically useful, cost-effective, and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients, and third-party payors. The degree of market acceptance of any of our products will depend on a number of factors, including but not limited to:

- the efficacy or safety of the product as demonstrated in clinical trials and potential advantages over competing treatments;
- the prevalence and severity of the disease and any side effects;
- the clinical indications for which approval is granted, including any limitations or warnings contained in a product's approved labeling;
- the convenience and ease of administration;
- the cost of treatment;
- the willingness of the patients and physicians to accept these therapies;
- the perceived ratio of risk and benefit of these therapies by physicians and the willingness of physicians to recommend these therapies to patients based on such risks and benefits;

- the marketing, sales, and distribution support for the product;
- the publicity concerning our products or competing products and treatments; and
- the pricing and availability of third-party payor coverage and adequate reimbursement.

Even if a product displays a favorable efficacy and safety profile upon approval, market acceptance of the product remains uncertain. We may be unable to penetrate the existing TED market and successfully commercialize our product candidates, if approved. Efforts to educate the medical community and third-party payors on the benefits of the products may require significant investment and resources and may never be successful. If our products fail to achieve an adequate level of acceptance by physicians, patients, third-party payors, and other healthcare providers, we will not be able to generate sufficient revenue to become or remain profitable.

In addition, the market for TED therapies may fail to continue its growth, or may shrink, which could affect the commercial viability of our product candidates and could negatively impact revenues from any approved products. For example, sales of Tepezza® may fall, and this could cause our business to be negatively impacted. Our estimates of the market size and market opportunity for our product candidates may prove inaccurate, which could negatively impact their commercial viability.

***We may not be successful in any efforts to identify, license, discover, develop, or commercialize additional product candidates.***

Although a substantial amount of our effort will focus on clinical testing, potential approval, and commercialization of our existing product candidates, the success of our business is also expected to depend in part upon our ability to identify, license, discover, develop, or commercialize additional product candidates. Research programs to identify new product candidates require substantial technical, financial, and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Our research programs or licensing efforts may fail to yield additional product candidates for clinical development and commercialization for a number of reasons, including but not limited to the following:

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in preclinical or clinical testing;
- our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our program so that such a product may become unreasonable to continue to develop;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and

- a product candidate may not be accepted as safe and effective by patients, the medical community, or third-party payors.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, license, discover, develop, or commercialize additional product candidates, which would have a material adverse effect on our business, financial condition, or results of operations and could potentially cause us to cease operations.

***Failure to obtain or maintain adequate 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 2023 Annual Report on Form 10-K.

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.

**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.***

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, natural disasters, public health crises such as the COVID-19 pandemic, political crises, geopolitical events, such as the crisis in Ukraine, or other macroeconomic conditions, may have serious adverse consequences on our business and financial condition.***

The global economy, including credit and financial markets, have experienced extreme volatility and disruptions at various points over the last few decades, including, among other things, diminished liquidity and

credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates, and uncertainty about economic stability. For example, the COVID-19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. 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, may increase economic uncertainty and affect consumer spending. Similarly, the ongoing military conflict between Russia and Ukraine, the rising tensions between China and Taiwan, the conflict in Israel and surrounding area and domestic tensions within the U.S. have created, or may create, significant volatility in the capital markets and may have further global economic consequences, including disruptions of the global supply chain. Any such volatility and disruptions may adversely affect our clinical trials, our business and the third parties on whom we rely.

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

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

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

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

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

Our ability to execute our business plan and maintain operations depends on the continued and uninterrupted performance of our information technology ("IT") systems or 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 now 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 and made other significant efforts to safeguard against such threats, it is virtually impossible for us 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 and generally are not recognized until launched against a target. 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, or to respond to any data security incidents, breaches or other unauthorized access, acquisition, or disclosure of sensitive information (including, without limitation personal information), may result in financial losses, additional cost and/or liability to us, including costs from governmental investigations, enforcement actions, regulatory fines, litigation, costs of doing business or damage to our reputation. Any of these events could cause harm to our reputation, business, financial condition or operational results.

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

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

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. Our most recent analysis of possible ownership changes was completed for certain tax periods ending through December 31, 2023. 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 Preferred Stock and the provisions of our warrants issued in 2020 may delay or prevent a change in control of our company. At any time while at least 30% of the originally issued Series A Preferred Stock remains issued and outstanding, we may not consummate a Fundamental Transaction (as defined in the Certificate of Designation of the Series A 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 Preferred Stock. As of December 31, 2023, a majority of the then outstanding shares of Series A 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. In addition, pursuant to such warrants, under certain circumstances each warrant holder has the right to demand that we redeem the warrant for a cash amount equal to the Black-Scholes value of a portion of the warrant upon the occurrence of specified events, including a merger, an asset sale or certain other change of control transactions. A takeover of us may trigger the requirement that we redeem the warrants, which could make it more costly for a potential acquirer to engage in a business combination transaction with us.

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

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

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

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

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

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

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

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

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

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

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

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

#### **General Risk Factors**

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

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

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

- changes in the structure of health care payment systems; and
- period-to-period fluctuations in our financial results.

Moreover, the capital markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies, including volatility resulting from general global macroeconomic conditions. These broad market fluctuations may also adversely affect the trading price of our common stock. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our business and reputation.

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

From time to time in the ordinary course of its business, we and our directors and officers may become involved in various legal proceedings, including commercial, employment 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 transition to being a large accelerated filer and compliance with Section 404 of the Sarbanes-Oxley Act of 2002 has been and will continue to be time consuming and costly. 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. We became a large accelerated filer effective December 31, 2023, and 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. Our transition to becoming subject to additional requirements of Section 404 of the Sarbanes-Oxley Act has been and will continue to be time-consuming, and there is a risk of noncompliance. Further, the costs associated with the compliance with and implementation of procedures under these and future laws and related rules could have a material impact on our results of operations.

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, 2024, 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.

<b>Incorporated by Reference</b>				
<b>Exhibit No.</b>	<b>Description of Exhibit</b>	<b>Form</b>	<b>Filing Date</b>	<b>Number</b>
3.1	<a href="#"><u>Second Restated Certificate of Incorporation of the Registrant, effective as of March 9, 2022.</u></a>	10-K	3/11/2022	3.1
3.2	<a href="#"><u>Fourth Amended and Restated Bylaws of the Registrant, effective as of December 15, 2023.</u></a>	8-K	12/18/2023	3.1
3.3	<a href="#"><u>Certificate of Designation of Series A Non-Voting Convertible Preferred Stock.</u></a>	8-K	10/28/2020	3.1
3.4	<a href="#"><u>Certificate of Designation of Series B Non-Voting Convertible Preferred Stock.</u></a>	8-K	9/23/2021	3.1
4.1	<a href="#"><u>Specimen Common Stock Certificate.</u></a>	S-1	3/19/2014	4.1
4.2	<a href="#"><u>Form of Warrant to Purchase Common Stock.</u></a>	8-K	2/7/2020	4.1
10.1	<a href="#"><u>Fifth Amendment to Lease by and between Registrant and Watch City Ventures MT, LLC dated as of September 19, 2024.</u></a>			x
10.2	<a href="#"><u>Amended and Restated License Agreement by and between Registrant and Paragon Therapeutics, Inc. dated as of September 20, 2024.</u></a>			x
31.1	<a href="#"><u>Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities and Exchange Act, as amended.</u></a>			x

31.2	<a href="#"><u>Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities and Exchange Act, as amended.</u></a>	x
32.1*	<a href="#"><u>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.</u></a>	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

+ 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 12, 2024

By: /s/ Stephen Mahoney

Stephen Mahoney  
President, Chief Executive Officer and Director  
(Principal Executive Officer)

Date: November 12, 2024

By: /s/ Seth Harmon

Seth Harmon  
Senior Vice President of Finance and Accounting  
(Principal Financial Officer; Principal Accounting Officer)

FIFTH AMENDMENT TO LEASE

This **FIFTH AMENDMENT TO LEASE** (this "Amendment") is made as of the 19<sup>th</sup> of September, 2024 (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 401, 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, and as further amended by that certain Fourth Amendment to Lease dated April 8, 2024 (the "Fourth Amendment") (as amended, the "Lease") for certain premises consisting of approximately 10,427 rentable square feet on the first (1<sup>st</sup>) floor of Buildings #18 and #19, as shown as Suite 103A on the plan attached to the Lease as Exhibit A-1.4 (the "Suite 103A Premises" or the "Original Premises").

**WHEREAS**, Tenant desires to exercise its right of first refusal to lease an additional approximately 2,788 rentable square feet on the first (1<sup>st</sup>) floor of Building #20, as shown as Suite 103B on the plan attached hereto as Exhibit A-1.5 (the "New Premises" or the "Suite 103B Premises");

**WHEREAS**, Landlord and Tenant acknowledge that nothing contained in this Amendment shall be deemed to modify any of the terms and conditions of the Fourth Amendment with respect to **(a)** Tenant's lease and occupancy of the Suite 103A Premises, **(b)** the New Premises Rent Commencement Date (as that term is defined in the Fourth Amendment) with respect to the Suite 103A Premises, **(c)** the payment of Suite 103A Premises Base Rent, **(d)** Landlord's payment of the Suite 103A Tenant Improvement Allowance, or **(e)** Tenant's surrender of the Original Premises (as defined in the Fourth Amendment collectively as the Suite 102 Premises, the Suite 401 Premises, the Suite 406 Premises, the Suite 110 Premises, and the Suite 111 Premises) on the Original Premises Surrender Date (as defined in the Fourth Amendment), it being the intent of Landlord and Tenant that Tenant is simply exercising its right of first refusal with respect to the Suite 103B Premises as set forth in the Fourth Amendment;

**WHEREAS**, the rent commencement date for the Suite 103B Premises shall be the later to occur of (a) delivery of the Suite 103B Premises to Tenant, and (b) September 1, 2024 (the "New Premises Rent Commencement Date");

**WHEREAS**, Tenant has agreed to accept the Suite 103B 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 103B 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 a one-time right of first refusal solely with respect to space, consisting of (a) approximately 2,737 rentable square feet located on the first (1<sup>st</sup>) floor of Building #4 (the "Suite 110 Premises"), and (b) approximately 2,503

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rentable square feet located on the first (1<sup>st</sup>) floor of Building #4 (the "Suite 111 Premises"), all as shown on the plan attached hereto as Exhibit A-1.6 (the "ROFR Expansion Premises") 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 103B Premises**: approximately 2,788 rentable square feet on the first (1<sup>st</sup>) floor of Building #20, as shown as Suite 103B on the plan attached hereto as Exhibit A-1.5.

**Suite 103B Premises Commencement Date ("S103BPCD")**: The Suite 103B Premises Delivery Date. See Section 2.1.5 below.

**Suite 103B Premises Rent Commencement Date ("S103BPRCD")**: The later to occur of (a) the Suite 103B Premises Delivery Date, or (b) September 1, 2024.

**Suite 103B Premises Base Rent**:

<b><u>Period</u></b>	<b><u>RSF Paying Rent On</u></b>	<b><u>Base Rent</u></b>	<b><u>Yearly Base Rent</u></b>	<b><u>Monthly Base Rent</u></b>
S103BPRCD – End of Lease Year 1	2,788	\$44.00/RSF	\$122,672.00	\$10,222.67
Lease Year 2	2,788	\$45.00/RSF	\$125,460.00	\$10,455.00
Lease Year 3	2,788	\$46.00/RSF	\$128,248.00	\$10,687.33
Lease Year 4	2,788	\$47.00/RSF	\$131,036.00	\$10,919.67
Lease Year 5 (through S103ATD)	2,788	\$48.00/RSF	\$133,824.00	\$11,152.00

**Suite 103A Termination Date ("S103ATD")**: The last day of the sixtieth (60<sup>th</sup>) consecutive full calendar month following the Suite 103A Premises Rent Commencement Date.

**Suite 103B Premises Term:** The period commencing on the Suite 103B Premises Commencement Date and ending at 11:59 P.M. on the Suite 103A Termination Date, unless sooner terminated or extended as provided in this Lease.

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 102 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 2020; 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 2020 (July 1, 2019 – June 30, 2020); **(b)** with respect to the Suite 401 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 2021; 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 2022 (July 1, 2021 – June 30, 2022); **(c)** with respect to the Suite 110/111 Premises and the Suite 406 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 2022; 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 2023 (July 1, 2022 – June 30, 2023); **(d)** 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)** 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)."

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 102 Premises, the first "Lease Year" shall be the period commencing on the Commencement Date and ending on the last day of the calendar month in which the first anniversary of the Rent Commencement Date occurs if the Rent Commencement Date is other than the first day of a calendar month. If the Rent Commencement Date is the first day of a calendar month, then the first "Lease Year" with respect to the Suite 102 Premises shall be the period commencing on the Commencement Date and ending on the day (last of the calendar month) immediately prior to the first (1<sup>st</sup>) anniversary of the Rent Commencement Date. With respect to the Suite 401 Premises, the first "Lease Year" shall be the period commencing on the Suite 401 Premises Commencement Date and ending on the last day of the calendar month in which the first anniversary of the Suite 401 Premises Rent Commencement Date occurs if the Suite 401 Premises Rent Commencement Date is other than the first day of a calendar month. If the Suite 401 Premises Rent Commencement Date is the first day of a calendar month, then the first "Lease Year" with respect to the Suite 401 Premises shall be the period commencing on the Suite 401 Premises Commencement Date and ending on the day (last of the calendar month) immediately prior to the first (1<sup>st</sup>) anniversary of the Suite 401 Premises Rent Commencement Date. With respect to the Suite 406 Premises, the first "Lease

Year" shall be the period commencing on the Suite 406 Premises Commencement Date and ending on the last day of the calendar month in which the first anniversary of the Suite 406 Premises Rent Commencement Date occurs if the Suite 406 Premises Rent Commencement Date is other than the first day of a calendar month. If the Suite 406 Premises Rent Commencement Date is the first day of a calendar month, then the first "Lease Year" with respect to the Suite 406 Premises shall be the period commencing on the Suite 406 Premises Commencement Date and ending on the day (last of the calendar month) immediately prior to the first (1<sup>st</sup>) anniversary of the Suite 406 Premises Rent Commencement Date. With respect to the Suite 110/111 Premises, the first "Lease Year" shall be the period commencing on the Suite 110/111 Premises Commencement Date and ending on the last day of the calendar month in which the first anniversary of the Suite 110/111 Premises Rent Commencement Date occurs if the Suite 110/111 Premises Rent Commencement Date is other than the first day of a calendar month. If the Suite 110/111 Premises Rent Commencement Date is the first day of a calendar month, then the first "Lease Year" with respect to the Suite 110/111 Premises shall be the period commencing on the Suite 110/111 Premises Commencement Date and ending on the day (last of the calendar month) immediately prior to the first (1<sup>st</sup>) anniversary of the Suite 110/111 Premises Rent Commencement Date. 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 (1<sup>st</sup>) 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 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 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 (1<sup>st</sup>) anniversary of the Suite 103A Premises Rent Commencement Date, it being the intention of the parties that the first "Lease Year" with respect to both the Suite 103A Premises and the Suite 103B Premises, be co-terminus. In either case of the Suite 102 Premises, the Suite 110/111 Premises, the Suite 401 Premises, the Suite 406 Premises, the Suite 103A Premises or the Suite 103B 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 102 Premises, the Suite 110/111 Premises, the Suite 401 Premises, and the Suite 406 Premises, all ending on the Original Premises Surrender Date (as defined in the Fourth Amendment), and with the final Lease Year of the Suite 103A Premises and the Suite 103B Premises ending on the Suite 103A 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 thirty-six (36) parking spaces in the parking lots serving the Buildings as shown on **Exhibit A-2**, attached hereto, ("Parking Facilities"), and from and after the Original Premises Surrender Date, 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 forty-four (44) parking spaces in the 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 102 Premises during the Suite 102 Premises Term, Sixty-Seven One Hundredths percent (0.67%), (b) with respect to the Suite 110/111 Premises during the Suite 110/111 Premises Term, Three and Twenty-Four One Hundredths percent (3.24%), (c) with respect to the Suite 401 Premises during the Suite 401 Premises Term, Two and Three One Hundredths percent (2.03%), (d) with respect to the Suite 406 Premises during the Suite 406 Premises Term, One and Fifty One Hundredths percent (1.50%), (e) with respect to the Suite 103A Premises during the Suite 103A Premises Term, Six and Forty-Four One Hundredths percent (6.44%), and (f) with respect to the Suite 103B Premises during the Suite 103B Premises Term, One and Seventy-Two One Hundredths percent (1.72%), which percentages have been determined by dividing the total number of rentable square feet in the Suite 102 Premises, Suite 110/111 Premises, the Suite 401 Premises, the Suite 406 Premises, and the Suite 103A 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 102 Premises, the period commencing on the Commencement Date and ending at 11:59 p.m. on the Original Premises Surrender Date, (b) with respect to the Suite 110/111 Premises, the period commencing on the Suite 110/111 Premises Commencement Date and ending at 11:59 p.m. on the Original Premises Surrender Date, (c) with respect to the Suite 401 Premises, the period commencing on the Suite 401 Premises Commencement Date and ending at 11:59 p.m. on the Original Premises Surrender Date, (d) with respect to the Suite 406 Premises, the period commencing on the Suite 406 Premises Commencement Date and ending at 11:59 p.m. on the Original Premises Surrender Date, (e) 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 Suite 103A Termination Date, and (f) 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 Suite 103A Termination Date, it being the intention of the parties that the Term with respect to the Suite 103A Premises and the Suite 103B Premises be co-terminus.

