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# VIRIDIAN THERAPEUTICS, INC.\DE

## FORM 10-Q
(Quarterly Report)

Filed 11/04/26 for the Period Ending 09/30/26

| | |
|---|---|
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| Telephone | 617.272.4600 |
| CIK | 0001590750 |
| Symbol | VRDN |
| SIC Code | 2834 - Pharmaceutical Preparations |
| Industry | Biotechnology & Medical Research |
| Sector | Healthcare |
| Fiscal Year | 12/31 |

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

# FORM 10-Q

**(Mark One)**

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

**For the quarterly period ended September 30, 2026**

**or**

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

**For the transition period from to**

**Commission File No. 001-36483**

# VIRIDIAN THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

| **Delaware** | **47-1187261** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| **221 Crescent Street, Suite 103A**<br>**Waltham, MA**<br>(Address of principal executive offices) | **02453**<br>(Zip Code) |

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

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

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

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common Stock, $0.01 par value per share | VRDN | The Nasdaq Stock Market LLC |

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of November 2, 2026, there were 113,558,449 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. The words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "will," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Forward-looking statements contained in this Quarterly Report include, but are not limited to, statements about:

- the ability of our clinical trials to demonstrate safety and efficacy of our product candidates and other results;
- the potential utility, efficacy, potency, safety, clinical benefits, half-life, clinical response, convenience and number of indications of our product and product candidates, including our belief that veligrotug, trade name Lumvoa™ (veligrotug-vvze), provides a compelling new treatment option for thyroid eye disease ("TED") patients in the United States;
- the timing and focus of our ongoing and future nonclinical studies and clinical trials and the timing of reporting data from those studies and trials;
- the timing or likelihood of regulatory filings and approvals, including the potential approval of the Marketing Authorization Application ("MAA") for veligrotug submitted to the European Medicines Agency ("EMA") in January 2026 and our potential submission of a biologics license application ("BLA") for elegrobart in the first quarter of 2027;
- our plans relating to the further development of our product candidates, including additional indications we may pursue and our efforts to continue to identify and engineer novel product candidates, our expectation that we will communicate development plans for our FcRn inhibitor portfolio in the fourth quarter of 2026, and our plans to initiate a phase 1 clinical trial of our anti-TSHR antibody, VRDN-292, starting in patients with Graves' disease in the fourth quarter of 2026;
- supply chain disruptions, enrollment in clinical trials involving our product candidates or other delays in such trials;
- our plans relating to commercializing veligrotug and our product candidates, including our plans to commercialize product candidates as combination products, if approved, including the geographic areas of focus and sales strategy;
- potential market sizes and market opportunities, including the rate and degree of market acceptance and clinical utility for veligrotug and our product candidates;
- our expectations regarding the initiation of clinical trials and interactions and alignment with regulatory authorities;
- our expectations regarding pricing, coverage and reimbursement for veligrotug and our product candidates, if approved, including expected discounts, rebates, chargebacks, returns and other adjustments;
- our plans to obtain or protect intellectual property rights;
- our continued reliance on third parties to conduct additional clinical trials of our product candidates and for the manufacture of our product candidates for nonclinical studies, clinical trials and commercialization;
- our plans regarding any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- our estimates regarding expenses, future revenue, capital requirements and our ability to obtain additional financing to fund our operations and complete further development and commercialization of our product candidates;
- our expectations regarding the ability of our existing cash, cash equivalents, and anticipated commercial revenues from veligrotug and elegrobart, if approved, to fund our future anticipated operating expenses and capital expenditure requirements.

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

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

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

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

**SUMMARY OF THE MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS**

*Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Item 1A. Risk Factors" and should be carefully considered, together with other information in this Quarterly Report and our other filings with the SEC, before making an investment decision regarding our common stock.*

