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 March 31, 2024

or

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

For the transition period from to

Commission File 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 401, 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 o

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 o

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 May 1, 2024, there were 63,822,468 shares of the registrant's common stock outstanding.

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

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

- the ability of our clinical trials to demonstrate safety and efficacy of our product candidates and other positive results;
- the potential utility, efficacy, potency, safety, clinical benefits, half-life, clinical response and convenience of our product candidates;
- the timing and focus of our ongoing and future preclinical studies and clinical trials and the reporting of 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, if approved, including the geographic areas of focus and sales strategy;
- the size of the market opportunity for our product candidates, including our estimates of the number of patients who suffer from the diseases we are targeting;
- the rate and degree of market acceptance and clinical utility for our product candidates;
- the success of competing therapies that are or may become available;
- 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 ability to obtain and maintain regulatory approval of our product candidates;
- our plans relating to the further development of our product candidates, including additional indications we may pursue;
- existing regulations and regulatory developments in the United States, Europe and other jurisdictions;
- our plans and ability 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 and clinical trials;

- our plans regarding, and our ability to obtain, and negotiate favorable terms of, 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;
- 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;
- developments relating to our competitors and our industry, including the impact of government regulation;
- the impact of geopolitical or macroeconomic conditions, including from conflicts such as the ongoing military conflicts between Russia and Ukraine and in Israel and surrounding areas, rising tensions between China and Taiwan and other political tensions, slower GDP growth or recession, capital markets volatility, instability in the banking sector and inflation; and
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals.

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.

- We will need to raise additional capital, and if we are unable to do so when needed, we will not be able to continue as a going concern.
- 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 an approved label, 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 FDA 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 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 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.

- 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)

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 91,641	$ 102,827
Short-term investments	521,546	374,543
Prepaid expenses and other current assets (including related party of $1,137 and $0 as of March 31, 2024 and December 31, 2023, respectively)	13,529	9,006
Unbilled revenue - related party	102	102
Total current assets	626,818	486,478
Property and equipment, net	1,526	1,672
Operating lease right-of-use asset	1,482	1,670
Other assets	555	604
Total assets	$ 630,381	$ 490,424
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,676	$ 2,239
Accrued liabilities and other (including related party of $637 and $374 as of March 31, 2024 and December 31, 2023, respectively)	23,163	24,108
Current portion of deferred revenue - related party	288	288
Total current liabilities	26,127	26,635
Long-term debt, net	20,328	20,205
Deferred revenue - related party	500	573
Other liabilities	896	989
Total liabilities	47,851	48,402
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, series A non-voting convertible preferred stock, $0.01 par value; 435,000 shares authorized; 157,435 and 172,435 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	71,429	78,235
Preferred stock, series B non-voting convertible preferred stock, $0.01 par value; 500,000 shares authorized; 143,522 shares issued and outstanding as of March 31, 2024 and December 31, 2023	128,281	128,281
Common stock, $0.01 par value; 200,000,000 shares authorized; 63,798,536 and 53,986,112 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	638	540
Additional paid-in capital	1,156,999	960,536
Accumulated other comprehensive (loss) gain	(367)	338
Accumulated deficit	(774,450)	(725,908)
Total stockholders' equity	582,530	442,022
Total liabilities and stockholders' equity	$ 630,381	$ 490,424

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 March 31,	
	2024	**2023**
Revenue:		
Collaboration revenue - related party	$ 72	$ 98
Operating expenses:		
Research and development (including related party expenses of $ 661 and $3,244 during the three months ended March 31, 2024 and 2023, respectively.)	40,944	50,740
General and administrative	15,025	21,831
Total operating expenses	$ 55,969	$ 72,571
Loss from operations	(55,897)	(72,473)
Other income:		
Interest and other income	7,942	4,487
Interest and other expense	(587)	(165)
Other income, net	7,355	4,322
Net loss	$ (48,542)	$ (68,151)
Net loss per share, basic and diluted	$ (0.79)	$ (1.61)
Weighted-average shares used to compute basic and diluted net loss per share	61,099,038	42,242,309
Comprehensive loss:		
Net loss	$ (48,542)	$ (68,151)
Other comprehensive (loss) gain:		
Change in unrealized (loss) gain on investments	(705)	216
Total other comprehensive (loss) gain	(705)	216
Total comprehensive loss	$ (49,247)	$ (67,935)

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)	Accumulated Deficit	Total Stockholders' Equity
	Series A		Series B							
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance as of December 31, 2023	172,435	$ 78,235	143,522	$128,281	53,986,112	$ 540	$ 960,536	$ 338	$(725,908)	$ 442,022
Issuance of common stock upon the conversion of convertible preferred stock	(15,000)	(6,806)	—	—	1,000,048	10	6,796	—	—	—
Issuance of common stock, 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 gain 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

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	188,381	$ 85,470	51,210	$ 56,677	41,305,947	$ 414	$741,067	$ (390)	$(488,174)	$ 395,064
Issuance of common stock upon the conversion of convertible preferred stock	(15,946)	(7,235)	—	—	1,063,118	10	7,225	—	—	—
Issuance of common stock 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	172,435	$ 78,235	51,210	$ 56,677	43,055,318	$ 431	$771,705	$ (174)	$(556,325)	$ 350,549