5. The following shall be added as new Section 2.1.5:

**2.1.5 Suite 103B Premises:** Landlord hereby leases to Tenant the Suite 103B Premises for the Suite 103B Premises Term, subject to the terms and conditions set forth herein. For the purposes of this Lease, the "Suite 103B 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 103B Premises available to Tenant.

6. The following shall be added as new Section 2.2.5:

**2.2.5 Acceptance of Suite 103B Premises.** Tenant acknowledges and agrees that Tenant is accepting the Suite 103B 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 103B Premises to Tenant free of other occupants and personal property and in broom clean condition. Landlord has no obligation and has made no promises to alter, remodel, improve, renovate, repair or decorate the Suite 103B 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 103B Premises or the Building have been made by Landlord to Tenant (except as otherwise specifically set forth herein). In no event shall Tenant be permitted to any portion of the Suite 103A Tenant Improvement Allowance (as defined in the Fourth Amendment) toward any Suite 103B Alterations.

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 a one-time right (which shall be a one-time right held by Tenant, with respect to each respective suite comprising the ROFR Expansion Premises, only with respect to the first time each respective suite comprising the ROFR Expansion Premises becomes available during the Term, strictly in accordance with this Section 2.7, and subject to the rights of any of Landlord's other existing tenants in the Buildings, to lease (a) (a) approximately 2,737 rentable square feet located on the first (1<sup>st</sup>) floor of Building #4 (the "**Suite 110 Premises**"), and (b) approximately 2,503 rentable square feet located on the first (1<sup>st</sup>) floor of Building #4 (the "**Suite 111 Premises**"), and as shown on the plan attached hereto as **Exhibit A-1.6** (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; and (vi) 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 Rent Commencement Date with respect to the Suite 102 Premises, (ii) the date which is two (2) months after the Suite 401 Premises Commencement Date (the "**Suite 401 Premises Rent Commencement Date**") with respect to the Suite 401 Premises, (iii) the Suite 406 Premises Rent Commencement Date with respect to the Suite 406 Premises, (iv) the Suite 110/111 Premises Rent Commencement Date with respect to the Suite 110/111 Premises, (v) the Suite 103A Premises Rent Commencement Date with respect to the Suite 103A Premises, and (vi) the Suite 103B Premises Rent Commencement Date with respect to the Suite 103B Premises, Tenant agrees to pay the Base Rent, with respect to the Suite 102 Premises, the Suite 401 Premises Base Rent, with respect to the Suite 401 Premises, the Suite 406 Premises Base Rent, with respect to the Suite 406 Premises, the Suite 110/111 Premises Base Rent, with respect to the Suite 110/111 Premises, the Suite 103A Base Rent, with respect to the Suite 103A Premises, the Suite 103B Base Rent, with respect to the Suite 103B 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. Tenant's payment of any increased Security Deposit shall be due and payable within thirty (30) days from full execution and delivery of this Amendment. 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 Base Rent, Suite 401 Premises Base Rent, the Suite 406 Premises Base Rent, the Suite 110/111 Premises Base Rent, the Suite 103A Premises Base Rent, the Suite 103B Premises Base Rent, and Additional Rent for any partial month shall be prorated on the basis of a 30 day month.

9. Exhibit A-1.5 attached hereto showing the Suite 103B Premises shall be added as new Exhibit A-1.5 of the Lease.

10. Exhibit A-1.6 attached hereto showing the ROFR Expansion Premises shall be added as new Exhibit A-1.6 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 103B Premises, with any broker or had its attention called to the Premises, Suite 103B 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 the Suite 103B 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 S103BPCD, all references appearing in the Lease to the Premises shall be amended and read hereafter to be references to the Original Premises (as defined in the Fourth Amendment), the Suite 103A Premises, and the Suite 103B Premises, unless specifically set forth in this Amendment to the contrary. From and after the Original Premises Surrender Date (as defined in the Fourth Amendment), all references appearing in the Lease to the Premises shall be amended and read thereafter to be references only to the Suite 103A Premises and the Suite 103B Premises.

13. From and after the S103BPCD, all references appearing in the Lease to the Rent shall be amended and read hereafter to include, without limitation, the Suite 103B Premises Base Rent.

14. The Lease is hereby ratified and confirmed and, as modified by this Amendment, shall remain in full force and effect.

15. 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.

16. 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.

17. 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.

18. 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

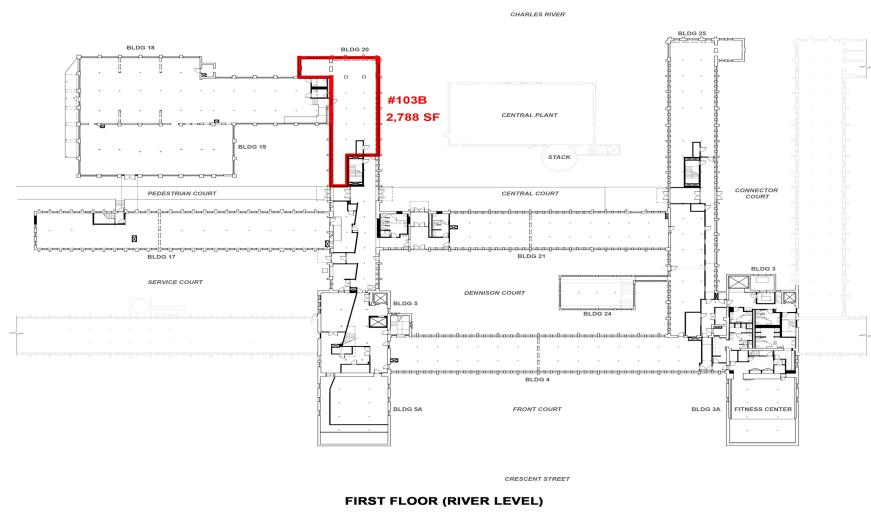
By: /s/ Young Park  
Name: Young Park  
Its: Authorized signatory  
(hereunto duly authorized)

**TENANT:** **VIRIDIAN THERAPEUTICS, INC.,**  
a Delaware corporation

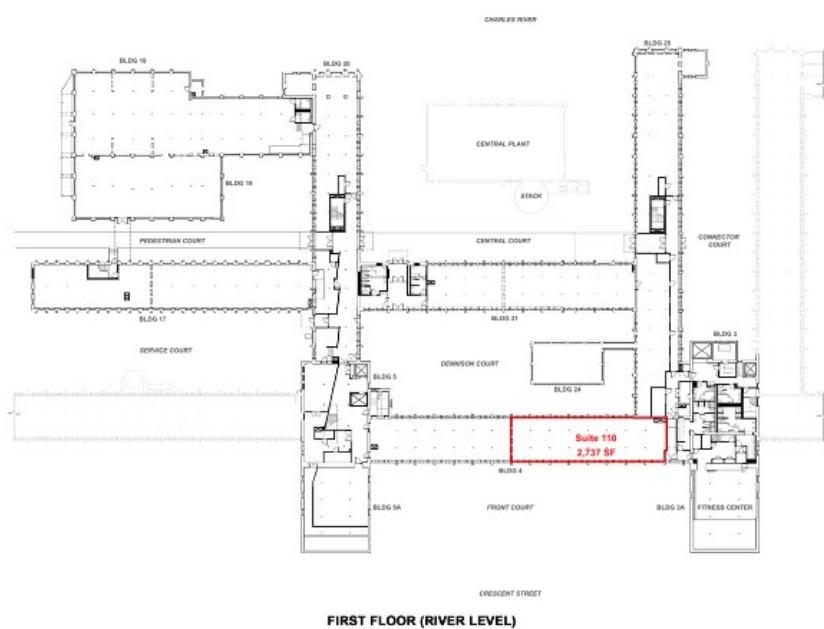
By: /s/ Tom Beetham  
Name: Tom Beetham  
Title: COO

**EXHIBIT A-1.5**

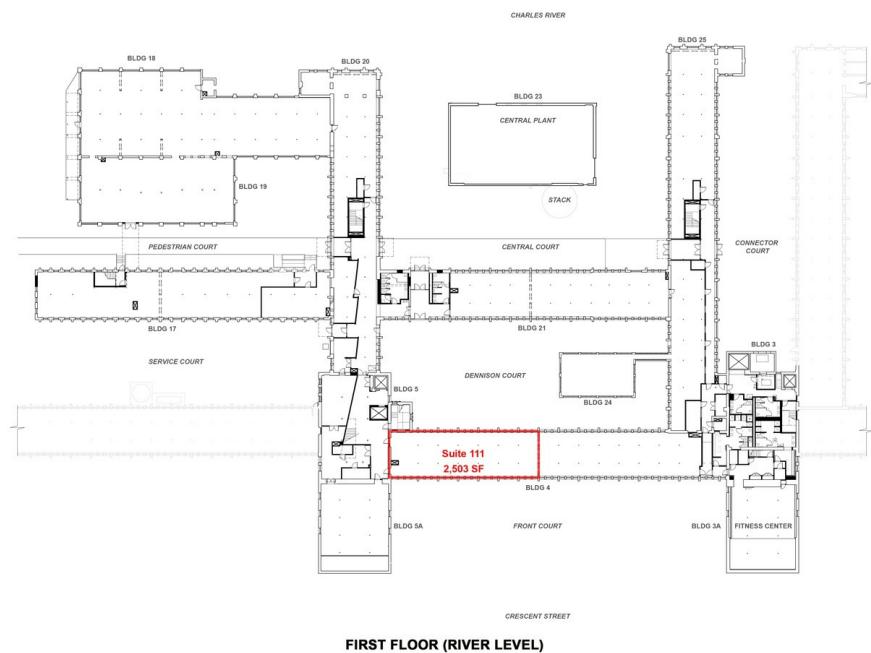
**PLAN SHOWING SUITE 103B PREMISES**



**EXHIBIT A-1.6**  
**PLAN SHOWING ROFR EXPANSION PREMISES**



**FIRST FLOOR (RIVER LEVEL)**



[\*\*\*] = Identified information has been excluded from this exhibit because it is both (i) information that the Company customarily and actually treats as private or confidential and (ii) is not material.

## AMENDED AND RESTATED LICENSE AGREEMENT

This Amended and Restated License Agreement (this "Agreement") is entered into and effective as of September 20, 2024 (the "A&R Effective Date"), by and between Paragon Therapeutics, Inc., a company organized under the laws of the State of Delaware, having its principal place of business at 221 Crescent Street, Suite 105, Waltham, MA 02453 ("Paragon"), and Viridian Therapeutics, Inc., a company organized under the laws of the State of Delaware, having its principal place of business at 221 Crescent Street, Suite 103A, Waltham, MA 02453 ("Viridian"). Paragon and Viridian are referred to herein individually as a "Party" or collectively as the 'Parties".

### BACKGROUND

A. Pursuant to that certain Antibody Discovery and Option Agreement entered into by and between the Parties, dated January 19, 2022, as amended by that certain First Amendment to Antibody Discovery and Option Agreement, dated December 12, 2022, and that certain Second Amendment to Antibody Discovery and Option Agreement, dated as of the A&R Effective Date (collectively, the "Research Agreement"), Viridian engaged Paragon to leverage its proprietary platform technology for therapeutic antibody discovery to identify, evaluate and develop one or more therapeutic antibody-based candidates directed to the human FcRn.

B. Under the Research Agreement, Paragon granted Viridian exclusive options with respect to each of the [\*\*\*] Program and the [\*\*\*] Program thereunder to obtain exclusive licenses to develop, manufacture and commercialize resulting antibodies, antibody-based proteins and associated products.

C. Viridian exercised both such options with respect to the Licensed Target under the Research Agreement, and the Parties entered into that certain License Agreement, dated October 30, 2023 (the "Original Effective Date"), under which Paragon granted to Viridian the License with respect to such Licensed Target (the "Original License Agreement").

D. Pursuant to the Research Agreement and that certain Letter Agreement entered into by and between the Parties, dated January 26, 2024, as renewed by that certain First Renewal of Letter Agreement, dated July 16, 2024 (collectively, the "Letter Agreement"), Viridian has continued to engage Paragon to identify, evaluate, and develop therapeutic antibody candidates under the Research Agreement.

E. The Parties desire to amend and restate the Original License Agreement to ensure that Viridian obtains all necessary rights to Develop, Manufacture and Commercialize the Licensed Antibodies, Derived Antibodies and Products resulting from any and all past, present or future activities conducted by the Parties under the Research Agreement, and to reflect other terms and conditions not covered in the Original License Agreement.

Now Therefore, in consideration of the foregoing premises and the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which

are hereby acknowledged, the Parties, intending to be legally bound, agree to amend and restate the Original License Agreement in its entirety as follows:

## ARTICLE I DEFINITIONS

The following initially capitalized terms have the following meanings (and derivative forms of them shall be interpreted accordingly):

1.1 **“Accounting Standards”** means U.S. generally accepted accounting principles (GAAP), or International Financial Reporting Standards (IFRS), in each case consistently applied.

1.2 **“Acquirer”** means, collectively, the Third Party referenced in the definition of Change of Control and such Third Party’s Affiliates, other than the applicable Party in the definition of Change of Control and such Party’s Affiliates, determined as of immediately prior to the closing of such Change of Control.

1.3 **“Affiliate”** means any entity controlled by, controlling, or under common control with a Party. For the purpose of this definition, “control” (including, with correlative meaning, the terms “controlled by” or “under common control”) means the direct or indirect ownership of more than fifty percent (50%) of the voting interest in, or more than fifty percent (50%) in the equity of, or the right to appoint more than fifty percent (50%) of the directors or management of, such corporation or other business entity. Notwithstanding the foregoing, (a) with respect to either Party, Affiliates of such Party do not include [\*\*\*] or its Affiliates other than such Party and its subsidiaries, (b) Paragon and its subsidiaries, on the one hand, and Viridian and its subsidiaries, on the other hand, shall not be deemed to be Affiliates of each other, and (c) Affiliates of Paragon do not include new entities formed by or on behalf of Paragon for the sole *bona fide* purpose of further developing, manufacturing, commercializing or otherwise exploiting antibodies and antibody products (excluding any Licensed Antibodies, Derived Antibodies or Products) using, among other sources, funds from Third Party investors (such new entities, **“Excluded Entities”**). However, if any Licensed Antibody Technology Controlled by Excluded Entities were used in the performance of Development Activities by or on behalf of Paragon, such Excluded Entities will be deemed Affiliates of Paragon under this Agreement.

1.4 “[\*\*\*]” means [\*\*\*], a Delaware limited liability company, and any permitted assignee of [\*\*\*] under the terms of the [\*\*\*] License Agreement.

1.5 “[\*\*\*] IP” means the [\*\*\*] Licensed Patents and the [\*\*\*] Licensed Know-How.

1.6 “[\*\*\*] License Agreement” means that certain License Agreement dated [\*\*\*], between Paragon and [\*\*\*], as amended by that certain First Amendment to License Agreement dated [\*\*\*], as such agreement may be amended or restated from time to time, subject to the terms of this Agreement. A copy of the [\*\*\*] License Agreement as of the A&R Effective Date is attached hereto as Exhibit B, which shall be updated by Paragon from time to time in the event of any amendment to or restatement of the [\*\*\*] License Agreement becoming effective or executed after the A&R Effective Date.

1.7 “[\*\*\*] Licensed Know-How” means any Know-How (as defined in the [\*\*\*] License Agreement) that (a) is licensed by [\*\*\*] to Paragon under Section 2.1(a)(ii) of the [\*\*\*]

License Agreement, and (b)(i) actually used by Paragon in the course of performing any Development Activities under any Research Program or (ii) is reasonably necessary or useful for the research, use, Development, Manufacturing, sale, import, Commercialization, or other exploitation of Licensed Antibodies, Derived Antibodies and Products in the Field in the Territory.

1.8 **“[\*\*\*] Licensed Patents”** means any Patent Rights (as defined in the [\*\*\*] License Agreement) that are (a) licensed by [\*\*\*] to Paragon under Section 2.1(a)(ii) of the [\*\*\*] License Agreement, and (b)(i) actually used by Paragon in the course of performing any Development Activities under any Research Program or (ii) reasonably necessary or useful for the research, use, Development, Manufacturing, sale, import, Commercialization, or other exploitation of Licensed Antibodies, Derived Antibodies and Products in the Field in the Territory.

1.9 **“Antibody”** means any molecule, including [\*\*\*].

1.10 **“Applicable Law”** means any national, supra-national, federal, state or local laws, rules, guidances and regulations, in each case, as applicable to the subject matter and the Party at issue.

1.11 **“Background IP”** means all Patents and Know-How Controlled by a Party (a) as of December 12, 2022 (the effective date of the Research Agreement), or (b) that otherwise arise outside of and independently of the Research Agreement and this Agreement. Paragon’s Background IP includes the Paragon Platform Technology.