- 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 have a limited history of generating revenue from product sales and may never be profitable.
- If we are unable to secure additional capital when needed, we would be forced to delay, reduce, or eliminate our research and product development programs or future commercialization efforts.
- 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. Any of our product candidates may fail in development or experience significant delays.
- Regulatory approval processes are lengthy, time consuming and inherently unpredictable, and we may be unable to obtain approval for our product candidates or approval may be delayed due to factors beyond our control, including as a result of disruptions at the U.S. Food and Drug Administration ("FDA") and other agencies caused by shutdowns, funding shortages, and policies pursued by the current U.S. administration. 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, or result in significant negative consequences following marketing approval, if any.
- We are heavily dependent on the commercial success of veligrotug and the success of our product candidates in clinical development. Some of our product candidates have produced results only in nonclinical settings, or for other indications than those for which we contemplate conducting development and seeking FDA or other regulatory approval, and we cannot give any assurance that we will generate data for any of our product candidates sufficiently supportive to receive regulatory approval in our planned indications, which will be required before they can be commercialized.
- Product development involves a lengthy and expensive process with an uncertain outcome, and results of earlier nonclinical studies and clinical trials may not be predictive of future clinical trial results.
- If we are unable to maintain commercial manufacturing, sales and marketing capabilities or enter into agreements with third parties to commercially manufacture, market and sell veligrotug or our product candidates, we may be unable to generate sufficient revenue to sustain or grow our business.
- We face substantial competition and our competitors may discover, develop, or commercialize products faster or more successfully than us.
- We rely on third parties to conduct our nonclinical development activities and clinical trials, manufacture our commercial product and product candidates, and perform other services. If these third parties do not successfully perform and/or comply with regulatory requirements, we may not be able to successfully complete clinical development, obtain regulatory approval, or maintain our commercial operations and our business could be substantially harmed.
- We are subject to ongoing regulatory oversight. We may incur significant liability if enforcement authorities allege or determine that we have not complied with regulatory requirements.

- The market may not be receptive to veligrotug or other product candidates we may develop in the future upon their commercial introduction and we may not be able to sell veligrotug or our other product candidates, if approved, and may be unable to generate sufficient revenue to sustain or grow our business.
- We rely on patent rights, trade secret protections, and confidentiality agreements to protect intellectual property, including intellectual property related to our product candidates and any future product candidates. If we are unable to obtain or maintain exclusivity from the combination of these approaches, we may not be able to compete effectively in our markets.
- Our future success depends in part on our ability to attract, retain, and motivate qualified personnel. If we lose key personnel, or if we fail to recruit additional highly skilled personnel, our ability to develop our product candidates will be impaired and our business may be harmed.

**PART I. FINANCIAL INFORMATION**

**ITEM 1. FINANCIAL STATEMENTS**

**VIRIDIAN THERAPEUTICS, INC.**
**CONDENSED CONSOLIDATED BALANCE SHEETS**
**(In thousands, except share and per share data)**
**(Unaudited)**

| | September 30, 2026 | December 31, 2025 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 172,860 | $ 212,382 |
| Restricted cash | 1,300 | — |
| Marketable securities | 782,346 | 662,270 |
| Accounts receivable, net | 29,782 | — |
| Inventory | 85 | — |
| Prepaid expenses and other current assets | 26,757 | 19,581 |
| Total current assets | 1,013,130 | 894,233 |
| Property and equipment, net | 2,972 | 1,228 |
| Operating lease right-of-use asset | 2,645 | 2,421 |
| Intangible asset, net | 9,792 | — |
| Other assets | 131 | 1,536 |
| Total assets | $ 1,028,670 | $ 899,418 |
| | | |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 9,297 | $ 8,683 |
| Accrued liabilities | 60,756 | 62,013 |
| Total current liabilities | 70,053 | 70,696 |
| Long-term debt, net | — | 49,940 |
| Derivative liability | 11,620 | 20,030 |
| Liability related to the sale of future revenue, net | 121,608 | 34,244 |
| Convertible notes, net | 242,461 | — |
| Other liabilities | 2,230 | 2,341 |
| Total liabilities | 447,972 | 177,251 |
| Commitments and contingencies (Note 9) | | |
| Stockholders' equity: | | |
| Preferred stock, series A non-voting convertible preferred stock, $0.01 par value; 435,000 shares authorized; 133,191 and 134,864 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively | 60,432 | 61,188 |
| Preferred stock, series B non-voting convertible preferred stock, $0.01 par value; 500,000 shares authorized; 48,463 and 79,620 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively | 37,592 | 70,868 |
| Common stock, $0.01 par value; 200,000,000 shares authorized; 113,525,222 and 101,826,500 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively | 1,135 | 1,018 |
| Additional paid-in capital | 2,155,427 | 1,927,104 |
| Accumulated other comprehensive income (loss) | (2,201) | 447 |
| Accumulated deficit | (1,671,687) | (1,338,458) |
| Total stockholders' equity | 580,698 | 722,167 |
| Total liabilities and stockholders' equity | $ 1,028,670 | $ 899,418 |