See accompanying notes to these condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (48,542)	$ (68,151)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	12,688	15,216
Non-cash interest expense and amortization of debt issuance costs	123	53
Depreciation and amortization	145	105
Accretion and amortization of premiums and discounts on available-for-sale securities	(4,663)	(2,975)
Non-cash lease expense	(16)	12
Other non-cash items	—	30
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(4,474)	(2,094)
Unbilled revenue - related party	—	(26)
Deferred revenue - related party	(72)	(72)
Accounts payable	482	(6,647)
Accrued and other liabilities	(894)	2,576
Net cash used in operating activities	(45,223)	(61,973)
Cash flows from investing activities:		
Purchases of short-term investments	(225,609)	(77,280)
Proceeds from maturities of short-term investments	82,564	64,100
Purchase of property and equipment	—	(115)
Net cash used in investing activities	(143,045)	(13,295)
Cash flows from financing activities:		
Proceeds from the issuance of common stock, pursuant to 2024 Public Offering and September 2022 ATM Agreement	186,265	—
Payments of issuance costs associated with the sale of common stock	(10,377)	—
Proceeds from the issuance of common stock upon the exercise of warrants	—	946
Proceeds from the issuance of common stock upon the exercise of stock options	838	6,938
Proceeds from the issuance of common stock for cash under employee stock purchase plan	356	320
Net cash provided by financing activities	177,082	8,204
Net decrease in cash and cash equivalents	(11,186)	(67,064)
Cash and cash equivalents at beginning of period	102,827	155,579
Cash and cash equivalents at end of period	$ 91,641	$ 88,515
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 452	$ 112
Supplemental disclosure of non-cash investing and financing activities		
Conversion of preferred stock to common stock	$ 6,806	$ 7,235

Unpaid common stock issuance costs included in accrued liabilities		100	$	—
Purchase of property and equipment in accounts payable and accrued liabilities	$	—	$	285

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, 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 version of VRDN-001 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 March 31, 2024, the Company has generated an accumulated deficit of $774.5 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 March 31, 2024, the Company had approximately $ 613.2 million in cash, cash equivalents, and short-term investments. 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 continue to 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, 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 three months ended March 31, 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 manufacture or have manufactured clinical trial materials, 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 three months ended March 31, 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 three months ended March 31, 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, 2025. 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.

3. INVESTMENTS AND FAIR VALUE MEASUREMENTS

Investments

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

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
March 31, 2024				
Money market funds	$ 73,945	$ 7	$ —	$ 73,952
U.S. treasury securities	281,086	25	(288)	280,823
U.S. corporate paper and bonds	239,990	47	(160)	239,877
International corporate bond holdings	15,272	11	(9)	15,274
Total	$ 610,293	$ 90	$ (457)	$ 609,926
December 31, 2023				
Money market funds	$ 77,724	$ 7	$ —	$ 77,731
U.S. treasury securities	148,423	255	(5)	$ 148,673
U.S. corporate paper and bonds	227,463	142	(85)	$ 227,520
International corporate bond holdings	9,304	24	—	9,328
Total	$ 462,914	$ 428	$ (90)	$ 463,252

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

As of March 31, 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 months ended March 31, 2024 and 2023. The Company did not have any sales of short-term investments during the three months ended March 31, 2024 and 2023. The contractual maturity dates of all of the Company’s investments are all less than 24 months.

Fair Value Measurements

The following table summarizes the Company’s assets and liabilities that are measured at fair value on a recurring basis:

(in thousands)	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
March 31, 2024				
Cash equivalents:				
Money market funds	$ 73,952	$ —	$ —	$ 73,952
U.S. treasury securities	—	7,981	—	7,981
U.S. corporate paper and bonds	—	6,447	—	6,447
Short-term investments:				
U.S. treasury securities	—	272,842	—	272,842
U.S. corporate paper and bonds	—	233,430	—	233,430
International corporate bond holdings	—	15,274	—	15,274
Total cash equivalents and short-term investments	$ 73,952	$ 535,974	$ —	$ 609,926
December 31, 2023				
Cash equivalents:				
Money market funds	$ 77,731	$ —	$ —	$ 77,731
U.S. corporate paper and bonds	—	10,978	—	10,978
Short-term investments:				
U.S. treasury securities	—	148,673	—	148,673
U.S. corporate paper and bonds	—	216,542	—	216,542
International corporate bond holdings	—	9,328	—	9,328
Total cash equivalents and short-term investments	$ 77,731	$ 385,521	$ —	$ 463,252

4. ACCRUED LIABILITIES AND OTHER

Accrued liabilities consisted of the following:

	March 31, 2024	December 31, 2023
	(in thousands)	
Accrued outsourced clinical trials and preclinical studies	$ 13,075	$ 10,724
Accrued employee compensation and related taxes	7,057	10,513
Operating lease liability, short-term	732	843
Accrued legal fees and expenses	527	399
Accrued other professional service fees	1,028	473
Value of liability-classified stock purchase warrants	100	100
Accrued interest payable	154	154
Other accrued liabilities	490	902
Total accrued liabilities	$ 23,163	$ 24,108

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”), consisting of (1) an initial tranche of $25.0 million, available to the Company through June 15, 2023; (2) a second tranche of $ 10.0 million, subject to the achievement of certain regulatory milestones, available through June 15, 2023; (3) a third tranche of $15.0 million, subject to the achievement of certain regulatory milestones, available through March 15, 2024; and (4) a fourth tranche of $25.0 million, subject to approval by the Lenders’ investment committee(s), available through December 15, 2024. The milestones for the third tranche were not achieved prior to the amendment of the Hercules Loan and Security Agreement in August 2023. 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.