1.12 **“Bankruptcy Code”** has the meaning set forth in Section 8.5 (Insolvency).

1.13 **“Bankruptcy Event”** has the meaning set forth in Section 8.5 (Insolvency).

1.14 **“Biologics License Application”** means a Biologics License Application for Regulatory Approval of a Product that is filed with the United States Food and Drug Administration, or any successor entity thereof performing substantially the same functions.

1.15 **“[\*\*\*] Program”** means the development program that has been or to be conducted by or on behalf of Paragon under the Research Agreement to discover, identify, generate, and characterize [\*\*\*] Antibodies [\*\*\*], as such program is further described in the Research Plan attached to the Research Agreement.

1.16 **“Business Day”** means any day other than Saturday, Sunday or other national holiday in the United States.

1.17 **“Calendar Quarter”** means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.18 **“Calendar Year”** means each successive period of twelve (12) months commencing on January 1 and ending on December 31.

1.19 **“Change of Control”** means, with respect to a Party, (a) a merger or consolidation of such Party with a Third Party that results in the voting securities of such Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent more than 50% of the combined voting power of the surviving

entity or the parent of the surviving entity immediately after such merger or consolidation, (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the beneficial owner of more than 50% of the combined voting power of the outstanding voting securities of such Party, or (c) the sale or other transfer to a Third Party of all or substantially all of such Party's business or assets to which the subject matter of this Agreement relates. For clarity, a Change of Control does not include (i) an internal consolidation, merger, share exchange or other reorganization of a Party between or among such Party and one or more of its Affiliates, or (ii) a sale of assets, merger, or other transaction effected exclusively for the purpose of changing domicile of a Party.

1.20 **"Claim"** has the meaning set forth in Section 9.3 (Indemnification Procedures).

1.21 **"Commercialize"** or **"Commercializing"** means to market, promote, distribute, offer for sale, sell, have sold, import, have imported, export, have exported or otherwise commercialize an Antibody, including any Licensed Antibody or Derived Antibody, or Product, as applicable. When used as a noun, **"Commercialization"** means any and all activities involved in Commercializing.

1.22 **"Commercially Reasonable Efforts"** means the level of efforts, expertise, and resources commonly applied by Viridian to carry out a particular task or obligation consistent with the general practice followed by Viridian relating to other pharmaceutical compounds, products or therapies owned by it, or to which it has exclusive rights, which are of similar market potential at a similar stage in their development or product life, taking into account issues of safety and efficacy, product profile, the competitiveness of other products in development and in the marketplace, supply chain management considerations, the regulatory structure involved, the profitability of the applicable compound, product or therapy (including pricing and reimbursement status achieved), and other relevant technical, legal, scientific or medical factors.

1.23 **"Competing Program"** has the meaning set forth in Section 2.1(b) (Non-Compete).

1.24 **"Confidential Information"** of a Party means any and all non-public scientific, business, regulatory or technical information that is disclosed or made available by or on behalf of one Party (the **"Disclosing Party"**) to the other Party (the **"Receiving Party"**) in connection with this Agreement, whether in writing, orally, visually or otherwise. As between the Parties, the [\*\*\*] IP constitute the Confidential Information of Paragon.

1.25 **"Control"** (including any variations such as **'Controlled'** and **"Controlling"**) means, with respect to any Know-How or other Intellectual Property Rights, possession by a Party and the ability (whether by ownership, license or otherwise) to grant a license or a sublicense of or under such Know-How or Intellectual Property Rights without violating the terms of any agreement or other arrangement with any Third Party.

Notwithstanding anything in this Agreement to the contrary, a Party or its Affiliate will not be deemed to Control Know-How or other Intellectual Property Rights that are owned or inlicensed by an Acquirer, unless (1) such Know-How or other Intellectual Property Rights owned or in-licensed by the Acquirer were generated from participation by employees or consultants of such Acquirer in the performance of Development Activities under a Research Program after such Change of Control, (2) such Know-How or other Intellectual Property Rights owned or in-licensed

by such Acquirer are used by such acquired Party or any of its Affiliates in the performance of Development Activities under a Research Program, or (3) if, prior to the consummation of such Change of Control, such acquired Party or any of its Affiliates also Controlled such Know-How or other Intellectual Property Rights, in each of which cases ((1)-(3)), such Know-How or other Intellectual Property Rights owned or in-licensed by such Acquirer will be deemed Controlled by the acquired Party for purposes of this Agreement.

1.26 **"Cover"** or **"Covering"** means, with respect to a particular product, any Patent, that, in the absence of a license granted under, or ownership of, such Patent, the making, using, selling, importation, or exportation of such product would infringe a valid and unexpired claim of such Patent.

1.27 **"CREATE Act"** has the meaning set forth in [Section 5.3\(d\) \(CREATE Act\)](#).

1.28 **"Deliverables"** means collectively all deliverables, samples, Sequence Information and such other data, results, summaries, information, or reports as Paragon may be required to deliver under the Research Agreement. For the avoidance of doubt, any **"Deliverables"** (as such term is defined under the Research Agreement) provided by Paragon under the Research Agreement, shall be Deliverables under this Agreement.

1.29 **"Derived Antibody"** means any Antibody (including any chimeric, humanized, human, non-human, single chain, monovalent, divalent, polyvalent, monospecific, bispecific or other Antibody, fragment thereof, or polynucleotide encoding any of the foregoing) that [\*\*\*].

1.30 **"Develop"** or **"Developing"** means to discover, evaluate, test, research or otherwise develop an Antibody, including a Licensed Antibody or Derived Antibody, or Product. When used as a noun, **"Development"** means any and all activities involved in Developing.

1.31 **"Development Activities"** means the development activities that have been performed or are to be performed by or on behalf of Paragon for the Research Programs, as further described in the Research Plan attached to the Research Agreement.

1.32 **"Directed To"** means, with regard to an Antibody or Product, that such Antibody or Product is developed or designed to [\*\*\*].

1.33 **"Disclosing Party"** has the meaning set forth in [Section 1.24 \(The Definition of "Confidential Information"\)](#).

1.34 **"Dispute"** has the meaning set forth in [Section 10.7 \(Dispute Resolution\)](#).

1.35 **"Dollar"** means a U.S. dollar, and **"\$"** shall be interpreted accordingly.

1.36 **"Field"** means the prophylaxis, palliation, treatment and diagnosis of human disease and disorders in all therapeutic areas.

1.37 **"First Commercial Sale"** means the first sale of a Product by Viridian, or one of its Affiliates or its or their Sublicensees, to a Third Party after receipt of all Regulatory Approvals required to market and sell the Product have been obtained in the country in which such Product is sold. **"First Commercial Sale"** shall not include (i) [\*\*\*] or (ii) [\*\*\*].

1.38 “[\*\*\*] Program” means the portion of the [\*\*\*] Program that is described [\*\*\*] in the Research Plan attached to the Research Agreement.

1.39 “**Indemnified Party**” has the meaning set forth in Section 9.3 (Indemnification Procedures).

1.40 “**Indemnifying Party**” has the meaning set forth in Section 9.3 (Indemnification Procedures).

1.41 “**Intellectual Property Rights**” means any and all proprietary rights provided under (a) patent law, including any Patents; (b) copyright law; or (c) any other applicable statutory provision or common law principle, including trade secret law, that may provide a right in Know-How, or the expression or use thereof.

1.42 “**Know-How**” means all technical information and know-how in any tangible or intangible form, including (a) inventions, discoveries, trade secrets, data, specifications, instructions, processes, formulae, materials (including cell lines, vectors, plasmids, nucleic acids and the like), methods, protocols, expertise and any other technology, including the applicability of any of the foregoing to formulations, compositions or products or to their manufacture, development, registration, use or marketing or to methods of assaying or testing them or processes for their manufacture, formulations containing them or compositions incorporating or comprising them, and (b) all data, instructions, processes, formulae, strategies, and expertise, whether biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical, analytical, or otherwise and whether related to safety, quality control, manufacturing or other disciplines. Notwithstanding the foregoing, Know-How excludes Patent claims.

1.43 “**License**” has the meaning set forth in Section 2.1(a) (License).

1.44 “**Licensed Antibody**” means any and all Antibodies that are discovered, generated, identified or characterized by or on behalf of Paragon in the course of performing the Development Activities under a Research Program under the Research Agreement that [\*\*\*].

1.45 “**Licensed Antibody Invention**” means (a) any Know-How Controlled by Paragon or its Affiliates, whether or not patentable, that is discovered, made or created in the course of, or that results from performance of, any activity(ies) by or on behalf of either Party, under the Research Agreement, including any invention or discovery that constitutes the composition of matter of, or any method of making or using, any Licensed Antibody, any Derived Antibody, any fragment of the foregoing, any polynucleotide encoding any of the foregoing, or any Product; and (b) all Intellectual Property Rights in each of the foregoing. For the avoidance of doubt, Licensed Antibody Inventions include all Project Antibody Inventions (as such term is defined under the Research Agreement) generated under the Research Agreement, including [\*\*\*].

1.46 “**Licensed Antibody Patents**” means all Patents Controlled by Paragon or any of its Affiliates as of the Original Effective Date or during the Term, that Cover any Licensed Antibody Invention, Licensed Antibody, Derived Antibody, or Product in the Territory. The Licensed Antibody Patents existing as of the A&R Effective Date are set forth on Exhibit A hereto. Upon the request of Viridian from time to time during the Term, Paragon shall update Exhibit A to include the then-existing Licensed Antibody Patents. Notwithstanding anything to the contrary herein, Licensed Antibody Patents exclude [\*\*\*].

1.47 **“Licensed Antibody Technology”** means (a) all Licensed Antibody Inventions; (b) all Licensed Antibody Patents; (c) all Deliverables, including all Sequence Information and Results; and (d) all Intellectual Property Rights therein. For the avoidance of doubt, Licensed Antibody Technology includes [\*\*\*].

1.48 **“Licensed Background IP”** means all Background IP that is Controlled by Paragon (including any Paragon Platform Technology) during the term of any Research Program and that is [\*\*\*].

1.49 **“Licensed Target”** means human FcRn.

1.50 **“Losses”** has the meaning set forth in Section 9.1 (By Viridian).

1.51 **“MAA”** means (a) a New Drug Application in the United States, as defined in the United States Federal Food, Drug and Cosmetics Act, and applicable regulations promulgated thereunder by the FDA; (b) a Biologics License Application in the United States; or (c) any application filed with any Regulatory Authority in a country other than the United States that is equivalent to either of the foregoing.

1.52 **“Major Market Country”** means [\*\*\*].

1.53 **“Manufacture”** or **“Manufacturing”** means to make, produce, manufacture, process, fill, finish, package, label, perform quality assurance testing, release, ship or store an Antibody, including any a Licensed Antibody or Derived Antibody, or Product or any component thereof. When used as a noun, “Manufacture” or “Manufacturing” means any and all activities involved in Manufacturing an Antibody, including any a Licensed Antibody or Derived Antibody, or Product or any component thereof.

1.54 **“Milestone”** has the meaning set forth in Section 4.2 (Milestones Payment).

1.55 **“Milestone Payment”** has the meaning set forth in Section 4.2 (Milestones Payment).

1.56 **“[\*\*\*] Program”** means the development program that has been or to be conducted by or on behalf of Paragon under the Research Agreement to discover, identify, generate, and characterize [\*\*\*] Antibodies [\*\*\*] as such program is further described in the Research Plan attached to the Research Agreement. [\*\*\*].

1.57 **“Net Sales”** means the gross amounts received for Products by Viridian, its Affiliates and Sublicensees for sales, transfers or other commercial disposition of Products, less the following reasonable and customary deductions, in each case related specifically to the Product and actually incurred, paid or accrued by Viridian, its Affiliates or Sublicensees and not otherwise recovered by or reimbursed to Viridian, its Affiliates, or Sublicensees:

- (a) [\*\*\*];
- (b) [\*\*\*];
- (c) [\*\*\*];
- (d) [\*\*\*];

- (e)     [\*\*\*]; and
- (f)     [\*\*\*].

Net Sales will include [\*\*\*]. Net Sales will be calculated only once for the first *bona fide* arm's length sale of the Product by Viridian, its Affiliates or its Sublicensees to a Third Party, and will not include sales of Products between or among [\*\*\*] where the purchaser will resell such Product. Net Sales shall not include [\*\*\*].

Net Sales shall be determined from the books and records of Viridian, Affiliates of Viridian or any Sublicensee maintained in accordance with Accounting Standards, in each case as consistently applied throughout such entity's organization.

If a Product is sold as a Combination Product (as defined below), the Net Sales of such Combination Product shall be determined as follows: [\*\*\*]. If any Other Component in the Combination Product is not sold separately, Net Sales shall be calculated by [\*\*\*]. If both the Licensed Component and any of the Other Components are not sold separately, the adjustment to Net Sales shall be determined by the Parties [\*\*\*] to reasonably reflect [\*\*\*] of such Combination Product.

For purposes of this definition, "**Combination Product**" means any pharmaceutical product that contains two (2) or more active ingredients, including both (A) a Product (the "**Licensed Component**"); and (B) one (1) or more active pharmaceutical or biological ingredients that are not a Product ("**Other Components**"), either as a [\*\*\*].

- 1.58    "**Notice of Dispute**" has the meaning set forth in [Section 10.7 \(Dispute Resolution\)](#).
- 1.59    "**Other Component**" has the meaning set forth in [Section 1.57 \(Definition of Net Sales\)](#).
- 1.60    "**Original Effective Date**" has the meaning set forth in the recitals.
- 1.61    "**Paragon Indemnitee**" has the meaning set forth in [Section 9.1 \(By Viridian\)](#).
- 1.62    "**Paragon Know-How**" means all Know-How in the Licensed Antibody Technology.
- 1.63    "**Paragon Platform Technology**" means Paragon Platform Know-How, Paragon Platform Know-How Improvements and Paragon Platform Patents. For the avoidance of doubt, Paragon Platform Technology does not include [\*\*\*].

For purposes of this definition, '**Paragon Platform Know-How**' means Know-How Controlled by Paragon or its Affiliates prior to or during the Term relating generally to Antibody discovery, (b) all methods, materials, and other Know-How Controlled and used by Paragon or its Affiliates generally in connection with Antibody discovery, and (c) physical platforms embodying components, component steps or other portions of any of the foregoing in (a) and (b) that are Controlled by Paragon or its Affiliates. '**Paragon Platform Know-How Improvement**' means all Know-How, other than Licensed Antibody Invention, that is developed or discovered through or as a result of the Development Activities by or on behalf of Paragon

under the Research Agreement and that is Controlled by Paragon [\*\*\*]. **‘Paragon Platform Patents’** means all Patents that Paragon or its Affiliates Control prior to or during the Term that Cover Paragon Platform Know-How or Paragon Platform Know-How Improvements.

1.64 **“Patent Challenge”** has the meaning set forth in [Section 5.4\(a\) \(Notice of Patent Infringement and Patent Challenge\)](#).

1.65 **“Patent Infringement”** has the meaning set forth in [Section 5.4\(a\) \(Notice of Patent Infringement and Patent Challenge\)](#).

1.66 **“Patents”** means (a) unexpired patents and patent applications, (b) any and all divisionals, continuations, continuations-in-part, reissues, renewals, substitutions, registrations, re-examinations, revalidations, extensions, supplementary protection certificates and the like of any such patents and patent applications, and (c) any and all foreign equivalents of the foregoing.

1.67 **“Phase I Trial”** means a human clinical trial in any country of the type described in 21 C.F.R. §312.21(a), or the foreign equivalent thereof, regardless of where such clinical trial is conducted.

1.68 **“Phase III Trial”** means a human clinical trial in any country of the type described in 21 C.F.R. § 312.21(c), or the foreign equivalent thereof, regardless of where such clinical trial is conducted.

1.69 **“Product”** means (i) any product that constitutes, incorporates, comprises or contains any Licensed Antibody or Derived Antibody, (ii) any Licensed Antibody or (iii) any Derived Antibody; in each case ((i)-(iii)), alone or in combination with one or more Other Components or as part of a combination therapy with one or more other products concurrently or sequentially administered, in any form, mode of administration, dosage form, formulation or strength.

1.70 **“Prosecute”** or **“Prosecution”** has the meaning set forth in [Section 5.3\(a\) \(Prosecution Generally\)](#).

1.71 **“Receiving Party”** has the meaning set forth in [Section 1.24 \(Definition of Confidential Information\)](#).

1.72 **“Regulatory Approval”** means all clearances, approvals (including approval of an MAA as well as any applicable pricing and/or reimbursement approvals), licenses, registrations or authorizations of any Regulatory Authority necessary to commercially distribute, sell and market a pharmaceutical product in a country or territory under this Agreement.

1.73 **“Regulatory Authority”** means any supranational, multinational, federal, national, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the clinical development, manufacture, marketing or sale of a Product in a country or region, including the FDA in the United States and the EMA in Europe.

1.74 **“Representatives”** of a Party means such Party’s officers, directors, employees, contractors, subcontractors, agents and consultants.