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

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 | 2025 |
| Revenues: | | | | |
| Product revenue, net | $ 24,671 | $ — | $ 24,671 | $ — |
| License revenue | 125 | 70,000 | 364 | 70,000 |
| Collaboration revenue[1] | 956 | 570 | 1,142 | 717 |
| Total revenues | 25,752 | 70,570 | 26,177 | 70,717 |
| Operating expenses: | | | | |
| Cost of revenues | 1,527 | — | 1,527 | — |
| Research and development[2] | 70,093 | 86,261 | 219,301 | 249,721 |
| Selling, general and administrative | 57,609 | 24,322 | 151,263 | 61,642 |
| Total operating expenses | 129,229 | 110,583 | 372,091 | 311,363 |
| Loss from operations | (103,477) | (40,013) | (345,914) | (240,646) |
| Other income (expense), net: | | | | |
| Interest income | 9,537 | 5,521 | 25,899 | 19,607 |
| Interest expense | (9,273) | (560) | (21,042) | (1,666) |
| Change in fair value of derivative liability | 2,070 | — | 8,410 | — |
| Other income (expense), net | (66) | 453 | (582) | 459 |
| Total other income, net | 2,268 | 5,414 | 12,685 | 18,400 |
| Net loss | $ (101,209) | $ (34,599) | $ (333,229) | $ (222,246) |
| | | | | |
| Net loss per share, basic and diluted, common stock | $ (0.81) | $ (0.34) | $ (2.75) | $ (2.22) |
| Weighted-average common shares outstanding, basic and diluted | 113,407,432 | 81,784,499 | 107,875,408 | 81,576,987 |
| Net loss per share, basic and diluted, Series A convertible preferred stock | $ (53.76) | $ (22.96) | $ (183.26) | $ (147.81) |
| Weighted-average Series A convertible preferred shares outstanding, basic and diluted | 133,191 | 134,864 | 134,263 | 134,864 |
| Net loss per share, basic and diluted, Series B convertible preferred stock | $ (53.76) | $ (22.96) | $ (183.26) | $ (147.81) |
| Weighted-average Series B convertible preferred shares outstanding, basic and diluted | 48,463 | 145,160 | 66,004 | 145,160 |
| | | | | |
| Comprehensive loss: | | | | |
| Net loss | (101,209) | $ (34,599) | $ (333,229) | $ (222,246) |
| Other comprehensive income (loss): | | | | |
| Unrealized gain (loss) on available-for-sale securities | (1,020) | 294 | (2,626) | 373 |
| Foreign currency translation adjustment | (28) | — | (22) | — |
| Total other comprehensive income (loss) | (1,048) | 294 | (2,648) | 373 |
| Comprehensive loss | $ (102,257) | $ (34,305) | $ (335,877) | $ (221,873) |

[1] Includes related party amount of $0 and $186 for the three and nine months ended September 30, 2026, respectively, and $570 and $717 for the three and nine months ended September 30, 2025.

[2] Includes related party amount of $0 and $1,500 for the three and nine months ended September 30, 2026, respectively, and $0 and $4,528 for the three and nine months ended September 30, 2025.