Per the terms of the Hercules Loan and Security Agreement, the Company was originally obligated to make interest-only payments through April 1, 2024. However, upon the achievement of a development milestone in August 2022 the interest-only period was extended to October 1, 2024. If additional development milestones were met, the interest-only period would be further extended to April 1, 2025. The Borrower was 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, 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.

Upon signing the Hercules Loan and Security Agreement, the Company drew an initial principal amount of $ 5.0 million. The Company incurred debt issuance costs of $0.2 million in connection with the Term Loan.

In addition, in connection with the initial draw, the Company 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"). The debt issuance costs and the Lender Expenses were being amortized as additional interest expense over the term of the loan.

In August 2023, the Company executed an amendment to the Hercules Loan and Security Agreement (the "Hercules Amendment"). Under the Hercules Amendment, the Lenders provided the Company access to an increased term loan with an aggregate principal amount of up to $150 million, in four tranches (collectively the "Amended Term Loan"), consisting of (1) an initial tranche of $50.0 million, $5.0 million of which was drawn at closing of the Hercules Loan and Security Agreement in April 2022, $15.0 million of which was drawn at closing of the Hercules Amendment in August 2023, $5.0 million of which was available through December 15, 2023, and $ 25.0 million of which 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 March 31, 2024 was 8.95%.

Per the terms of the Hercules Amendment, the Company is obligated to make interest-only payments through April 1, 2025. If certain development milestones are met, then the interest-only period will be 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.

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.

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 $0.6 million and $0.2 million during the three months ended March 31, 2024 and 2023, respectively.

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

	March 31, 2024
	(in thousands)
Gross proceeds	$ 20,000
Accrued end-of-term fee	328
Unamortized debt issuance costs	—
Carrying value	$ 20,328

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 March 31, 2024 are as follows (in thousands):

Fiscal Year	
2024 (remainder)	$ —
2025	9,101
2026	10,899
Total	$ 20,000

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 months ended March 31, 2024 and 2023, the Company recognized $0.1 million 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, of which $0.4 million was recorded as research and development expense during the three months ended March 31, 2024 for services performed to date.

As of March 31, 2024, 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 Agreement") under which the Company and Paragon will cooperate to develop one or more proteins or antibodies. Under the terms of the Paragon 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 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 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 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. In consideration for rights granted by Paragon, the Company is obligated to make certain future development milestone payments of up to $16.0 million on a program-by-program basis upon the achievement of specified clinical and regulatory milestones. Additionally, if the Company successfully commercializes any product candidate subject to the Paragon License Agreement, it is responsible for royalty payments equal to a percentage in the mid-single digits of net sales.

In January 2024, the Company entered into a letter agreement with Paragon (the "Paragon Letter Agreement") pursuant to which Paragon agreed to continue to perform development activities under the existing Paragon Agreement and Paragon License Agreement. 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.

During the three months ended March 31, 2024, the Company recorded $ 0.7 million and $3.2 million, respectively, in research and development costs related to the Paragon Agreement.

As of March 31, 2024, the Paragon Agreement is considered a related party transaction because Fairmount beneficially owns more than 5% of the Company's capital stock and has two seats on the Company's board of directors, and beneficially owns more than 5% of Paragon, which is a joint venture between Fairmount and FairJourney Biologics, and has appointed the sole director on Paragon's board of directors and has the contractual right to approve the appointment of any executive officers.

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 VRDN-001 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 VRDN-001. 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 VRDN-001, amount which was paid in January 2023 and which was included in accounts payable in the consolidated balance sheet as of December 31, 2022. Additionally, if 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.

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, Viridian 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 three months ended March 31, 2023 in the accompanying condensed consolidated statement 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.

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, Viridian 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.

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 and July 2022, 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. The Massachusetts Lease provides for annual base rent of approximately $0.4 million during the lease term. The Company is also obligated to pay the landlord certain costs, taxes and operating expenses. The Massachusetts Lease will expire in April 2027. The Company has the option to extend the lease term for an additional period of three years upon notice to the landlord.

Future lease payments under noncancellable leases as of March 31, 2024 are as follows:

	(in thousands)
2024 (remainder)	722
2025	464
2026	474
2027	159
Total future minimum lease payments	1,819
Less: imputed interest	(191)
Total	$ 1,628

As of March 31, 2024, the Company's operating lease obligations were reflected as short-term operating lease liabilities of $ 0.7 million within accrued liabilities and $0.9 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 $0.1 million for the three months ended March 31, 2024 and 2023,

respectively, which was included in operating expense in the condensed consolidated statements of operations and comprehensive loss.

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 for the three months ended March 31, 2024 and 2023. 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 SM (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. 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 three months ended March 31, 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.

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 ("Leerink Partners") relating to the offer and sale (the "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 2024 Public Offering were approximately $150.0 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 March 31, 2024 and December 31, 2023, there were 157,435 and 172,435 shares of Series A Preferred Stock outstanding, respectively. During the three months ended March 31, 2024, 15,000 shares of Series A Preferred Stock were converted into 1,000,048 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 March 31, 2024 and December 31, 2023, there were 143,522 shares of Series B Preferred Stock outstanding. No shares of Series B Preferred Stock were converted into common stock during the three months ended March 31, 2024.