1.75 “**Research Plan**” means the research plan attached to the Research Agreement as Exhibit A, which may be updated from time-to-time in accordance with the terms of the Research Agreement.

1.76 “**Research Program**” means any past, present or future research program conducted by the Parties pursuant to the Research Agreement and the Letter Agreement with respect to the Licensed Target, including the [\*\*\*] Program and the [\*\*\*] Program.

1.77 “**Results**” means all data, results, analysis, conclusions, outcomes, information, documentation and reports (in each case, excluding Licensed Antibody Inventions, Licensed Antibody Patents, and the Sequence Information) that are generated by or on behalf of Paragon in performance of a Research Program, excluding Licensed Antibodies.

1.78 “**Reversion Products**” has the meaning set forth in [Section 8.6 \(Effect of Termination of this Agreement\)](#).

1.79 “**Royalty Payments**” has the meaning set forth in [Section 4.3 \(Royalties\)](#).

1.80 “**Royalty Term**” means, on a Product-by-Product and country-by-country basis, the period commencing on First Commercial Sale of the applicable Product in the applicable country and ending, with respect to the particular Product and country at issue on the latest of the following dates: (a) the twelfth (12<sup>th</sup>) anniversary of the date of First Commercial Sale of such Product in such country; and (b) the expiration of the last-to-expire Valid Claim of a Licensed Antibody Patent Covering the manufacture, use or sale of such Product in such country.

1.81 “**Sequence Information**” means electronic files containing all Licensed Antibody sequences generated under a Research Program.

1.82 “**Sublicensee**” means any Third Party with respect to Viridian, to whom Viridian grants a sublicense of, or other authorization or permission granted under, the rights granted to Viridian in [Section 2.1 \(License Grant from Paragon\)](#).

1.83 “**Target**” means a protein molecule that (a) is chemically distinct from other molecules, and (b) wherein a binding entity derives recognized therapeutic value from binding to such molecule.

1.84 “**Term**” has the meaning set forth in [Section 8.1 \(Term\)](#).

1.85 “**Territory**” means worldwide.

1.86 “**Third Party**” means any person or entity other than Paragon or Viridian or an Affiliate of either Paragon or Viridian.

1.87 “**Third Party Claim**” has the meaning set forth in [Section 9.1 \(By Viridian\)](#).

1.88 “**US**” or “**United States**” means the United States of America and its possessions and territories, including Puerto Rico.

1.89 “**Valid Claim**” means, with respect to a particular country, a claim (including a process, use, or composition of matter claim) of an issued and unexpired patent (or a supplementary protection certificate thereof) that has not (a) irretrievably lapsed or been

abandoned, permanently revoked, dedicated to the public or disclaimed, or (b) been held invalid, unenforceable or not patentable by a court, governmental agency, national or regional patent office or other appropriate body that has competent jurisdiction, which holding, finding or decision is final and unappealable or unappealed within the time allowed for appeal.

1.90 “**Viridian Indemnitees**” has the meaning set forth in Section 9.2 (By Paragon).

1.91 “**Viridian Patent Challenge**” has the meaning set forth in Section 8.3 (Termination by Paragon).

## ARTICLE II LICENSES; TECHNOLOGY TRANSFER

### 2.1 License Grant from Paragon.

(a) License. Subject to the terms of this Agreement (including Section 2.4 (Reservation of Rights)), Paragon hereby grants to Viridian (i) a worldwide, royalty-bearing, exclusive (even as to Paragon and its Affiliates) right and license, including the right to sublicense through multiple tiers, under Paragon’s interest in and to the Licensed Antibody Technology; (ii) a worldwide, royalty-bearing, non-exclusive right and license, including the right to sublicense through multiple tiers, under Paragon’s interest in and to the Licensed Background IP; and (iii) a worldwide sublicense, including the right to further sublicense through multiple tiers, under Paragon’s interest in and to [\*\*\*] IP, in each case ((i), (ii) and (iii)), to research, use, make, have made, sell, offer for sale, have sold, import, export and otherwise exploit Licensed Antibodies, Derived Antibodies and Products in the Field in the Territory; *provided, however*, that notwithstanding the foregoing or any other provision herein to the contrary, (a) Viridian’s non-exclusive license under the foregoing clause (ii) shall *not* include the right to use or practice Licensed Background IP to research, use, make, have made, sell, offer for sale, have sold, import, export or otherwise exploit Derived Antibodies except to the extent such Licensed Background IP was incorporated by Paragon into any Licensed Antibody under any Research Program or to use Deliverables, in the form in which such Deliverables were provided to Viridian, in its research, use, making, having made, selling, offering for sale, having sold, importing, exporting or otherwise exploiting Derived Antibodies, even if those Deliverables contain or are based on Licensed Background IP, and (b) as between the Parties, the sublicense Viridian receives under the foregoing clause (iii) is exclusive, even with respect to Paragon (the “**License**”).

(b) Non-Compete. Paragon (itself and on behalf of its Affiliates) shall not

- (1) research, Develop, Manufacture or Commercialize (including seek Regulatory Approval for),
- (2) authorize or otherwise assist any Third Party in researching, Developing, Manufacturing or Commercializing or (3) supply to any Third Party: (x) any Licensed Antibody or Derived Antibody, or any other Antibody that binds to the Licensed Target and inhibits the binding of the Licensed Target to [\*\*\*] or (y) any product that constitutes, incorporates, comprises or contains any of the foregoing Antibodies, in each case ((x)-(y)) in the Field in the Territory, whether alone or in combination with one or more Other Components or as part of a combination therapy with one or more other products concurrently or sequentially administered, in any form, mode of administration, dosage form, formulation or strength; for a period of [\*\*\*] years from the Original Effective Date. For clarity, the foregoing restrictions shall not apply to [\*\*\*].

(c) Notwithstanding Section 2.1(b) (Non-Compete), if a Third Party becomes an Affiliate of Paragon during the Term through a Change of Control of Paragon and such new Affiliate, as of the effective date of such Change of Control, is engaged in Development, Manufacturing, Commercialization, or other exploitation activities that, if conducted by Paragon, would cause Paragon to violate the terms of Section 2.1(b) (Non-Compete) (the program of conduct of such activities, a "**Competing Program**"), then the new Affiliate will not be in violation of Section 2.1(b) (Non-Compete) as long as (A) no Licensed Antibody Technology, Licensed Background IP or other Confidential Information of Viridian is used by or on behalf of Paragon or its Affiliates in connection with any activities relating to the Competing Program, and (B) Paragon and its Affiliates institute commercially reasonable technical and administrative safeguards to comply with foregoing clause (A), including a customary "firewall" segregating personnel working on the research, Development, Manufacture, or Commercialization of the Competing Program from personnel working on Licensed Antibodies, Derived Antibodies, or Products.

## 2.2 Sublicenses.

(a) Paragon IP. Subject to Section 2.2(b), Viridian shall have the right to grant sublicenses (or further rights of reference), through multiple tiers of sublicensees, under the License to Sublicensees, provided that any such sublicense shall be consistent with the terms and conditions of this Agreement. No sublicense shall relieve or waive any obligations of Viridian hereunder. Viridian shall remain responsible for the performance by its Affiliates and Sublicensees of the rights and obligations hereunder. In respect of such sublicenses (or sub-sublicenses) and Affiliates and without limiting the foregoing:

(i) Viridian will remain responsible for the payment to Paragon of all Royalty Payments payable under this Agreement with respect to Net Sales made by Viridian's Affiliates and Sublicensees;

(ii) Viridian shall be responsible for failure by its Affiliates and Sublicensees to comply with the terms and conditions of this Agreement;

(iii) Viridian shall, within [\*\*\*] days of a grant of a sublicense, notify Paragon of each sublicense granted to any Third Party, including the identity of such Third Party and the scope of the license granted, and deliver a copy of such sublicense (and any amendments thereto), which may be reasonably redacted to remove sensitive financial data; provided, that for the avoidance of doubt the foregoing obligations shall not apply with respect to Third Party service providers or distributors; and

(iv) Subject to Section 8.8 (Survival of Sublicenses), all sublicenses shall automatically terminate upon termination (for whatever reason) of this Agreement, but not expiration of this Agreement.

(d) [\*\*\*] IP. If any sublicense granted by Viridian under this Section 2.2 (Sublicenses) includes a further sublicense by Viridian of the sublicense granted to Viridian in Section 2.1(a)(iii) under [\*\*\*] IP, then the following terms and conditions shall also apply:

(i) each sublicense of [\*\*\*] IP shall be subject and subordinate to the [\*\*\*] License Agreement, and shall contain provisions consistent with Section 2.5 ([\*\*\*] License Agreement) applicable to the sublicense of [\*\*\*] IP;

(ii) except as to sublicenses of [\*\*\*] IP to Affiliates, subcontractors and service providers, Viridian shall as soon as reasonably practicable provide Paragon with (or, at the request of Paragon, provide directly to [\*\*\*]) a copy of any executed sublicense agreement (which copy may be redacted to remove financial and other provisions that are not necessary to monitor compliance with this Section 2.2(b)([\*\*\*] IP) or Section 3.4 (Sublicenses to [\*\*\*] Programs) of the [\*\*\*] License Agreement); and

(iii) each such sublicense agreement shall contain a requirement that the sublicensee comply with the confidentiality and non-use restrictions at least as stringent as those set forth in the [\*\*\*] License Agreement with respect to [\*\*\*] Confidential Information (as defined under the [\*\*\*] License Agreement), provided that Paragon clearly marks such Confidential Information owned by [\*\*\*] and provided to Viridian as such.

**2.3 Initial Information Transfer to Viridian.** Within [\*\*\*] days after the A&R Effective Date, at Paragon's sole cost and expense, Paragon shall transfer to Viridian copies of all Paragon Know-How, Sequence Information, and Results in existence as of the A&R Effective Date that has not already been provided to Viridian. Except as otherwise reasonably requested by Viridian, any such transfer will be conducted via a secure data room selected by Viridian.

**2.4 Reservation of Rights.** Notwithstanding the License and subject to Article VI (Protection of Confidential Information) and Section 2.1(b) (Non-Compete), Paragon reserves the right to use and practice the Licensed Antibody Technology solely to perform any Research Program pursuant to the Research Agreement for the benefit of Viridian.

**2.5 [\*\*\*] License Agreement.**

**(a) Applicability of the [\*\*\*] License Agreement.** The Parties acknowledge and agree that:

(i) the [\*\*\*] IP has been or will be licensed by [\*\*\*] to Paragon under the [\*\*\*] License Agreement and sublicensed by Paragon to Viridian under Section 2.1(a)(iii) of this Agreement;

(ii) Viridian agrees to be bound by the following articles and sections of the [\*\*\*] License Agreement to the extent applicable to the sublicense of [\*\*\*] IP granted by Paragon to Viridian hereunder: Article 4 (Fees and Payments) (to the extent set for in Section 4.2 of this Agreement), Article 8 (Compliance with Law); Article 9 (Confidentiality); Section 3.4 (Sublicenses to [\*\*\*] Programs); Section 5.1 (Tax Matters), Section 5.2 (Records; Audits), Section 5.3 (Reports), Section 10.6 (Effect of Termination or Expiration; Surviving Obligations), Section 11.4 (Insurance).

(iii) in the event of any conflict between the terms of this Agreement and the terms of the [\*\*\*] License Agreement that are applicable to Viridian with respect to the sublicense granted to Viridian under Section 2.1(a)(iii), the terms of the [\*\*\*] License Agreement

shall control to the extent necessary for Paragon to maintain compliance with the terms of the [\*\*\*] License Agreement.

(b) **Required Disclosures under the [\*\*\*] License Agreement.** Notwithstanding anything else herein to the contrary, Viridian hereby consents to Paragon:

(i) providing an executed copy of this Agreement to [\*\*\*] (which copy shall be redacted to remove financial and other provisions that are not necessary for [\*\*\*] to monitor compliance with Section 3.4 (Sublicenses to [\*\*\*] Programs) of the [\*\*\*] License Agreement); and (ii) disclosing to [\*\*\*] any Confidential Information of Viridian that is expressly and specifically required to be disclosed by Paragon to [\*\*\*] under Section 3.4 (Sublicenses to Partnered Antibody Programs) and Section 5.3 (Reports) of the [\*\*\*] License Agreement. Paragon shall prominently mark such copy of this Agreement and copies of Viridian's Confidential Information as "Confidential Information of Viridian Therapeutics, Inc." and require [\*\*\*] to acknowledge in writing that it is bound by its obligations of confidentiality and non-use set forth in Article 9 (Confidentiality) of the [\*\*\*] License Agreement with respect thereto.

(c) **Covenants by Viridian.** Viridian hereby covenants and agrees that:

(i) On or before [\*\*\*] of each year during the Term, Viridian shall deliver to Paragon a written report for its activities under this Agreement meeting the reporting requirements set forth in Section 5.3 (Reports) of the [\*\*\*] License Agreement;

(ii) Viridian shall cure any breach of the [\*\*\*] License Agreement caused by Viridian, its Affiliates or Sublicensees within [\*\*\*] days of written notice thereof, and shall provide Paragon with written notice of such cure upon completion thereof; and

(iii) Except as expressly required under this Agreement solely with respect to the [\*\*\*] License Agreement, Viridian shall not communicate directly with [\*\*\*] with respect to matters under this Agreement without Paragon's prior written consent, which consent may be withheld in Paragon's sole discretion, unless required by Applicable Law or administrative order.

## ARTICLE III

### DEVELOPMENT, MANUFACTURING & COMMERCIALIZATION

**3.1 Development, Manufacturing and Commercialization.** As between the Parties, Viridian shall be solely responsible for and have sole authority over and control of all aspects of the Development, Manufacturing, and Commercialization of Licensed Antibodies, Derived Antibodies and Products in the Territory in the Field. As between the Parties, Viridian shall be solely responsible for selection, registration and maintenance of all trademarks associated with the Products in the Field in the Territory. As between the Parties, Viridian shall solely own such trademarks in the Territory and pay all relevant costs thereof.

**3.2 Regulatory.** As between the Parties, Viridian shall have the sole authority over and control of the regulatory strategy, regulatory filings, regulatory activities (including clinical trials for Products) and communication with each Regulatory Authority for the Products in the Field in the Territory and shall own all corresponding Regulatory Approvals.

3.3 **Diligence; Reporting.** Viridian shall, itself or through its Affiliates, Sublicensees, or contractors:

(a) use Commercially Reasonable Efforts to Develop and seek Regulatory Approval for at least one Product in the Field in each of (i) the United States and (ii) at least one other Major Market Country; and

(b) upon receipt of Regulatory Approval for a given Product in a given country, use Commercially Reasonable Efforts to Commercialize such Product in such country.

On or before [\*\*\*] of each Calendar Year prior to the First Commercial Sale of a Product in the Territory, Viridian shall deliver to Paragon a report summarizing its material development efforts with respect to any Licensed Antibodies, Derived Antibodies and Products, including preclinical and clinical activities, and achievement of any Milestones, during the preceding [\*\*\*]. Such report shall be the Confidential Information of Viridian.

## **ARTICLE IV** **FINANCIAL TERMS**

4.1 **Initial Payments.** In partial consideration of the rights granted under this Agreement:

(a) Viridian shall pay to Paragon an initial payment of Four Million Dollars (\$4,000,000) within [\*\*\*] days of the A&R Effective Date; and

(b) Within [\*\*\*] days of the A&R Effective Date, Paragon shall make a payment of the sublicense fee in the amount of [\*\*\*] to [\*\*\*] pursuant to Section 4.7 (Sublicense Fee) of the [\*\*\*] License Agreement. Paragon will provide Viridian with written confirmation thereof and will issue an invoice to Viridian for such amount Within [\*\*\*] days of Viridian's receipt of such invoice, Viridian shall make a one-time, non-refundable and non-creditable payment to Paragon to reimburse Paragon for the sublicense fee under Section 4.7 (Sublicense Fee) of the [\*\*\*] License Agreement paid by Paragon to [\*\*\*] with respect to this Agreement.

4.2 **Milestones Payments.**

(a) **Milestone Payment.** Viridian shall make the following one-time payments to Paragon on a Research Program-by-Research Program basis (each, a "**Milestone Payment**"), based on the achievement of the corresponding milestone (each, a "**Milestone**") by Viridian, its Affiliates, or its Sublicensees with respect to the first Product within each of (i) the portion of the [\*\*\*] Program other than the [\*\*\*] Program, (ii) the [\*\*\*] Program, and (iii) the [\*\*\*] Program to achieve such Milestone, [\*\*\*]. Notwithstanding anything to the contrary in this Agreement, the [\*\*\*] Program and the portion of the [\*\*\*] Program other than the [\*\*\*] Program shall be deemed two separate Research Programs for the purposes of this Section 4.2 (Milestones Payment). Viridian shall, within [\*\*\*] days after the occurrence of each Milestone, make the corresponding Milestone Payment to Paragon. Each Milestone Payment shall be paid no more than once per Research Program, for the first achievement thereof by any Product in such Research Program, irrespective of how many Products in such Research Program achieve each Milestone, and Viridian's total Milestone Payments hereunder shall not exceed (i) Forty Million Dollars (\$40,000,000) in the aggregate for all three Research Programs [\*\*\*].