9. WARRANTS

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

	Number of Underlying Shares (1)			
	March 31, 2024	December 31, 2023	Weighted-Average Exercise Price at March 31, 2024	Remaining Contractual Life at March 31, 2024 (No. Years)
Liability-classified warrants				
Issued April 2017	781	781	$127.95	1.08
Equity-classified warrants				
Acquired October 2020	29,446	29,446	$0.02	6.48
Issued February 2020 (2)	218,050	218,050	$14.44	0.87
Issued November 2017	1,606	1,606	$0.69	0.62
Subtotal	249,102	249,102	$15.15	
Total warrants	249,883	249,883	$15.51	

(1) If the Company subdivides (by any stock split, stock dividend, recapitalization, or otherwise) its outstanding shares of its common stock into a smaller number of shares, the warrant exercise price is proportionately reduced and the number of shares under outstanding warrants is proportionately increased. Additionally, if the Company combines (by combination, reverse stock split, or otherwise) its outstanding shares of common stock into a smaller number of shares, the warrant exercise price is proportionately increased and the number of shares under outstanding warrants is proportionately decreased.

(2) Subject to specified conditions, the Company may voluntarily reduce the warrant exercise price of the warrants issued in February 2020.

A summary of the Company's warrant activity during the three months ended March 31, 2024 is as follows:

	Common Stock Warrants	
	Number	Weighted Average Exercise Price
Outstanding at December 31, 2023	249,883	$ 15.51
Exercised	—	$ —
Outstanding at March 31, 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. The 2016 Plan will terminate on June 14, 2033.

As of March 31, 2024, the Company had the following balances by plan:

	Restricted Stock Units Outstanding	Stock Options Outstanding	Shares Available for Issuance
Inducement Awards	—	4,096,167	—
2020 Plan	—	312,162	—
2016 Plan	669,096	5,911,220	2,113,343
2008 Plan	—	24	—
Total	669,096	10,319,573	2,113,343

Restricted Stock Units

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

A summary of RSU activity is as follows:

	RSUs	Weighted-Average Grant Date Fair Value
Nonvested, December 31, 2023	804,947	$15.82
Granted	4,500	$19.89
Vested	(19,115)	$35.40
Forfeited	(121,236)	$15.08
Nonvested, March 31, 2024	669,096	$15.42

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 vest 25% on the first anniversary of the vesting commencement date and 75% ratably in equal monthly installments over the remaining 36 months or in equal monthly or quarterly amounts over periods of up to 48 months.

A summary of common stock option activity is as follows:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2023	11,533,484	$19.68	8.50	$ 54,772
Granted	721,750	$20.05		
Exercised	(66,191)	$12.65		
Forfeited or expired	(1,869,470)	$24.71		
Outstanding as of March 31, 2024	10,319,573	$18.84	8.09	$ 22,530
Vested and expected to vest as of March 31, 2024	10,319,573	$18.84	8.09	$ 22,530
Exercisable as of March 31, 2024	2,782,868	$21.38	4.60	$ 3,510
Vested as of March 31, 2024	2,782,868	$21.38	4.60	$ 3,510

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 three months ended March 31, 2024 and 2023 was $ 14.43 and $26.16, respectively. The fair value was determined by the Black-Scholes option pricing model using the following weighted-average assumptions:

	Three Months Ended March 31,	
	2024	2023
Expected term, in years	5.11	5.57
Expected volatility	89.5%	91.4%
Risk-free interest rate	4.1%	3.8%
Expected dividend yield	—%	—%
Weighted average exercise price	$20.05	$34.95

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. New six-month offering periods occur twice per year. As

of March 31, 2024, the Company had 1,208,603 shares available for issuance, and 80,932 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 March 31,	
	2024	2023
	(in thousands)	
Research and development	$ 6,678	$ 3,564
General and administrative	6,010	11,652
Total share-based compensation expense	$ 12,688	$ 15,216

During the three months ended March 31, 2024, the Company recorded an additional $ 3.5 million in share-based compensation related to the acceleration of vesting for former executive officers. During the three months ended March 31, 2023, the Company recorded an additional $6.5 million in share-based compensation related to the acceleration of vesting for its former Chief Executive Officer, an amount which includes $1.6 million related to the modification of the terms of options outstanding at the time of termination which would have otherwise forfeited.

As of March 31, 2024, the Company had $ 92.3 million of total unrecognized share-based compensation costs related to stock options, which the Company expects to recognize over a weighted-average remaining period of 3.22 years. As of March 31, 2024, the Company had $ 9.4 million of total unrecognized share-based compensation costs related to unvested RSUs, which the Company expects to recognize over a weighted-average remaining period of 3.48 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:

	March 31,	
	2024	2023
Series A Preferred Stock (as converted to shares of common stock)	10,496,191	11,496,241
Series B Preferred Stock (as converted to shares of common stock)	9,568,612	3,414,170
Options to purchase common stock	10,319,573	7,879,797
Warrants to purchase common stock	249,883	306,549
Restricted stock units	669,096	375,125
Total	31,303,355	23,471,882

12. SUBSEQUENT EVENTS

Fourth Amendment to Massachusetts Lease

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. Under the Fourth Amendment, the Company has the option to extend the lease term for an additional period of three years upon notice to the landlord. The Fourth Amendment provides for annual base rent for the New Premises of approximately $0.5 million and includes annual base rent escalation clauses during the lease term. The Company is also obligated to pay the landlord certain costs, taxes and operating expenses.