	Milestone	Milestone Payment for First Products Within the First Two Research Programs with First Products to Achieve the Relevant Milestone	Milestone Payment for the First Product within the Last of the Three Research Programs with a Product to Achieve the Relevant Milestone
#1	[***]	[***]	[***]
#2	[***]	[***]	[***]
#3	[***]	[***]	[***]

The obligation to make any Milestone Payment is independent of the occurrence or non-occurrence of any prior Milestone. If any Milestone is achieved without the achievement of a numerically lower numbered Milestone applicable to the same Product within such Research Program, then Viridian will pay Paragon the Milestone Payment applicable to such earlier Milestone at the same time Viridian pays the applicable Milestone Payment. For example, if the Milestone Payment for Milestone #3 becomes due before the Milestone Payment for Milestone #2, then upon achievement of Milestone #3, the Milestone Payments for both Milestone #2 and Milestone #3 shall be due and payable.

(b) **Payment Obligations Pursuant to the [\*\*\*] License Agreement**

(i) [\*\*\*] **Payment Obligations.** In consideration for the rights granted by Paragon to Viridian with respect to a Product (as defined in Section 4.2(b)(v)([\*\*\*]Related Definitions)), including under the [\*\*\*] IP pursuant to Section 2.1(a)(iii), following Paragon's [\*\*\*] pursuant to Section 4.4 ([\*\*\*] Program Fee) of the [\*\*\*] License Agreement, and without limiting amounts payable by Viridian to Paragon pursuant to Section 4.1 (Initial Payments), Section 4.2(a) (Milestone Payments), or Section 4.3 (Royalties), Viridian shall make the following payments due to [\*\*\*] under the [\*\*\*] License Agreement as provided in Section 4 (Fees and Payments) of the [\*\*\*] License Agreement and in accordance with Section 4.2(b)(iii)(Payments by Viridian to [\*\*\*]) of this Agreement:

(A) each annual [\*\*\*] Program Fee in the amount of [\*\*\*] that becomes due to [\*\*\*] under Section

4.4 ([\*\*\*] Program Fee) of the [\*\*\*] License Agreement arising from Paragon's activities under this Agreement or the Research Agreement or activities conducted by or on behalf of Viridian, its Affiliates and Sublicensees under this Agreement or the Research Agreement, in each case with respect to Products; provided, that (i) any such payments paid by Viridian pursuant to this Section 4.2(b)(i)(A) (including the initial [\*\*\*] Program Fee and any subsequent [\*\*\*] Program Fees to be paid on each

anniversary of the date of payment of the initial [\*\*\*] Program Fee), shall be creditable under Section 4.4 ([\*\*\*] Program Fee) of the [\*\*\*] License Agreement against the Development Milestone payments payable by Viridian to [\*\*\*] on behalf of Paragon under Section 4.2(b)(i)(B) below, and more than one [\*\*\*] Program Fee may be creditable towards the same Development Milestone payment under Section 4.2(b)(i)(B) below; (ii) any such payments shall only be payable until the First Commercial Sale of a Product developed under the applicable [\*\*\*] Program, after which, no [\*\*\*] Program Fee will be due from Viridian for such [\*\*\*] Program; and (iii) any such payments shall only be payable once and on an annual basis per [\*\*\*] Program;

(B) the Development Milestone payments under Section 4.5 (Development Milestone Payments) of the [\*\*\*] License Agreement, subject to any credits that may be applied to such payments as described under Section 4.4 ([\*\*\*] Program Fee) of the [\*\*\*] License Agreement and Section 4.2(b)(i)(A) of this Agreement, to the extent payable due to achievement of the applicable Development Milestones by Viridian, its Affiliates, or Sublicensees with respect to a Product; and

(C) the Commercial Payments under Section 4.6 (Commercial Payment) of the [\*\*\*] License Agreement to the extent payable due to achievement of the applicable milestones by Viridian, its Affiliates, or Sublicensees with respect to a Product.

(ii) **[\*\*\*] Payment Buyout.** Viridian shall have the right to exercise and fund on behalf of Paragon the buyout rights under Section 4.11 (Product Payment Buyout) of the [\*\*\*] License Agreement for each Product in lieu of Viridian's ongoing payment obligations with respect to the Development Milestone payments and Commercial Payments under Section 4.2(b)(i) ([\*\*\*] Payment Obligations) of this Agreement . On a Product-by-Product basis, Viridian, or any assignee or Sublicensee of Viridian, may, after [\*\*\*], elect to buy out all remaining payment obligations under Section 4.2(b)(i) ([\*\*\*] Payment Obligations) that are payable to [\*\*\*] with respect to such Product including [\*\*\*]. Upon any such election by Viridian or any assignee or Sublicensee of Viridian, Viridian shall make a one-time payment to [\*\*\*] of the sum of: [\*\*\*].

(iii) **Payments by Viridian to [\*\*\*].** Unless directed otherwise by Paragon in writing, (x) Viridian shall, on behalf of Paragon, make all payments due to [\*\*\*] under Section 4.2(b)(i) ([\*\*\*] Payment Obligations) directly to [\*\*\*] in accordance with this Section 4.2(b)(iii) (Payments by Viridian to [\*\*\*]) Paragon will provide to Viridian a copy of any invoice received from [\*\*\*] under Section 4.10 (Invoicing) of the [\*\*\*] License Agreement that is relevant to any payments for which Viridian is responsible under Section 4.2(b)(ii) ([\*\*\*] Payment Obligations) within [\*\*\*] days of receipt, or direct [\*\*\*] to provide such invoices directly to Viridian, and Viridian will make any applicable payments to [\*\*\*] within [\*\*\*] days of receipt of the applicable invoice, and will promptly provide Paragon with written confirmation of such payments. Viridian will not be responsible for any delay in making a payment to [\*\*\*] as required by Section 4.2(b)(ii) ([\*\*\*] Payment Obligations) to the extent that Paragon fails to deliver the applicable invoice from [\*\*\*] to Viridian within the time window as set forth in the preceding sentence and [\*\*\*] has not provided such invoice directly to Viridian. Viridian will deliver to Paragon (i) notice of the successful completion of each Development Milestone payments or Commercial Payments by Viridian, its Affiliates or Sublicensees with respect to a Product within [\*\*\*] days of such successful completion, and (ii) notice of the First Commercial

Sale of each Product within [\*\*\*] days of such occurrence. Viridian will comply with Sections 5.1 (Tax Matters) and 5.2 (Records; Audits) of the [\*\*\*] License Agreement to the extent applicable to the payments for which Viridian is responsible.

(iv) **Offsets.** To the extent that any Development Milestone payment or Commercial Payment owed by Paragon to [\*\*\*] under 4.5 (Development Milestone Payments) and Section 4.6 (Commercial Payment) the [\*\*\*] License Agreement is reduced, whether pursuant to and in accordance with Section 4.9 (Offsets) of the [\*\*\*] License Agreement, or as expressly permitted in this Section 4.2 (b) (Payment Obligations Pursuant to the [\*\*\*] License Agreement), then the corresponding Development Milestone payment or Commercial Payment due under Section 4.2(b)(i)(B) and Section 4.2(b)(i)(B) will be reduced by an equal amount. Paragon will promptly notify Viridian of any such reduction.

(v) **[\*\*\*]-Related Definitions.** For the purposes of this Section 4.2(b) (Payment Obligations Pursuant to the [\*\*\*] License Agreement), (a) a “**Product**” means a Licensed Antibody, Derived Antibody and Product as defined under this Agreement, in each case that is also a “Product” as defined in the [\*\*\*] License Agreement; (b) “**First Commercial Sale**” means with respect to any Product (defined in the foregoing clause (a)) in any country or jurisdiction in the Territory, the first sale of such Product by Viridian or any of its Affiliates or Sublicensees to a Third Party for distribution, use or consumption in such country or jurisdiction after the Regulatory Approval for the commercial sale of such Product has been obtained in such country or jurisdiction; “[\*\*\*] **Program**” means a Research Program that is also “[\*\*\*] Program” as defined in the [\*\*\*] License Agreement; and “[\*\*\*] **Program Fee**,” “[\*\*\*] **Selection Notice**,” “[\*\*\*] **Development Milestone**,” and “[\*\*\*] **Commercial Payment**” shall have the meanings ascribed to them under the [\*\*\*] License Agreement.

#### 4.3 Royalties.

(a) In consideration of the License granted to Viridian hereunder, but subject to adjustment as described in Section 4.3(b), Viridian shall make quarterly, non-refundable, non- creditable royalty payments to Paragon, on a Product-by-Product basis, on each portion of Net Sales of each Product during a Calendar Year in the Field in the Territory at the applicable percentage set forth below during the applicable Royalty Term (“**Royalty Payments**”):

<b>Increments of Worldwide Aggregate Net Sales within a Calendar Year</b>	<b>Royalty (Percentage of Net Sales)</b>
That portion of Net Sales in a Calendar Year for a Product up to [***]	[***]
That portion of Net Sales in a Calendar Year for a Product between [***]	[***]
That portion of Net Sales in a Calendar Year for a Product exceeding [***]	[***]

(b) On a country-by-country and Product-by-Product basis, if a given Product in a given country ceases to be covered by a Valid Claim within the Licensed Antibody Patents in

such country, then for the purposes of calculating royalties due under this Agreement, Net Sales of such Product in such country shall thereafter be deemed to be reduced by [\*\*\*].

**4.4 Payment and Reports.** Within [\*\*\*] days after the end of each [\*\*\*], Viridian shall provide to Paragon a written report stating the [\*\*\*]. All Royalty Payments described in such written report shall be made by Viridian at the same time it submits such written report to Paragon.

**4.5 Payment Method.** All payments due under this Agreement to Paragon shall be made in US Dollars by bank wire transfer in funds to an account designated by Paragon from time to time reasonably in advance of any payment due date.

**4.6 Taxes.** The Parties agree to cooperate with one another and use reasonable efforts to minimize obligations for any and all income or other taxes required by Applicable Law to be withheld or deducted from any Royalty Payments, Milestone Payments or other payments made by Viridian to Paragon under this Agreement, including by completing all procedural steps, and taking all reasonable measures, to ensure that any withholding tax is reduced or eliminated to the extent permitted under Applicable Law, including income tax treaty provisions and related procedures for claiming treaty relief. To the extent that Viridian is required to deduct and withhold taxes on any payment to Paragon, Viridian shall: (i) deduct such taxes from such payment to Paragon, (ii) pay the amounts of such taxes to the proper government authority in a timely manner, and (iii) promptly submit to Paragon an official tax certificate or other available evidence of such withholding sufficient to enable Paragon to claim such payment of taxes. For the avoidance of doubt, Viridian's remittance of such withheld amounts to the appropriate governmental authority, together with payment to Paragon of the remaining amount owed, shall constitute full satisfaction of the applicable payment due to Paragon. Viridian shall provide Paragon with reasonable assistance in order to allow Paragon to recover, as permitted by Applicable Law, withholding taxes, value added taxes or similar obligations resulting from payments made hereunder or to obtain the benefit of any present or future treaty against double taxation which may apply to such payments. Paragon shall promptly provide Viridian with any requested tax forms that may be reasonably necessary in order for Viridian to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral tax income treaty.

**4.7 Foreign Exchange.** If any currency conversion shall be required in connection with the calculation of amounts payable hereunder, such conversion shall be made using the exchange rates used by Viridian in accordance with applicable Accounting Standards consistently applied by Viridian.

**4.8 Late Payments.** Any amount owed by Viridian to Paragon under this Agreement that is not paid within the applicable time period set forth herein will accrue interest at the per annum rate of [\*\*\*] above the then-applicable United States prime rate as quoted in the Wall Street Journal (East Coast Edition) (or if it no longer exists, a similarly authoritative source), calculated on a [\*\*\*] basis, or, if lower, the highest rate permitted under Applicable Law.

**4.9 Blocked Currency.** If by Applicable Law of a country in which Net Sales occurred, conversion of funds into Dollars or transfer of funds from such country to the United States is restricted, forbidden or delayed for more than [\*\*\*] days, then Viridian can elect, at its sole discretion, that the amounts accrued in such country and owed by Viridian to Paragon under

this Agreement shall be paid to Paragon in such country in local currency by deposit in a local bank designated by Paragon, unless the Parties otherwise agree in writing.

#### **4.10 Records; Inspection.**

(a) Viridian shall, and shall cause its applicable Affiliates and Sublicensees to, create and keep complete and accurate records of its sales and other dispositions of all Products in accordance with Accounting Standards, including all records that are reasonably necessary for the purposes of calculating all payments due under this Agreement.

(b) Upon reasonable advance written notice to Viridian, Paragon shall have the right to retain a nationally recognized (in the US) independent certified public accounting firm acceptable to Viridian (which acceptance shall not be unreasonably withheld, conditioned or delayed) to perform on behalf of Paragon an audit, conducted in accordance with Accounting Standards, of such books and records of Viridian or its applicable Affiliates or Sublicensees as may be reasonably necessary to verify the accuracy of any reports provided pursuant to Section 4.4 (Payment and Reports) for any Calendar Quarter ending not more than [\*\*\*] calendar months prior to the date of such request. Such audits shall not occur more frequently than [\*\*\*] in each Calendar Year and shall not be conducted more than [\*\*\*] with respect to any reporting period, in each case except where the previous audit demonstrated material inaccuracies of reports provided pursuant to Section 4.4. (Payment and Reports). All information disclosed or observed during any audit pursuant to this Section 4.10 (Records; Inspection) shall be the Confidential Information of Viridian, and Paragon shall cause the accounting firm to retain all such information as Confidential Information, including, if requested by Viridian, by requiring such accounting firm to enter into a customary confidentiality agreement with Viridian prior to the initiation of any such audit.

(c) Upon completion of any audit hereunder, the accounting firm shall provide both Viridian and Paragon a written report disclosing whether the reports submitted by Viridian are correct or incorrect, whether the amounts paid are correct or incorrect, and in each case, the specific details concerning any discrepancies. No other information regarding Viridian's records shall be provided to Paragon.

(d) Paragon shall bear its internal expenses and the out-of-pocket costs for engaging such accounting firm in connection with performing such audits; provided, however, that if any such audit uncovers an underpayment by Viridian that exceeds [\*\*\*] of the total owed for such payment or payment period, as applicable, then Viridian shall reimburse Paragon for the amounts actually paid to such accounting firm for performing such audit.

(e) If such accounting firm concludes that Viridian has in aggregate underpaid amounts owed to Paragon during the audited period, Viridian shall pay Paragon the amount of the discrepancy within [\*\*\*] days of the date Paragon delivers to Viridian such accounting firm's written report and an invoice for such amounts. If such accounting firm concludes that Viridian has overpaid amounts owed to Paragon during the audited period, then such overpayments shall be, at Viridian's election, credited against any future payment obligation to Paragon hereunder or paid to Viridian within [\*\*\*] days of Viridian's request.

## ARTICLE V INTELLECTUAL PROPERTY

5.1 **Ownership.** Other than the License granted to Viridian, nothing in this Agreement shall affect or limit Paragon's rights in any Patents, Know-How, or other Intellectual Property Rights Controlled by Paragon, now or in the future. Nothing in the Agreement shall affect Viridian's rights in any Patents, Know-How, or other Intellectual Property Rights Controlled by Viridian, now or in the future.

5.2 **No Implied Licenses.** Except for the License, no right or license under any Patents, Know-How or Intellectual Property Right of either Party or its Affiliates is granted or shall be granted by implication hereunder, and all such rights or licenses are or shall be granted only as expressly provided in this Agreement, and each Party reserves to itself all rights not expressly granted under this Agreement.

### 5.3 Patent Prosecution.

(a) **Prosecution Generally.** For the purpose of this Article V (Intellectual Property), (i) "**Prosecute**" and "**Prosecution**" shall include any patent interference, opposition, pre-issuance Third Party submission, ex parte re-examination, post-grant review, inter partes review or other similar proceeding, appeals or petitions to any board of appeals in a patent office, appeals to any court for any patent office decisions, reissue proceedings, and applications for patent term extensions and the like.

(b) **Prosecution by Viridian.** As between the Parties, Viridian shall be solely responsible for, and have sole discretion over, preparing, filing, enforcing, defending, Prosecuting and maintaining the Licensed Antibody Patents, in each case, at Viridian's sole expense.

(i) **Consultation with Paragon.** Viridian shall provide Paragon with copies of all material correspondence from and to any patent office relating to the Licensed Antibody Patents, and Viridian shall provide Paragon with drafts of all proposed filings to any patent office with respect to such Licensed Antibody Patents in reasonably adequate time before submission of such filings for Paragon's review and comment. Viridian will take into consideration Paragon's reasonable comments prior to submitting such filings.

(ii) **Paragon's Backup Right to Prosecute.** Viridian shall notify Paragon of any decision not to prepare or file, or to abandon, cease Prosecution or not maintain any Licensed Antibody Patent anywhere in the Territory. Viridian shall provide such notice at least [\*\*\*] days prior to any filing or payment due date, or any other due date that requires action, in connection with such Licensed Antibody Patent. In such event, Paragon shall have a backup right, but not the obligation, to prepare, file, or continue Prosecution or maintenance of, such Licensed Antibody Patent in Viridian's name, at Paragon's expense.

(iii) **Cooperation in Patent Prosecution.** Each Party shall cooperate with the other Party in the preparation, filing, Prosecution and maintenance of Licensed Antibody Patents, including in each case by providing the Prosecuting Party with data and other information as appropriate and executing all necessary affidavits, assignments and other paperwork. Without limiting the generality of the foregoing, upon the written request of Viridian, Paragon will promptly provide to Viridian any Paragon Know-How, Sequence Information and Results

generated by Paragon that (i) has not been provided to Viridian and (ii) is reasonably necessary and useful for the preparation, filing, and Prosecution of a related Licensed Antibody Patent to enable Viridian to timely prepare, file and prosecute any such Licensed Antibody Patent in accordance with this Section 5.3(b) (Prosecution by Viridian).

(c) **Prosecution by Paragon.** Except with respect to Licensed Antibody Patents, Paragon shall be solely responsible for, and have sole discretion over, preparing, filing, Prosecuting and maintaining any Patents that it owns or otherwise Controls. Paragon's Prosecution of such Patents shall be at Paragon's sole expense.

(d) **CREATE Act.** Notwithstanding anything to the contrary in this Agreement, each Party will have the right to invoke the Cooperative Research and Technology Enhancement Act of 2004, 35 U.S.C. § 103(c)(2)-(c)(3) (the "CREATE Act") when exercising its rights under this Article V (Intellectual Property), without the prior written consent of the other Party. Where such Party intends to invoke the CREATE Act, it will notify the other Party and the other Party will cooperate and coordinate its activities with such Party with respect to any submissions, filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a joint research agreement (JRA) as defined in the CREATE Act.

#### 5.4 Patent Enforcement and Defense.

(a) **Notice of Patent Infringement and Patent Challenge.** Each Party shall give the other Party notice of any known or suspected infringement by a Third Party of any Licensed Antibody Patent ("Patent Infringement") and any known or suspected challenge by a Third Party against the validity or enforceability of any Licensed Antibody Patent ("Patent Challenge") within [\*\*\*] days after such Patent Infringement or Patent Challenge comes to such Party's attention.

(b) **Viridian's First Right to Enforce or Defend.** Viridian shall have the first right, but not the obligation, to bring and control any legal action, including by declaratory judgment action, patent litigation or similar proceeding, in connection with any Patent Infringement or Patent Challenge with respect to the Licensed Antibody Patents in the Field and the Territory at its own expense and discretion as it reasonably determines appropriate. Viridian shall keep Paragon informed and reasonably consult with Paragon in the course of such legal action. Paragon shall have the right to be represented in any such legal action by counsel of its choice at its own expense.

(c) **Settlement.** In connection with any such legal action or proceeding, Viridian shall not enter into any settlement, consent to any judgment or make any admission in any way that would impose any obligation on Paragon, and Viridian shall have no right in such legal action or proceeding to deny the validity or enforceability of any Patent, Patent claim or Patent application included in the Licensed Antibody Patents or admit the invalidity or unenforceability of any Patent, Patent claim or patent application in the Licensed Antibody Patents without the prior written consent of Paragon, such consent not to be unreasonably withheld.

(d) **Paragon's Backup Right to Enforce or Defend.** If Viridian does not initiate a legal action for Patent Infringement or Patent Challenge or take other reasonable action within [\*\*\*] days after a notice from Paragon under Section 5.4(a) (Notice of Patent Infringement)

and Patent Challenge), then Paragon shall have a backup right, but not the obligation, to initiate such legal action at its own expense.

(e) **Allocation of Recoveries.** Any recoveries resulting from such legal action initiated by Viridian or Paragon hereunder relating to Patent Infringement or Patent Challenge, including pursuant to a settlement, shall be applied as follows: [\*\*\*].

(f) **Cooperation with Patent Enforcement.** At the request of the enforcing Party (and at the requesting Party's expense), the other Party shall reasonably cooperate and provide any information or assistance in connection with any legal action under this Section 5.4 (Patent Enforcement and Defense), including executing reasonably appropriate documents, cooperating in discovery and, if required by Applicable Law, joining as a party to the legal action at its own expense.

**5.5 Defense of Claims Brought by Third Parties** If Paragon becomes aware of any actual or potential claim that the Development, Manufacture or Commercialization of any Licensed Antibody, Derived Antibody, or Product under this Agreement infringes, misappropriates, or otherwise violates the Intellectual Property Rights of any Third Party, Paragon will promptly notify Viridian. In any such instance, Viridian will have the sole right to undertake and control the defense or settlement of any Third Party infringement claim, using counsel of its choice, at its cost and expense. Paragon will provide reasonable cooperation and assistance to Viridian in connection with Viridian's defense or settlement of such Third Party infringement claim.

**5.6 Common Interest Agreement.** The Parties acknowledge and agree that, with regard to the Prosecution of the Licensed Antibody Patents, the interests of the Parties under this Agreement, are to obtain the strongest patent protection possible, and as such, are aligned and are legal in nature. The Parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning the Licensed Antibody Patents or their Confidential Information, including privilege under the common interest doctrine and similar or related doctrines. With regard to any information or opinions disclosed pursuant to this Agreement by one Party or its Affiliates to the other Party or its Affiliates regarding Intellectual Property Rights or technology owned by Third Parties, the Parties agree that they have a common legal interest in determining whether, and to what extent, Third Party Intellectual Property Rights may affect the Licensed Antibody, Derived Antibody or Products, and have a further common legal interest in defending against any actual or prospective Third Party infringement claims based on allegations of misuse or infringement of Intellectual Property Rights of Third Party relating to the Licensed Antibodies, Derived Antibodies or Products. Accordingly, the Parties agree that all such information and materials obtained by the Parties from each other will be used solely for purposes of the Parties' common legal interests with respect to the conduct of this Agreement. All information and materials will be treated as protected by the attorney-client privilege, the work product privilege, and any other privilege or immunity that may otherwise be applicable. By sharing any such information and materials, neither Party intends to waive or limit any privilege or immunity that may apply to the shared information and materials. Neither Party shall have the authority to waive any privilege or immunity on behalf of the other Party without such other Party's prior written consent, nor shall the waiver of privilege or immunity resulting from the conduct of one Party be deemed to apply against the other Party. At the request of either Party to conduct the activities under this Article V (Intellectual Property), the Parties shall cooperate in

good faith to enter into any necessary common-interest agreement intended to preserve attorney-client privilege with respect to disclosures and communications by or on behalf of either Party or its Affiliates in connection with such activities.

**5.7 [\*\*\*] Licensed Patents.** Notwithstanding anything to the contrary in this Agreement, the Parties acknowledge and agree that Viridian has no right under this Agreement to prepare, file, enforce, defend, Prosecute or maintain the [\*\*\*] Licensed Patents.

## ARTICLE VI PROTECTION OF CONFIDENTIAL INFORMATION

**6.1 Confidentiality.** Except to the extent expressly authorized by this Agreement, the Receiving Party agrees that, during the Term, and for all time thereafter until one of the exception in Section 6.2 (Exceptions) is met, it shall keep confidential and shall not publish or otherwise disclose to any Third Party, and shall not use for any purpose other than as expressly provided for in this Agreement, any Confidential Information of the Disclosing Party. The Receiving Party may disclose Confidential Information of the Disclosing Party to those of the Receiving Party's Representatives who have a need for such information, provided that the Receiving Party shall advise such Representatives of the confidential nature thereof, shall ensure that each such Representative is bound in writing by obligations of confidentiality and non-use at least as stringent as those contained in this Agreement, and shall be responsible for the compliance of its Representatives with the terms of this Agreement. The Receiving Party shall use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but in no event less than reasonable care) to ensure that its Representatives do not disclose or make any unauthorized use of the Confidential Information of the Disclosing Party. The Receiving Party shall promptly notify the Disclosing Party upon discovery of any unauthorized use or disclosure of the Confidential Information of the Disclosing Party. Notwithstanding anything to the contrary in this Agreement, (a) all Licensed Antibody Inventions, Licensed Antibody Patents, and Deliverables, to the extent directly and exclusively related to the Licensed Antibodies, Derived Antibodies or Products, are the Confidential Information of Viridian and Viridian will be deemed the Disclosing Party and Paragon the Receiving Party with respect thereto, and (b) any Confidential Information included in the Deliverables, to the extent not related to the Licensed Antibodies, Derived Antibodies or Products is the Confidential Information of both Parties.

**6.2 Exceptions.** The Receiving Party's obligations under Section 6.1 (Confidentiality) shall not apply to any Confidential Information of the Disclosing Party that the Receiving Party can prove by competent evidence: (a) is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party in breach of this Agreement, generally known or available; (b) is known by the Receiving Party at the time of receiving such information from the Disclosing Party; (c) is hereafter furnished to the Receiving Party by a Third Party, as a matter of right and without restriction on disclosure; or (d) is independently discovered or developed by the Receiving Party, without the aid, use or application of any Confidential Information of the Disclosing Party.

**6.3 Authorized Disclosure.**

(a) **Compelled Disclosure.** Notwithstanding the provisions of this Article VI (Protection of Confidential Information), the Receiving Party may disclose Confidential

Information, without violating its obligations under this Agreement, to the extent the disclosure is required by a valid order of a court or other governmental body of competent jurisdiction or as otherwise required by Applicable Law, rule, regulation (including securities laws and regulations), government requirement, or as may be required in connection with any filings made with, or by the disclosure policies of, a stock exchange, provided that the Receiving Party shall give reasonable prior written notice to the Disclosing Party of such required disclosure and, at the [\*\*\*] request and expense, shall cooperate with the Disclosing Party's efforts to contest such requirement, to obtain a protective order requiring that the Confidential Information so disclosed be used only for the purposes for which the order was issued or the law, rule or regulation required, or to obtain other confidential treatment of such Confidential Information.

(b) **Other Permitted Disclosure.** Notwithstanding the provisions of this Article VI (Protection of Confidential Information), each Party is permitted to disclose the other Party's Confidential Information to its actual or *bona fide* potential investors, investment bankers, acquirers, merger partners, and other potential or actual *bona fide* financial partners, licensees, sublicensees, or collaborators; provided that, in each such case, such persons are bound by obligations of confidentiality and non-use at least as stringent as those set forth in this Agreement prior to any such disclosure, except that, where the disclosee is an investor, investment banker, or financial partner, such disclosee will only need to be bound by commercially reasonable obligations of confidentiality and non-use.

**6.4 Confidentiality of this Agreement.** This Agreement and its terms are considered Confidential Information of both Parties, and each Party shall keep confidential and shall not publish or otherwise disclose the terms of this Agreement without the prior written consent of the other Party, except as expressly permitted by Section 6.3 (Authorized Disclosure), and except that both Parties may disclose this Agreement and its terms to its legal, financial and investment banking advisors; bona fide potential and actual investors, acquirers, merger partners, assignees, collaborators, investment bankers, lenders, licensees, sublicensees, or strategic partners in connection with license or partnering transactions, due diligence or similar investigations by such Third Parties or in confidential financing documents; and counsel or other advisors for the foregoing; provided, in each case, that any such Third Party agrees to be bound by obligations of confidentiality and non-use at least as restrictive as those set forth in this Article VI (Protection of Confidential Information) (provided that the confidentiality term applicable to such Third Party may be shorter so long as it is commercially reasonable).

**6.5 Press Release.** Neither Party may issue a press release or other public statement disclosing any information relating to or regarding this Agreement or the transactions contemplated hereby without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed. The Parties agree that after a press release or other public announcement has been issued in accordance with this Section 6.5 (Press Release), each Party may make subsequent public disclosures of the information contained in such press release or other public announcement without the further approval of the other Party, 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. Notwithstanding anything to the contrary set forth in this Agreement, each Party may issue a press release or public announcement as required, in the reasonable judgment of such Party, by Applicable Law, including by the rules or regulations of the United States Securities and Exchange Commission or

similar regulatory agency in a country other than the United States or of any stock exchange or listing entity.

**6.6 Use of Name in Announcements.** Except as permitted in Section 6.5 (Press Release), neither Party will use the name, trade name, service marks, trademarks, trade, dress or logos of the other Party (or any of its Affiliates) in press releases, advertising, public announcement, or any other publication, without the other Party's prior written consent in each instance.

**6.7 Return of Confidential Information.** Promptly after the termination or expiration of this Agreement for any reason, each Party will return to the other Party or destroy, as such other Party will direct, all tangible manifestations of such other Party's Confidential Information at that time in the possession of the Receiving Party, subject to the Receiving Party's right to maintain one copy of such tangible manifestations of such other Party's Confidential Information solely for purposes of monitoring its compliance with this Agreement, provided that the Receiving Party will not be required to delete or destroy any electronic back-up tapes or other electronic back-up files that have been created solely by the Receiving Party's automatic or routine archiving and back-up procedures, to the extent created and retained in a manner consistent with its standard archiving and back-up procedures.

## **ARTICLE VII** **REPRESENTATIONS, WARRANTIES AND COVENANTS**

**7.1 Mutual Representations.** Each Party represents and warrants to the other Party that: (a) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof; (b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder; and (c) this Agreement is legally binding upon it, enforceable in accordance with its terms, and does not and will not conflict with any agreement, instrument, or understanding, oral or written, to which it is or may become a party or by which it may be or become bound.

**7.2 Representations of Paragon.** Paragon hereby represents, warrants and covenants to Viridian as of the A&R Effective Date that:

(a) Other than [\*\*\*] IP, Paragon has not incorporated any Third-Party Know-How into the Product nor used any Third Party Know-How in performance of any Research Program without Viridian's prior written consent.

(b) There are no judgments against or awards or settlements against Paragon or any of its Affiliates, and there are no claims, actions, or proceedings pending or, to Paragon's knowledge, threatened, nor to Paragon's knowledge are there any formal inquiries initiated or written notices received that are reasonably likely to lead to the institution of any such legal proceedings, in each case (i) relating to the use of Licensed Antibodies, Derived Antibodies, or Licensed Antibody Technology; or (ii) alleging that any Licensed Antibody Patent is unpatentable, invalid, unenforceable, or not infringed.

(c) Exhibit A sets forth a complete and accurate list of all Licensed Antibody Patents in existence as of the A&R Effective Date.

(d) Other than the [\*\*\*] License Agreement, Paragon is not party to any inlicense agreements (other than in-license agreements for non-exclusive licenses to enable use of intellectual property owned or controlled by Third Party service providers) relating to (i) the Licensed Antibody Technology, or (ii) the Licensed Antibodies, Derived Antibodies and Products.

(e) As of the A&R Effective Date, (i) Paragon Controls the Licensed Antibody Technology, Licensed Background IP, and [\*\*\*] IP, and (ii) Paragon is the sole and exclusive owner of and Controls all of the Licensed Antibody Patents and is listed in the records of the appropriate governmental authorities as the sole and exclusive owner of record for each registration, grant, and application included in the Licensed Antibody Patents.

(f) Paragon has used commercially reasonable efforts to preserve the confidentiality and trade secret protections of the Paragon Know-How.

(g) Other than [\*\*\*] IP, Paragon has obtained from all individuals who participated in any respect in the research, invention or Development of any Licensed Antibodies, Derived Antibodies, Products or Deliverables or authorship or invention of any Licensed Antibody Technology effective assignments of all ownership rights of such individuals in Intellectual Property Rights generated by such individuals in the course of such work, either pursuant to written agreement or by operation of Applicable Law, in each case to the extent necessary to effectuate the license provisions of this Agreement.

(h) To its knowledge, Paragon has the right to: (i) grant to Viridian the License that Paragon purports to grant hereunder; and (ii) use and disclose and to enable Viridian to use and disclose (in each case under appropriate conditions of confidentiality) the Paragon Know-How.

(i) All activities conducted by or, to Paragon's knowledge, on behalf of Paragon or its Affiliates with respect to the Licensed Antibodies, Derived Antibodies and Products prior to the A&R Effective Date have been conducted materially in accordance with Applicable Laws and regulations (including good laboratory practices, as applicable).

(j) To the extent Paragon controlled the Prosecution of any Licensed Antibody Patents, Paragon has (i) filed and Prosecuted Patent applications within the Licensed Antibody Patents in good faith and complied with all duties of disclosure and candor with respect thereto; (ii) paid all application, registration, maintenance, and renewal fees in respect of the Licensed Antibody Patents necessary to maintain the Licensed Antibody Patents as of the A&R Effective Date (as applicable); (iii) filed all necessary documents and certificates with the relevant agencies for the purpose of maintaining the Licensed Antibody Patents; and (iv) not received any information, except for the information disclosed to the U.S. Patent and Trademark Office during Prosecution of the Patent applications included in the Licensed Antibody Patents, that Paragon believes as of the A&R Effective Date (without taking into account any other belief that Paragon may form after the A&R Effective Date, whether due to the passage of time, the receipt of additional information, or otherwise) has a material adverse effect on the validity or enforceability of any of the claims of such Patent applications.