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

We are developing two product candidates, VRDN-001 for intravenous and VRDN-003 for subcutaneous administration, to treat patients who suffer from TED. Our most advanced program, VRDN-001, 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 VRDN-001 is a potentially differentiated full antagonist of IGF-1R, compared to teprotumumab's incomplete antagonism of IGF-1R. We also conducted Phase 1/2 clinical trials of VRDN-001 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 VRDN-001 (n=21) showed significant and rapid improvement in both the signs and symptoms of TED after two infusions of VRDN-001 compared to placebo. Across all VRDN-001 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 VRDN-001 (n=12) showed significant and rapid improvement in the signs and symptoms of TED after two infusions of VRDN-001 compared to placebo. Across all VRDN-001 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, VRDN-001 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 VRDN-001, including evaluating its efficacy and safety in two global well controlled Phase 3 clinical trials, THRIVE and THRIVE-2, for the treatment of active and chronic TED, respectively. THRIVE and THRIVE-2 are each designed to compare a five-dose IV treatment arm of VRDN-001 at 10 mg/kg, dosed three weeks apart, to placebo. This five-dose VRDN-001 regimen features fewer infusions and a shorter time per infusion compared to teprotumumab, the currently marketed IGF-1R inhibitor. We expect to report topline THRIVE and THRIVE-2 data in September 2024 and by year end 2024, respectively. In addition, to meet the 300 patient safety database requirements for a BLA filing, we are actively enrolling patients into our recently initiated STRIVE clinical trial. STRIVE is a global study of VRDN-001 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 VRDN-001 in the second half of 2025.

In addition to our VRDN-001 IV program, in December 2023 we selected VRDN-003 as our prioritized subcutaneous program 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 program 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 its parent molecule, VRDN-001, and was engineered to have a longer half-life. VRDN-003 is designed to be a low-volume, self-administered, infrequently-dosed subcutaneous IGF-1R for TED.

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 its parent molecule, VRDN-001. Because of the similarities between the VRDN-001 and VRDN-003 antibodies, we expect VRDN-003 to have similar clinical responses at the exposure levels of

VRDN-001 that led to robust clinical activity in its Phase 2 clinical trial in TED. Further, pharmacokinetic modeling of VRDN-003 predicted that exposure levels of VRDN-003 could be achieved that are equivalent to exposure levels of VRDN-001 that produced clinically meaningful results with multiple dosing regimens of VRDN-003, i.e., subcutaneous injection every two, four, or eight weeks. Based on these results, we expect to initiate a global pivotal program with VRDN-003 in mid-2024, with planned trials in both active and chronic TED patients.

In addition to developing therapies for TED, we are also 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 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 monoclonal anti-FcRn antibodies. In our head-to-head non-human primate studies, VRDN-006 demonstrated comparable potency and IgG lowering to Vyvgart® (efgartigimod), 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, 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 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 three months ended March 31, 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 March 31, 2024 and 2023.

	Three Months Ended March 31,		
	2024	2023	Increase (Decrease)
	(in thousands)		
Collaboration revenue - related party	$ 72	$ 98	$ (26)
Research and development expenses	40,944	50,740	(9,796)
General and administrative expenses	15,025	21,831	(6,806)
Other income, net	7,355	4,322	3,033

Revenue

Revenue for both the three months ended March 31, 2024 and 2023 was attributable to our collaboration agreement with Zenas BioPharma. The $26 thousand decrease in revenue is due to the timing of activities performed under the collaboration agreement.

Research and Development Expenses

Research and development expenses were $40.9 million during the three months ended March 31, 2024, compared to $50.7 million during the three months ended March 31, 2023. The $9.8 million decrease in research and development expenses is primarily attributable to the following:

- $15.0 million decrease in milestone, license and option fees due to the upfront payment for development of subcutaneous delivery systems during the three months ended March 31, 2023;
- $5.3 million decrease in chemistry, manufacturing, and controls costs due to timing and stage of ongoing clinical trials;
- $4.7 million decrease in preclinical costs due to timing and stage of ongoing clinical trials and preclinical assets; partially offset by
- $9.1 million increase in clinical trial costs mainly due to expenses associated with our THRIVE and THRIVE-2 clinical trials;
- $3.0 million increase in severance costs primarily related to separation agreements with former executive officers, including a $2.1 million increase in share-based compensation related to the acceleration of stock option vesting during the three months ended March 31, 2024; and
- $2.6 million increase in personnel related costs, due primarily to increased share-based compensation and other employee compensation and recruiting costs.

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

General and Administrative Expenses

General and administrative expenses were $15.0 million during the three months ended March 31, 2024, compared to $21.8 million during the three months ended March 31, 2023. The $6.8 million decrease in general and administrative expenses is primarily attributable to the following:

- $7.5 million decrease in severance costs primarily related to separation agreements with former executive officers, including a $6.8 million decrease in share-based compensation related to the modification and acceleration of stock option vesting during the three months ended March 31, 2023; partially offset by
- $0.5 million increase in personnel-related costs, primarily due to increased share-based compensation expense.

Other Income, net

Other income, net was $7.4 million during the three months ended March 31, 2024 compared to $4.3 million during the three months ended March 31, 2023. Other income, net for the three months ended March 31, 2024 is comprised of $7.9 million of interest income earned on short-term investments as well as $0.1 million of sub-lease income, offset by $0.6 million in interest expense related to our Hercules Loan and Security Agreement (as defined below). Other income, net for the three months ended March 31, 2023 is comprised of $4.4 million of interest income earned on short-term investments as well as $0.1 million of sub-lease income, offset by $0.2 million in interest expense related to our Hercules Loan and Security Agreement. The increase in interest income is primarily attributable to higher average short-term investments balances during the three months ended March 31, 2024 as compared to the three months ended March 31, 2023.

Liquidity and Capital Resources

We have funded our operations to date principally through proceeds received from the sale of our common stock, our Series A Preferred Stock, our Series B Preferred Stock and other equity securities, debt financings, license fees, and reimbursements received under collaboration agreements. As of March 31, 2024, we had $613.2 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 2026.

We have no products approved for commercial sale and have not generated any revenue from product sales. Since our inception and through March 31, 2024, we have generated an accumulated deficit of $774.5 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 March 31, 2024, we were unable to estimate the timing or likelihood of achieving the milestones or making future product sales. For additional information regarding our agreements, see Note 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”), consisting of: (1) an initial tranche of $25.0 million, which was available through June 15, 2023; (2) a second tranche of $10.0 million, subject to the achievement of certain regulatory milestones, which was available through June 15, 2023; (3) a third tranche of $15.0 million, subject to the achievement of certain regulatory milestones, which was available through March 15, 2024; and (4) a fourth tranche of $25.0 million, subject to approval by the Lenders’ investment committee(s), available through December 15, 2024. The milestone related to the third tranche was not achieved prior to amendment of the Hercules Loan and Security Agreement in August 2023. The first and second tranches of $25.0 million and $10.0 million, respectively, were available to us through June 15, 2023. Upon signing we drew an initial principal amount of $5.0 million.

Per the terms of the Hercules Loan and Security Agreement, we were originally obligated to make interest-only payments through April 1, 2024. However, upon the achievement of a development milestone in August 2022,

the interest-only period was extended to October 1, 2024. If additional development milestones were met, the interest-only period would be further extended to April 1, 2025 pursuant to a second extension. 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 (se 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"). 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 March 31, 2024 was 8.95%.

Per the terms of the Hercules Amendment, we are obligated to make interest-only payments through April 1, 2025. If certain development milestones are met, then the interest-only period will be 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.

Upon execution of the Hercules Amendment in August 2023, we 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. We recognized a loss on debt extinguishment of $0.2 million in August 2023 related to unamortized debt discount and debt issuance costs.

Public Offerings

In January 2024, we entered into an underwriting agreement with Jefferies LLC ("Jefferies") and Leerink Partners LLC ("Leerink Partners") relating to the offer and sale (the "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 2024 Public Offering were approximately $150.0 million, before deducting underwriting discounts and commissions and other offering expenses payable by us.

Private Placements

In November 2023, we issued and sold in private placement transactions an aggregate of 8,869,797 shares of our common stock at a price per share of $12.38 and 92,312 shares of our Series B 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 SM (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 three months ended March 31, 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.

Summarized cash flows for the three months ended March 31, 2024 and 2023 are as follows:

	Three Months Ended March 31,		
	2024	2023	Increase (Decrease)
		(in thousands)	
Net cash provided by (used in):			
Operating activities	$ (45,223)	$ (61,973)	$ 16,750
Investing activities	(143,045)	(13,295)	(129,750)
Financing activities	177,082	8,204	168,878
Net increase (decrease) in cash and cash equivalents	$ (11,186)	$ (67,064)	$ 55,878

Operating Activities

Net cash used in operating activities was $45.2 million for the three months ended March 31, 2024, and primarily consisted of our net loss of $48.5 million, adjusted for non-cash items of $8.3 million (primarily share-based compensation of $12.7 million, offset by accretion and amortization of premiums and discounts on available-for-sale securities of $4.7 million), and changes in working capital of $5.0 million. The change in working capital was primarily related to a decrease of $0.4 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 and prepayments to vendors for ongoing clinical trial and manufacturing activities.

Net cash used in operating activities was $62.0 million for the three months ended March 31, 2023, and primarily consisted of a net loss of $68.2 million, adjusted for non-cash items of $12.4 million (primarily share-based compensation of $15.2 million) and changes in working capital of $6.3 million. The change in working capital was primarily related to a decrease of $4.1 million in accounts payable and accrued and other liabilities and an increase of $2.1 million in prepaid expenses and other current assets due to the timing of payments and prepayments to vendors for ongoing clinical trial and manufacturing activities.

Investing Activities

Net cash used in investing activities was $143.0 million during the three months ended March 31, 2024, and consisted primarily of $143.0 million in net purchases of short-term investments.

Net cash used in investing activities was $13.3 million during the three months ended March 31, 2023, and consisted primarily of $13.2 million in net purchases of short-term investments and $0.1 million in purchases of property and equipment.

Financing Activities

Net cash provided by financing activities was $177.1 million during the three months ended March 31, 2024, and consisted of primarily of net proceeds of $175.9 million from the 2024 Public Offering and the September 2022 ATM Agreement, as well as $0.8 million in proceeds from the exercise of stock options and $0.4 million in proceeds from the issuance of common stock under our employee stock purchase plan.

Net cash provided by financing activities was $8.2 million during the three months ended March 31, 2023, and consisted primarily of $6.9 million in proceeds from the exercise of stock options, $0.9 million in proceeds from the exercise of warrants and $0.3 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 three months ended March 31, 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 will need to raise additional capital, and if we are unable to do so when needed, we will not be able to continue as a going concern.