(k) (i) To the knowledge of Paragon and except with respect to [\*\*\*] IP, the exploitation of the Licensed Antibodies, Derived Antibodies and Products as contemplated

hereunder does not infringe the Patents or misappropriate the Know-How of any Third Party; and (ii) Paragon has not received any written notice alleging such infringement or misappropriation.

(l) Paragon has not entered into a funding relationship with a governmental authority that would result in rights to any Licensed Antibody, Derived Antibody or Product residing in the United States Government, National Institutes of Health, National Institute for Drug Abuse or other governmental authority (including counterparts of such agencies in any other countries), and the licenses granted hereunder are not subject to overriding obligations to the United States Government as set forth in Public Law 96 517 (35 U.S.C. 200 204) or any similar obligations under the Applicable Laws of any other country with respect to other governmental authorities.

(m) The [\*\*\*] License Agreement is in full force and effect, and Paragon has provided a true and complete copy of it under Exhibit B. Neither Paragon nor its Affiliates is in default with respect to a material obligation under the [\*\*\*] License Agreement, and [\*\*\*] has not claimed nor has grounds upon which to claim that Paragon is in breach or default under the [\*\*\*] License Agreement. During the Term, Paragon will maintain and not breach or terminate, and will cause its Affiliates to maintain and not breach or terminate, the [\*\*\*] License Agreement. Paragon will promptly notify Viridian in writing of any material breach by Paragon or its Affiliate, and will promptly notify Viridian in writing if Paragon or its Affiliate receives a notice from [\*\*\*] of Paragon's material breach of the [\*\*\*] License Agreement.

(n) During the Term, Paragon will not (i) grant any interest in, or take any action with respect to, the Licensed Antibody Technology and Licensed Background IP, including any sale, grant of license, assignment or transfer of the Licensed Antibody Technology or Licensed Background IP, or (ii) incur or permit to exist, with respect to any Licensed Antibody Technology or Licensed Background IP, any lien, encumbrance, charge, security interest, mortgage, liability, grant of license to Third Parties or other restriction (including in connection with any indebtedness), in each case ((a) and (b)) that conflict with or would conflict with, limit, or restrict the rights and licenses granted to Viridian hereunder or that is otherwise inconsistent with the terms and conditions of this Agreement, and Viridian will use all reasonable precautions to preserve the confidentiality of the Paragon Know-How.

(o) During the Term, Paragon will not, and will cause its Affiliates not to, amend, modify, or terminate the [\*\*\*] License Agreement in a manner that would restrict, limit, encumber, or adversely affect Viridian's rights or obligations with respect to the [\*\*\*] License Agreement as set forth under this Agreement without first obtaining Viridian's written consent, which consent may be withheld in Viridian's sole discretion.

(p) Paragon covenants that it will provide [\*\*\*] for the [\*\*\*] Program (as such term is defined under the [\*\*\*] License Agreement) directed to the Licensed Target related to this Agreement within [\*\*\*] of the A&R Effective Date.

(q) Other than the Licensed Antibody Technology and Licensed Background IP, Paragon does not own any Know-How or Intellectual Property Rights that is or was actually used in the course of performing any Development Activities under any Research Program. During the Term, other than Licensed Antibody Technology and Licensed Background IP, Paragon shall not, in performance of any Research Program, use or practice any Intellectual Property Rights or Know-How that Paragon owns but does not Control.

**7 . 3 DISCLAIMER OF WARRANTIES.** EXCEPT AS EXPRESSLY SET FORTH IN THIS Article VII (REPRESENTATIONS AND WARRANTIES), EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, DURABILITY, MERCHANTABILITY QUALITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES. PARAGON MAKES NO REPRESENTATIONS OR WARRANTIES WITH RESPECT TO THE LICENSED ANTIBODY TECHNOLOGY, OR THAT ANY CLAIMS IN ANY PATENT APPLICATIONS WITHIN THE LICENSED ANTIBODY PATENTS WILL ISSUE OR ARE VALID OR ENFORCEABLE, OR THAT THE MANUFACTURE, USE, SALE OR IMPORT OF PRODUCTS WILL NOT INFRINGE THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

## **ARTICLE VIII** **TERM; TERMINATION**

**8.1 Term.** The term of the Original License Agreement commenced on the Original Effective Date and continues, as amended and restated by this Agreement, as of the A&R Effective Date and shall expire on a Product-by-Product basis on the expiration of the last-to-expire Royalty Term, unless earlier terminated by a Party as set forth in this Article VIII (Term; Termination) (the “**Term**”). The Term of the Agreement will expire in its entirety on the expiration of the last-to-expire Royalty Term for the last Product for which there are Net Sales, unless earlier terminated by a Party as set forth in this Article VIII (Term; Termination). Upon expiration (but not termination) of the Royalty Term, on a Product-by-Product and country-by-country basis, the License shall survive and become royalty-free, fully paid-up, perpetual, and irrevocable with respect to the applicable Products in the applicable country.

**8.2 Termination by Viridian.** Viridian shall have the right to terminate this Agreement on a Research Program-by-Research Program basis, or in its entirety, for any or no reason upon sixty (60) days' notice to Paragon. Notwithstanding anything to the contrary in this Agreement, the [\*\*\*] Program and the portion of the [\*\*\*] Program other than the [\*\*\*] Program shall be deemed [\*\*\*] Research Programs for the purposes of this Section 8.2 (Termination by Viridian) and Section 8.6 (Effect of Termination of this Agreement).

**8.3 Termination by Paragon.** Paragon may terminate this Agreement in its entirety upon notice to Viridian if Viridian or its Affiliate or Sublicensee, directly or indirectly, individually or in association with any Third Party, asserts, assists or directs a Viridian Patent Challenge, where a “**Viridian Patent Challenge**” means any challenge by Viridian, or its Affiliate or Sublicensee, directly or indirectly, individually or in association with any Third Party, in a legal or administrative proceeding to the patentability, validity, ownership, enforceability, term or scope of any of the Licensed Antibody Patents (or any claim thereof), including by: (a) filing or pursuing a declaratory judgment action in which any of the Licensed Antibody Patents is alleged to be invalid or unenforceable; (b) citing prior art against any of the Licensed Antibody Patents (other than as necessary to comply with Applicable Laws in the course of exercising its rights under Section 5.3 (Patent Prosecution)), filing a request for or pursuing a re-examination of any of the Licensed Antibody Patents without Paragon's prior written consent, which shall not be unreasonably withheld, or voluntarily becoming a party to or pursuing an interference without

Paragon's prior written consent, which shall not be unreasonably withheld; (c) filing, or joining in, a petition under 35 U.S.C. § 311 (or any foreign statute or regulation that is equivalent or similar thereto) to institute inter partes review of any Licensed Antibody Patents; (d) filing, or joining in, a petition under 35 U.S.C. § 321 (or any foreign statute or regulation that is equivalent or similar thereto) to institute post-grant review of any Licensed Antibody Patents or any portion thereof; or (e) filing or pursuing any opposition, cancellation, nullity, or other like proceedings against any of the Licensed Antibody Patents. Notwithstanding the foregoing, Paragon will not have the right to terminate this Agreement if (i) such Viridian Patent Challenge is brought by a Sublicensee of Viridian whose sublicense agreement includes a provision prohibiting such Sublicensee from, directly or indirectly, individually or in association with any other person or entity, asserting or directing a Viridian Patent Challenge, and where such Viridian Patent Challenge is withdrawn within [\*\*\*] days of Viridian receiving notice thereof, or (ii) such Viridian Patent Challenge is asserted as a defense or counterclaim to an action first brought by Paragon against Viridian or if such Viridian Patent Challenge is asserted by Viridian in a declaratory judgment proceeding filed by Paragon pursuant to 28 U.S.C. §§ 2201-2202 in response to a threatened claim that Viridian or its Affiliates or Sublicensees are infringing any Licensed Antibody Patent, (iii) such Viridian Patent Challenge was initiated by prior to a Change of Control of Viridian by a Third Party acquiror that subsequently acquires Viridian in a Change of Control transaction, thereby becoming an Affiliate of Viridian, or (iv) such Viridian Patent Challenge was brought by an Acquirer of Viridian prior to consummation of a Change of Control of Viridian, and where such Viridian Patent Challenge is withdrawn within thirty (30) days of Viridian receiving notice thereof.

**8.4 Material Breach.** Each Party shall have the right to terminate this Agreement upon ninety (90) days' notice to the other Party upon or after the material breach of this Agreement by the other Party if the breaching Party has not cured such breach by the end of such ninety (90) day period; *provided, however,* that the cure period for Viridian's failure to make payment to Paragon hereunder shall be thirty (30) days; *provided, further,* that if such breach is capable of being cured but cannot be cured within such ninety (90) day period despite the breaching Party's efforts to do so, and the breaching Party initiates actions to cure such breach within such period and thereafter diligently pursues such actions, the breaching Party shall have such additional period as is reasonable in the circumstances to cure such breach, provided that such additional period shall in no event exceed one hundred twenty (120) days. Any Dispute regarding (a) the existence or materiality of a breach specified in a notice provided by a Party in accordance with this Section 8.4 (Material Breach), or (b) whether a material breach has been cured within the applicable cure period described in this Section 8.4 (Material Breach) will be resolved in accordance with the dispute resolution procedures described in Section 10.7 (Dispute Resolution). No purported termination of this Agreement pursuant to this Section 8.4 (Material Breach) shall take effect until the resolution of such Dispute, and the period for cure of such alleged breach shall be tolled during the pendency of any Dispute with respect to an alleged breach. If it is ultimately determined that the breaching Party committed such material breach, then the breaching Party will have the right to cure such material breach after such determination within the remainder of the applicable cure period (or extended cure period as provided for herein) which will commence as of the date of such determination. Any termination by any Party under this Section 8.4 (Material Breach) and the effects of termination provided herein shall be without prejudice to any damages or other legal or equitable remedies to which it may be entitled. The right of either Party to terminate this Agreement as provided in this Section 8.4 (Material Breach) will not be affected in any way by such Party's waiver of or failure to take action with respect to any previous breach under this Agreement.

## 8.5 Insolvency.

(a) Each Party will have the right to terminate this Agreement in the event of a Bankruptcy Event with respect to the other Party. “**Bankruptcy Event**” means the occurrence of any of the following: (i) the institution of any bankruptcy, receivership, insolvency, reorganization or other similar proceedings by or against a Party under any bankruptcy, insolvency, or other similar law now or hereinafter in effect, including any Section or chapter of the United States Bankruptcy Code, as amended or under any similar laws or statutes of the United States or any state thereof (the “**Bankruptcy Code**”), where in the case of involuntary proceedings such proceedings have not been dismissed or discharged within [\*\*\*] days after they are instituted, (ii) the insolvency or making of an assignment for the benefit of creditors or the admittance by a Party of any involuntary debts as they mature, (iii) the institution of any reorganization, arrangement or other readjustment of debt plan of a Party not involving the Bankruptcy Code, (iv) appointment of a receiver for all or substantially all of a Party’s assets, or (v) any corporate action taken by the board of directors of a Party in furtherance of any of the foregoing actions.

(b) The Parties agree that this Agreement constitutes an executory contract under Section 365 of the Bankruptcy Code for the license of “intellectual property” as defined under Section 101 of the Bankruptcy Code and constitutes a license of “intellectual property” for purposes of any similar laws in any other country in the Territory. The Parties further agree that each Party, as licensee of such rights under this Agreement, will retain and may fully exercise all of its protections, rights and elections under the Bankruptcy Code, including, but not limited to, Section 365(n) of the Bankruptcy Code, and any similar laws in any other country in the Territory. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party under the Bankruptcy Code and any similar laws in any other country in the Territory, the other Party will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and the same, if not already in its possession, will be promptly delivered to it (i) upon any such commencement of a bankruptcy proceeding upon its written request therefor, unless such Party elects to continue to perform all of its obligations under this Agreement, or (ii) if not delivered under clause (i) above, following the rejection of this Agreement by or on behalf of such Party upon written request therefor by the other Party.

(c) All rights, powers and remedies of each Party provided for in this Section 8.5 (Insolvency) are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including under the Bankruptcy Code and any similar laws in any other country in the Territory). In the event of an insolvency event in relation to Paragon in which Paragon has rejected this Agreement in the applicable bankruptcy proceeding, Viridian, in addition to the rights, power and remedies expressly provided herein, shall be entitled to exercise all other such rights and powers and resort to all other such remedies as may now or hereafter exist at law or in equity (including under the Bankruptcy Code).

8.6 **Termination of [\*\*\*] License Agreement.** In the event the [\*\*\*] License Agreement is terminated, this Agreement shall remain in full force and effect but the sublicense to [\*\*\*] IP under Section 2.1(a)(iii) shall terminate, and Paragon will promptly notify Viridian of such termination. Pursuant to Section 10.6(b) of the [\*\*\*] License Agreement, provided that (a) at the time of such termination, Viridian is not in material breach of the terms of this Agreement related to the grant of sublicense under the [\*\*\*] IP to Viridian under Section 2.1(a)(iii), and (b)

Viridian agrees to be bound to [\*\*\*] under the same terms as those included herein with respect to the [\*\*\*] IP, Viridian shall have the option to enter into an appropriate agreement with [\*\*\*] at Viridian's sole discretion, in which case the Parties will enter into an amendment to this Agreement to effectuate the foregoing. In such event, Viridian's obligations under this Agreement with respect to the [\*\*\*] IP and [\*\*\*] License Agreement (including Section 4.2(b) Payment Obligations Pursuant to [\*\*\*] License Agreement) will also terminate, and any payments payable by Viridian to [\*\*\*] in consideration for a direct license to [\*\*\*] IP shall be included in the applicable agreement between Viridian and [\*\*\*]. Paragon will use commercially reasonable efforts to provide Viridian with any necessary assistance for Viridian to enter into such direct agreement with [\*\*\*] pursuant to Section 10.6(b) of the [\*\*\*] License Agreement as reasonably requested by Viridian.

**8.7 Effect of Termination of this Agreement.** If this Agreement terminates for any reason (excluding expiration under Section 8.1 (Term)), then the following shall apply:

(a) The License shall automatically terminate (i) with respect to the applicable Research Program (and all Products under such Research Program), in the event of termination of the Agreement for a particular Research Program or (ii) in its entirety, in the event of termination of the Agreement in its entirety. Notwithstanding the foregoing, the License shall not automatically terminate to the extent (x) required for Viridian, its Affiliates, and Sublicensees to complete or wind down any ongoing clinical trials for any Product as may be required by Applicable Law or ethical principles or (y) to sell existing Product inventories for up to [\*\*\*] months (subject to Viridian's continued corresponding payment obligations under Section 4.3 (Royalties)).

(b) No later than [\*\*\*] days after the effective date of such termination, each Party shall return or cause to be returned to the other Party, or destroy, all Confidential Information received from the other Party and all copies thereof related to the terminated Product(s) in the terminated country(ies); *provided, however,* that each Party may retain any Confidential Information reasonably necessary for such Party's ongoing obligations and rights under this Agreement which do not terminate, and each Party may keep one (1) copy of Confidential Information received from the other Party in its confidential files for record purposes and such copy shall remain subject to Article VI (Protection of Confidential Information) of this Agreement.

(c) Upon Paragon's written request to Viridian, (which must be provided to Viridian within [\*\*\*] days after the effective date of termination), Viridian shall exclusively discuss in good faith, for a period of up to [\*\*\*] days following such written request, terms and conditions under which Viridian will grant to Paragon a royalty-bearing license under the Intellectual Property Rights Controlled by Viridian to make, have made, sell, offer for sale, have sold, import, export and otherwise exploit Products (but not including any Other Component) (or Products under a terminated Research Program, in the event this Agreement is terminated only with respect to a Research Program and not in its entirety) in the Field in the Territory ("Reversion Products"), as well as, at no additional cost to Paragon, the transfer of materials, ongoing clinical trials, and applicable regulatory filings and relevant data generated by Viridian with respect to the Reversion Products and necessary for the Development and Commercialization of such Reversion Products, such agreement to include commercially reasonable financial and other terms, which terms shall take into consideration Viridian's contributions made in the

Development, Commercialization and other exploitation of the Reversion Products. Notwithstanding the foregoing, Intellectual Property Rights Controlled by Viridian shall not include Intellectual Property Rights Controlled by Viridian as a result of a Change of Control of Viridian.

(d) The Parties shall negotiate in good faith the establishment of a transition and wind-down plan that will include a plan to transfer to Paragon any ongoing Product clinical trials, existing regulatory documentation and Regulatory Approvals pertaining to Products, trademarks that pertain to the Products, and any other Confidential Information of Viridian necessary or used as of the effective date of such termination to exploit Products.

**8.8 Survival of Sublicenses.** Upon termination of this Agreement, at the written request of any Sublicensee who is not then in breach of its sublicense agreement, Paragon will negotiate in good faith the terms and conditions of a direct license with such Sublicensee that is consistent with the terms of this Agreement (as adjusted for the scope of license, products, field of use, and other provisions of the original sublicense).