As of March 31, 2024, we had $613.2 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 2026. 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. 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 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 three months ended March 31, 2024 and 2023, our net loss was $48.5 million and $68.2 million, respectively. As of March 31, 2024, we had an accumulated deficit of $774.5 million and cash, cash equivalents, and short-term investments of $613.2 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 2026. 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 enter more advanced clinical trials. 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 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 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.

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, and obtain the regulatory and marketing approvals 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;
- 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;
- 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, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, 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.

We maintain our cash at financial institutions, often in balances that exceed federally-insured limits. The failure of financial institutions could adversely affect our ability to pay our operational expenses or make other payments.

Our cash held in non-interest-bearing and interest-bearing accounts exceeds the Federal Deposit Insurance Corporation (“FDIC”) insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. For example, the FDIC took control of Silicon Valley Bank on March 10, 2023. The Federal Reserve subsequently announced that account holders would be made whole. However, the FDIC may not make all account holders whole in the event of future bank failures. In addition, even if account holders are ultimately made whole with respect to a future bank failure, account holders’ access to their accounts and assets held in their accounts may be substantially delayed. Any material loss that we may experience in the future or inability for a material time period to access our cash and cash equivalents could have an adverse effect on our ability to pay our operational expenses or make other payments, which could adversely affect our business.

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 recruiting eligible patients and/or subjects in our clinical trials;
- failure by clinical sites, CROs, or other third parties to adhere to clinical trial requirements;
- failure by our clinical sites, CROs, or other third parties to perform in accordance with current good clinical practice ("GCP") requirements of the FDA or applicable foreign regulatory guidelines;
- 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 VRDN-001 IV for marketing approval in both active and chronic TED, respectively. However, the FDA or other regulatory authorities may require additional patients in this safety database or may require us to take other additional steps. We are also intending in mid-2024 to initiate what we expect to be a pivotal program for VRDN-003. The FDA or other regulatory authorities may require us to take other additional steps in the course of development and regulatory interaction regarding our product candidates, including VRDN-001 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, or requiring us to assess additional parameters related to safety or efficacy. These additional requirements 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 may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions, for example, under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market, or product recalls;
- fines, warning letters, or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products; 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 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 and efficacy and governing, among other things, clinical trials, commercial sales, pricing and distribution, and we cannot predict success in any such jurisdictions.

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, sBLA 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 or IRBs 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 a label that does not include the labeling 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 an approved label, 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 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 a restrictive drug label. 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 a restrictive drug label, 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 label;
- 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, drug-device combination products.

Some of our product candidates, including VRDN-003, VRDN-006 and VRDN-008, are or are anticipated to be drug-device 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, 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 may require that we amend the labeling of the product or recall the product or may even withdraw approval for the product.

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 program for TED. This data set includes preliminary data which was not subject to the standard quality control measures typically associated with final clinical trial results. Based on the comparable pharmacology of VRDN-003 to VRDN-001, we believe VRDN-003 has the potential to maintain the clinical response of VRDN-001 IV while significantly increasing patient convenience. If this preliminary clinical data on VRDN-003 changes following audit and verification, it could negatively impact the development of VRDN-003 and could harm our business prospects. However, the data from our Phase 2 trials for VRDN-001 may also not be fully reflective of topline results for our Phase 3 THRIVE and THRIVE-2 trials which are expected in the middle of 2024 and by year end 2024, respectively. If clinical data from VRDN-001 is not positive, it could negatively impact the development of VRDN-003 and could 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 and the masked data for VRDN-001 from our ongoing trials, 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 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 also face increased competition for eligible patients for enrollment, for example, as a result of additional therapies for TED being tested in clinical trials. 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. Accordingly, 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. Our failure to comply with these laws, regulations and guidelines may negatively impact the integrity of the data collected in our clinical trials and may require us to repeat clinical trials or add patients to ongoing clinical trials, which would be costly and delay the regulatory 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 drug-device 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 process is 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, infusing the patient with the product, manufacturing issues, or different product characteristics resulting from 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 drug-device combination products. In particular, we anticipate using an autoinjector device in connection with our product candidate VRDN-003. Drug-device 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, drug-device 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, or deviations from normal manufacturing processes could result in reduced production yields, product shortages, product defects, manufacturing failure, 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 devices and device components, and we intend to rely on third parties to produce and process our product candidates, if approved, and our commercialization of any of our product candidates could be stopped, delayed, or made less profitable if those third parties fail to obtain approval of government regulators, fail to provide us with sufficient quantities of drug product, devices, or device components, or fail to do so at acceptable quality levels or prices.

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 our drug product.

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 manufacturers of our 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 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.
- Manufacturers are subject to ongoing periodic unannounced inspection by the FDA 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 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, or have an adverse effect on our ability to secure significant 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 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 a single supplier 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 undertaking a technology transfer of certain drug product related to our VRDN-001 program from one manufacturer to another. If we encounter any material problems in connection with that process, we may be delayed in the development of our product candidates, including VRDN-001, and our business could be harmed.

The manufacture of drug products, including combination products that comprise a 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 drug-device combination products, like certain of our product candidates, due to the increased complexity in their manufacture and associated supply chain. Furthermore, if contaminants are discovered in our supply of our product candidates or

in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot be assured that any stability issue or other issues relating to the manufacture of our product candidates will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes, shortages, including from the effects of heath emergencies (such as novel viruses or pandemics) 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 foreign CROs and CMOs, including WuXi AppTec (Hong Kong) Limited and WuXi Biologics (Hong Kong) Limited (together, "WuXi"), to develop and manufacture our product candidates, and will likely continue to rely on foreign CROs and CMOs in the future. Such entities may be subject to U.S. legislation, including the proposed BIOSECURE Act, sanctions, investigations, regulations, trade restrictions, regulatory actions, and other foreign 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.

The biopharmaceutical industry in China is strictly regulated by the Chinese government, including Chinese collaborators and service providers such as CROs and contract development and manufacturing organizations. 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 public health, 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.

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 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.

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.

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 therefore they may be subject to competition.

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 are seeking Orphan drug designation for VRDN-001 from the FDA and may seek Orphan drug designation for future product candidates, but we might not receive such designation.

In September 2022, we filed an amended application for Orphan drug designation for VRDN-001 based on clinical data. In response, the FDA has indicated that further review of the application is suspended pending receipt of additional information. We are currently reviewing our submission further. There is no guarantee that upon submission of this additional data information the FDA will grant us Orphan drug designation. See "Business—Government Regulation—Orphan Drug Designation" in our 2023 Annual Report on Form 10-K.

Even with an orphan drug designation for its 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. 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. 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 FDA's interpretation of the scope of orphan drug exclusivity may change. The FDA's longstanding interpretation of the Orphan Drug Act is that exclusivity is specific to the orphan indication for which the drug was actually approved. As a result, the scope of exclusivity has been narrow and protected only against competition from the same "use or indication" rather than the broader "disease or condition." 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 studies be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. The FDA may require that any such confirmatory study be initiated or substantially underway prior to the submission of an application for 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. An unsuccessful post-marketing clinical trial or failure to complete such a trial could result in the withdrawal of marketing approval. Any government investigation of alleged violations of law would be expected to require us to expend significant time and resources in response and could generate adverse publicity. Any failure to comply 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. In addition, if we were able to obtain accelerated approval of any of our drug candidates, the FDA may require us to conduct a confirmatory study to verify the predicted clinical benefit. Other regulatory authorities outside of the United States may have similar requirements. The results from the confirmatory study may not support the clinical benefit, which could result in the approval being withdrawn. While operating under accelerated approval, we will be subject to certain restrictions that we would not be subject to upon receiving regular approval.

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.

Failure to comply 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 the failure to comply 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.

Failure to comply 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, Harbour BioMed, Acelyrin, Inc., Tourmaline Bio, Inc. and Sling Therapeutics, Inc. Other companies such as Kriya Therapeutics, Inc. 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, VRDN-001 and VRDN-003 will also compete against generic medications, such as corticosteroids, that are prescribed for and surgical procedures 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 VRDN-001 is approved, it may be priced at a significant premium over other competitive products. This may make it difficult for VRDN-001 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.

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 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, 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. (including the upcoming U.S. presidential election) 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. 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;
- 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 March 31, 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.

		Incorporated by Reference		
Exhibit No.	**Description of Exhibit**	**Form**	**Filing Date**	**Number**
3.1	Second Restated Certificate of Incorporation of the Registrant, effective as of March 9, 2022	10-K	3/11/2022	3.1
3.2	Fourth Amended and Restated Bylaws of the Registrant, effective as of December 15, 2023.	8-K	12/18/2023	3.1
3.3	Certificate of Designation of Series A Non-Voting Convertible Preferred Stock	8-K	10/28/2020	3.1
3.4	Certificate of Designation of Series B Non-Voting Convertible Preferred Stock	8-K	9/23/2021	3.1
4.1	Specimen Common Stock Certificate	S-1	3/19/2014	4.1
4.2	Form of Warrant to Purchase Common Stock	8-K	2/7/2020	4.1

31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities and Exchange Act, as amended.	x
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities and Exchange Act, as amended.	x
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	x
101.INS	XBRL Instance Document	x
101.SCH	XBRL Taxonomy Extension Schema Document	x
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	x
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	x
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	x
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	x
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	x

* 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: May 8, 2024	By:	/s/ Stephen Mahoney
		Stephen Mahoney
		President, Chief Executive Officer and Director
		(Principal Executive Officer)
Date: May 8, 2024	By:	/s/ Seth Harmon
		Seth Harmon
		Senior Vice President of Finance and Accounting
		(Principal Financial Officer; Principal Accounting Officer)

Exhibit 31.1

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: May 8, 2024

By: /s/ Stephen Mahoney

Stephen Mahoney

President, Chief Executive Officer and Director

(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Seth Harmon, certify that:

1. I have reviewed this 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: May 8, 2024

By: /s/ Seth Harmon

Seth Harmon

Senior Vice President of Finance and Accounting

(Principal Financial Officer; Principal Accounting Officer)

Exhibit 32.1

SECTION 1350 CERTIFICATION

Each of the undersigned, Stephen Mahoney, Chief Executive Officer of Viridian Therapeutics, Inc., a Delaware corporation (the "Company"), and Seth Harmon, 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 March 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Stephen Mahoney

Stephen Mahoney

President, Chief Executive Officer and Director

(Principal Executive Officer)

Date: May 8, 2024

/s/ Seth Harmon

Seth Harmon

Senior Vice President of Finance and Accounting

(Principal Financial Officer; Principal Accounting Officer)

Date: May 8, 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.