**8.9 Accrued Rights; Survival.** The expiration or termination of this Agreement for any reason shall not release either Party from any liability or obligation that, at the time of such expiration or termination, has already accrued to the other Party or that is attributable to a period prior to such expiration or termination, nor will expiration or any termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, or at law or in equity, with respect to breach of this Agreement. In the event of expiration or any termination of this Agreement, the following provisions of this Agreement shall survive such expiration or termination in accordance with their respective terms and conditions: Article I (Definitions); Section 2.2 (Sublicenses) and Section 4.2(b) (Payment Obligations Pursuant to the [\*\*\*] License Agreement) (with respect to any payments or other performance obligations prior to conversion (if any) to a direct license pursuant to Section 8.8 (Survival of Sublicenses)); Section 2.4 (Reservation of Rights); Article IV (Financial Term) (with respect to any outstanding payment obligations incurred prior to the date of termination or expiration or thereafter pursuant to Section 8.7(a)); Section 5.1 (Ownership); Article VI (Protection of Confidential Information) (for the duration set forth therein); Section 7.3 (Disclaimer of Warranties); Section 8.67 (Effect of Termination of this Agreement); Section 8.8 (Survival of Sublicenses); Section 8.9 (Accrued Rights; Survival); Article IX (Indemnification); and Article X (Miscellaneous).

## **ARTICLE IX** **INDEMNIFICATION**

**9.1 By Viridian.** Viridian shall defend, indemnify, and hold harmless Paragon, its Affiliates and its and their Representatives (each, an "**Paragon Indemnitee**") from and against any and all losses, damages, liabilities, expenses, and costs, including reasonable legal expense and attorneys' fees (collectively, "**Losses**"), to which any Paragon Indemnitee may become subject as a result of any claim, demand, action, or other proceeding by any Third Party ("**Third Party Claim**") to the extent such Losses result from: (a) the gross negligence, recklessness or willful misconduct of any Viridian Indemnitee or Sublicensee in the performance of this Agreement or exercise of rights under this Agreement; (b) Viridian's breach of any of its representations, warranties or covenants under this Agreement; (c) Viridian's or its Affiliates' or Sublicensee's research, testing, Development, Manufacture, use, sale, distribution, licensing or

Commercialization of Licensed Antibodies, Derived Antibodies or Products; or (d) any breach of the [\*\*\*] License Agreement to the extent caused by the actions or omissions of Viridian or its Affiliates or Sublicensees.

**9.2 By Paragon.** Paragon hereby agrees to defend, indemnify, and hold harmless Viridian, its Affiliates, and its and their Representatives (each, a "**Viridian Indemnitee**") from and against any and all Losses to which any Viridian Indemnitee may become subject as a result of any Third Party Claim to the extent such Losses result from: (a) the gross negligence, recklessness or willful misconduct of any Paragon Indemnitee in the performance of this Agreement or exercise of rights under this Agreement; or (b) Paragon's breach of any of its representations, warranties or covenants under this Agreement.

**9.3 Indemnification Procedures.** The Party claiming indemnity under this Article IX (Indemnification) (the "**Indemnified Party**") will give written notice to the Party from whom indemnity is being sought (the **Indemnifying Party**) promptly after learning of the claim, suit, proceeding or cause of action for which indemnity is being sought ("**Claim**"). The Indemnifying Party's obligation to defend, indemnify, and hold harmless pursuant to Section 9.1 (By Viridian) or Section 9.2 (By Paragon) as applicable, will be reduced to the extent the Indemnified Party's delay in providing notification pursuant to the previous sentence results in material prejudice to the Indemnifying Party; *provided, however,* that the failure by an Indemnified Party to give such notice or otherwise meet its obligations under this Section 9.3 (Indemnification Procedures) will not relieve the Indemnifying Party of its indemnification obligation under this Agreement. At its option, the Indemnifying Party may assume the defense and have exclusive control, at its own expense, of any Claim for which indemnity is being sought by giving written notice to the Indemnified Party within [\*\*\*] days after receipt of the notice of the Claim, provided that (a) it agrees to indemnify the Indemnified Party from and against all Losses the Indemnified Party may suffer arising out of the Claim; (b) the Claim involves only money damages and does not seek an injunction or other equitable relief against the Indemnified Party; and (c) the Indemnifying Party conducts the defense of the Claim diligently. The Indemnified Party will provide the Indemnifying Party with reasonable cooperation and assistance, at the Indemnifying Party's expense, in connection with the defense. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; *provided, however,* the Indemnifying Party will have the right to assume and conduct the defense of the Claim with counsel of its choice. The Indemnifying Party will not settle any Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, unless the settlement involves only the payment of money and unconditionally releases the Indemnified Party. The Indemnified Party will not settle any such Claim without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (i) the Indemnified Party may defend against, and consent to the entry of any judgment or enter into any settlement with respect to the Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (ii) the Indemnified Party reserves any right it may have under this Article IX (Indemnification) to obtain indemnification from the Indemnifying Party.

**9.4 LIMITATION OF LIABILITY.** NEITHER PARTY NOR ANY OF ITS AFFILIATES SHALL BE LIABLE IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE FOR ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE, OR CONSEQUENTIAL DAMAGES OR FOR ANY LOSS OF PROFITS

SUFFERED BY THE OTHER PARTY. NOTHING IN THIS SECTION 9.4 (LIMITATION OF LIABILITY) IS INTENDED TO OR SHALL LIMIT OR RESTRICT ANY DAMAGE (A) REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS ARTICLE IX (INDEMNIFICATION), (B) AVAILABLE WITH RESPECT TO A PARTY'S BREACH OF ARTICLE VI (PROTECTION OF CONFIDENTIAL INFORMATION), (C) AVAILABLE WITH RESPECT TO A PARTY'S GROSS NEGLIGENCE, FRAUD OR WILLFUL MISCONDUCT HEREUNDER, (D) CAUSED BY A PARTY'S INFRINGEMENT OR MISAPPROPRIATION OF THE OTHER PARTY'S INTELLECTUAL PROPERTY RIGHTS (INCLUDING RIGHTS GRANTED TO A PARTY UNDER THIS AGREEMENT), OR (E) WITH RESPECT TO CONSEQUENTIAL DAMAGES, IS CAUSED BY BREACH OF SECTION 7.2(Q).

## **ARTICLE X** **MISCELLANEOUS**

**10.1 Independent Contractor Relationship.** Nothing in this Agreement should be construed to create a partnership, joint venture, or employer-employee relationship between the Parties. Neither Party is an agent of the other Party or authorized to make any representation, contract, or commitment on behalf of the other Party.

**10.2 Force Majeure.** Neither Party will be charged with any liability for delay or failure in performance of an obligation under this Agreement (other than any obligation to pay monies when due) to the extent such delay or failure is due to a cause beyond the reasonable control of the affected Party, such as war, riots, labor disturbances, epidemic, pandemic, fire, explosion, and compliance in good faith with any Applicable Law. The Party affected will give prompt written notice to the other Party of the nature of the cause of any material delay or failure to perform, its anticipated duration and any action being taken to avoid or minimize the effect. The Party affected will use its diligent efforts to avoid or remove such causes of delay or failure to perform and to mitigate the effect of such occurrence, and will continue performance in accordance with the terms of this Agreement whenever such causes are removed. The Party affected will give prompt written notice to the other Party of such resumed performance. If any such failure or delay in a Party's performance hereunder continues for more than ninety (90) days, the other Party may terminate this Agreement upon written notice to the affected Party.

**10.3 Entire Agreement.** This Agreement, together with all Exhibits attached hereto, constitutes the final, complete, and exclusive agreement of the Parties with respect to the subject matter hereof and supersedes all prior and contemporaneous understandings and agreements, relating to its subject matter. This Agreement supersedes the Original License Agreement as of the A&R Effective Date, and the Original License Agreement shall cease to be of any force and effect as of the A&R Effective Date of this Agreement; *provided, however,* that the terms of the Original License Agreement shall continue to apply with regard to the rights and obligations of the Parties from the Original Effective Date and to the A&R Effective Date.

**10.4 Non-Waiver; Amendment.** The failure of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period

of time and shall be signed by such Party. This Agreement (including its Exhibits) may not be changed, modified, amended, or supplemented except by a written instrument signed by both Parties.

**10.5 Severability.** Should one or more of the provisions of this Agreement become void or unenforceable as a matter of Applicable Law, then this Agreement shall be construed as if such provision were not contained herein and the remainder of this Agreement shall be in full force and effect, and the Parties will use their best efforts to substitute for the invalid or unenforceable provision a valid and enforceable provision which conforms as nearly as possible with the original intent of the Parties.

**10.6 Assignment.** Neither this Agreement nor any rights or obligations hereunder may be assigned by either Party without the prior written consent of the other Party (which consent shall not be unreasonably withheld); *provided, however,* that either Party may assign this Agreement and its rights and obligations hereunder without the other Party's consent, but with prompt notice to the other Party, to an Affiliate or to its successor to all or substantially all of the business of such Party to which this Agreement relates, whether by merger, sale of stock, sale of assets or otherwise. The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties, and the name of a Party appearing herein will be deemed to include the name of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Section 10.6 (Assignment). Any assignment not in accordance with this Agreement shall be void.

**10.7 Dispute Resolution.** The Parties recognize that a bona fide dispute as to certain matters may arise from time to time during the Term relating to either Party's rights or obligations hereunder or otherwise relating to the validity, enforceability or performance of this Agreement, including disputes relating to alleged breach or termination of this Agreement but excluding any disputes relating to Article VI (Protection of Confidential Information) or disputes relating to the determination of the validity, scope, infringement, enforceability, inventorship or ownership of the Parties' respective Intellectual Property Rights (hereinafter, a "**Dispute**"). In the event of the occurrence of any Dispute, the Parties will follow the following procedures in an attempt to resolve the Dispute or disagreement:

(a) The Party claiming that such a Dispute exists will give notice in writing (a **Notice of Dispute**) to the other Party of the nature of the Dispute.

(b) The Dispute will be referred to the then Chief Operating Officer of Paragon and the then Chief Executive Officer of Viridian who will meet no later than thirty (30) days following the initial receipt of the Notice of Dispute and use reasonable endeavors to resolve the Dispute.

(c) If, within [\*\*] days of initial receipt of the Notice of Dispute, the Dispute has not been resolved, or if, for any reason, the meeting described in Section 10.7(b) hereof has not been held within [\*\*] days of initial receipt of the Notice of Dispute, then the Parties agree that such Dispute will be finally resolved through binding arbitration to be administered by JAMS pursuant to its Comprehensive Arbitration Rules and Procedures and in accordance with the Expedited Procedures in those Rules, as specifically modified by the provisions of this Section 10.7(c). The arbitration will be conducted by a panel of three arbitrators. Within [\*\*] days after the initiation of the arbitration, each Party will nominate one person to act as arbitrator, and the

two arbitrators so named will then jointly appoint the third arbitrator within [\*\*\*] days of their appointment, who will serve as chairman of the panel. All three arbitrators must be independent Third Parties having at least ten (10) years of dispute resolution experience (which may include judicial experience) or legal or business experience in the biotech or pharmaceutical industry. If either Party fails to nominate its arbitrator, or if the arbitrators selected by the Parties cannot agree on a person to be named as chairman within such [\*\*\*]-day period, JAMS will make the necessary appointments for such arbitrator(s) or the chairman. Once appointed by a Party, such Party will have no *ex parte* communication with its appointed arbitrator. The place of arbitration will be in Boston, Massachusetts or such other venue as the Parties may mutually agree. The arbitration proceedings and all communications with respect thereto will be in English. Any written evidence originally in another language will be submitted in English translation accompanied by the original or a true copy thereof. The arbitrators have the power to decide all matters in Dispute, including any questions of whether or not such matters are subject to arbitration hereunder. The arbitration will be governed by the Federal Arbitration Act, 9 U.S.C. §§1 et seq., and judgment upon the award rendered by the arbitrators may be entered in any court having competent jurisdiction thereof. The existence, content and results of any arbitration proceedings pursuant to this Section 10.7 (Dispute Resolution) will be deemed the Confidential Information of both Parties.

(d) Notwithstanding any provision of this Agreement to the contrary, either Party may immediately initiate litigation in any court of competent jurisdiction seeking any remedy at law or in equity, including the issuance of a preliminary, temporary or permanent injunction, to preserve or enforce its rights under this Agreement.

(e) The Parties agree that any Disputes relating to Article VI (Protection of Confidential Information) or Disputes relating to the determination of the validity, scope, infringement, enforceability, inventorship or ownership of the Parties' respective Intellectual Property Rights shall be subject to the exclusive jurisdiction of the state and federal courts in Boston, Massachusetts and each Party hereby submits to such jurisdiction.

(f) THE PARTIES EXPRESSLY WAIVE AND FOREGO ANY RIGHT TO A TRIAL BY JURY.

**10.8 Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts without reference to conflicts of laws principles.

**10.9 Notices.** Any notice to be given under this Agreement must be in writing and delivered either in person, by internationally recognized express courier, by email, or by facsimile, to the Party to be notified at its address(es) given below, or at any address such Party has previously designated by prior written notice to the other. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (a) the date of actual receipt; (b) if delivered by express courier, the next Business Day the express courier regularly makes deliveries; or (c) if delivered by email, upon the date upon which the receipt of such email is confirmed by return email. Together with any notice provided by a Party to the other Party in accordance with this Section 10.9 (Notices), the Party shall send a copy of such notice by email to the other Party.

If to Paragon: Paragon Therapeutics, Inc.  
221 Crescent Street

Suite 105  
Waltham, MA 02453  
Attn: Evan Thompson  
Email: [\*\*\*]

If to Viridian: Viridian Therapeutics, Inc.

221 Crescent Street, Suite 103A  
Waltham, MA 02453  
Attn: Legal Department  
Email: [\*\*\*]

**10.10 Interpretation.** Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation", (c) the word "will" shall 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 shall 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 or entity shall be construed to include such person's or entity's successors and assigns, (f) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections or Exhibits shall be construed to refer to Sections or Exhibits of this Agreement, and references to this Agreement include all Exhibits hereto, (h) the word "notice" means notice in writing (whether or not specifically stated) and shall 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" or "approve" or the like shall 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 article, Section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, and (k) the term "or" shall be interpreted in the inclusive sense commonly associated with the term "or." The headings of clauses contained in this Agreement preceding the text of the sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement or have any effect on its interpretation or construction. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist. This Agreement has been prepared in the English language, and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral, or other communications between the Parties regarding this Agreement shall be in the English language.

**10.11 No Third-Party Rights.** The provisions of this Agreement are for the exclusive benefit of the Parties and their successors and permitted assigns, and no other person shall have any right or claim against any Party by reason of these provisions or be entitled to enforce any of these provisions against any Party.

10.12 **Counterparts.** This Agreement may be executed in counterparts, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one instrument. This Agreement may be executed by facsimile or PDF signatures, which signatures shall have the same force and effect as original signatures.

10.13 **Expenses.** Each Party shall pay its own costs, charges and expenses incurred in connection with the negotiation, preparation and completion of this Agreement.

10.14 **Binding Effect.** This Agreement shall be binding upon and inure to the benefit of the Parties and their respective legal representatives, successors and permitted assigns.

10.15 **Construction.** The Parties hereto acknowledge and agree that: (a) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (b) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (c) the terms and provisions of this Agreement shall be construed fairly as to all Parties hereto and not in a favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement.

10.16 **Cumulative Remedies.** No remedy referred to in this Agreement is intended to be exclusive unless explicitly stated to be so, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law. Nothing in this Agreement is intended to limit either Party's rights under the Research Agreement.

10.17 **Performance by Affiliates.** A Party may perform some or all of its obligations under this Agreement through Affiliate(s) or may exercise some or all of its rights under this Agreement through Affiliates. However, each Party shall remain responsible and be guarantor of the performance by its Affiliates and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance as if such Party were performing such obligations itself, and references to a Party in this Agreement shall be deemed to also reference such Affiliate. In particular and without limitation, all Affiliates of a Party that receive Confidential Information of the other Party pursuant to this Agreement shall be governed and bound by all obligations set forth in Article VI (Protection of Confidential Information). A Party and its Affiliates shall be jointly and severally liable for their performance under this Agreement.

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

In Witness Whereof, the Parties have by duly authorized persons executed this Agreement effective as of the A&R Effective Date.

**PARAGON THERAPEUTICS, INC.**

By: /s/ Evan Thompson

Name: Evan Thompson

Title: COO

Date: 9/20/2024

**VIRIDIAN THERAPEUTICS, INC.**

By: /s/ Steve Mahoney

Name: Steve Mahoney

Title: CEO

Date: 9/20/2024

**EXHIBIT A**

[\*\*\*]

**EXHIBIT B**

**[\*\*\*] LICENSE AGREEMENT**

**[\*\*\*]**

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**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 12, 2024

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 12, 2024

By: /s/ Seth Harmon

Seth Harmon

Senior Vice President of Finance and Accounting

(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, Senior Vice President of Finance and Accounting 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, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Stephen Mahoney

Stephen Mahoney

President, Chief Executive Officer and Director  
(Principal Executive Officer)

Date: November 12, 2024

/s/ Seth Harmon

Seth Harmon

Senior Vice President of Finance and Accounting  
(Principal Financial Officer; Principal Accounting Officer)

Date: November 12, 2024

*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.*