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

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

| | Convertible Preferred Stock | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Series A | | Series B | | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Income (Loss) | Accumulated Deficit | Total Stockholders' Equity |
| | Shares | Amount | Shares | Amount | Shares | Amount | | | | |
| Balance as of December 31, 2025 | 134,864 | $ 61,188 | 79,620 | $ 70,868 | 101,826,500 | $ 1,018 | $ 1,927,104 | $ 447 | $ (1,338,458) | $ 722,167 |
| Issuance of common stock upon exercises of stock options | — | — | — | — | 424,648 | 5 | 6,352 | — | — | 6,357 |
| Issuance of common stock upon vesting of restricted stock units | — | — | — | — | 206,946 | 2 | (2) | — | — | — |
| Share-based compensation expense | — | — | — | — | — | — | 13,390 | — | — | 13,390 |
| Unrealized loss on available-for-sale securities | — | — | — | — | — | — | — | (1,008) | — | (1,008) |
| Change in cumulative translation adjustment | — | — | — | — | — | — | — | 3 | — | 3 |
| Net loss | — | — | — | — | — | — | — | — | (104,901) | (104,901) |
| Balance as of March 31, 2026 | 134,864 | $ 61,188 | 79,620 | $ 70,868 | 102,458,094 | $ 1,025 | $ 1,946,844 | $ (558) | $ (1,443,359) | $ 636,008 |
| Issuance of common stock upon conversion of convertible preferred stock | (1,673) | (756) | (31,157) | (33,276) | 2,188,771 | 22 | 34,010 | — | — | — |
| Issuance of common stock in an underwritten offering, net of issuance costs of $8,778 | — | — | — | — | 8,455,883 | 85 | 134,887 | — | — | 134,972 |
| Issuance of common stock upon exercises of stock options | — | — | — | — | 41,646 | — | 577 | — | — | 577 |
| Issuance of common stock under employee stock purchase plan | — | — | — | — | 92,842 | — | 1,270 | — | — | 1,270 |
| Issuance of common stock upon vesting of restricted stock units | — | — | — | — | 982 | — | — | — | — | — |
| Share-based compensation expense | — | — | — | — | — | — | 16,984 | — | — | 16,984 |
| Unrealized loss on available-for-sale securities | — | — | — | — | — | — | — | (598) | — | (598) |
| Change in cumulative translation adjustment | — | — | — | — | — | — | — | 3 | — | 3 |
| Net loss | — | — | — | — | — | — | — | — | (127,119) | (127,119) |
| Balance as of June 30, 2026 | 133,191 | $ 60,432 | 48,463 | $ 37,592 | 113,238,218 | $ 1,132 | $ 2,134,572 | $ (1,153) | $ (1,570,478) | $ 662,097 |
| Issuance of common stock upon exercises of stock options | — | — | — | — | 260,004 | 3 | 3,623 | — | — | 3,626 |
| Issuance of common stock upon vesting of restricted stock units | — | — | — | — | 27,000 | — | — | — | — | — |
| Share-based compensation expense | — | — | — | — | — | — | 17,232 | — | — | 17,232 |
| Unrealized loss on available-for-sale securities | — | — | — | — | — | — | — | (1,020) | — | (1,020) |
| Change in cumulative translation adjustment | — | — | — | — | — | — | — | (28) | — | (28) |
| Net loss | — | — | — | — | — | — | — | — | (101,209) | (101,209) |
| Balance as of September 30, 2026 | 133,191 | $ 60,432 | 48,463 | $ 37,592 | 113,525,222 | $ 1,135 | $ 2,155,427 | $ (2,201) | $ (1,671,687) | $ 580,698 |

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

| | Convertible Preferred Stock | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Series A | | Series B | | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Income (Loss) | Accumulated Deficit | Total Stockholders' Equity |
| | Shares | Amount | Shares | Amount | Shares | Amount | | | | |
| Balance as of December 31, 2024 | 134,864 | $ 61,188 | 145,160 | $ 127,697 | 80,994,046 | $ 810 | $ 1,477,811 | $ (10) | $ (995,857) | $ 671,639 |
| Issuance of common stock in at-the-market offerings, net of issuance costs of $149 | — | — | — | — | 245,388 | 3 | 4,792 | — | — | 4,795 |
| Issuance of common stock upon exercises of warrants | — | — | — | — | 115,146 | 1 | 1,617 | — | — | 1,618 |
| Issuance of common stock upon exercises of stock options | — | — | — | — | 185,426 | 2 | 2,295 | — | — | 2,297 |
| Issuance of common stock under employee stock purchase plan | — | — | — | — | 41,106 | — | 561 | — | — | 561 |
| Issuance of common stock upon vesting of restricted stock units | — | — | — | — | 8,315 | — | — | — | — | — |
| Share-based compensation expense | — | — | — | — | — | — | 10,220 | — | — | 10,220 |
| Unrealized gain on available-for-sale securities | — | — | — | — | — | — | — | 255 | — | 255 |
| Net loss | — | — | — | — | — | — | — | — | (86,912) | (86,912) |
| Balance as of March 31, 2025 | 134,864 | $ 61,188 | 145,160 | $ 127,697 | 81,589,427 | $ 816 | $ 1,497,296 | $ 245 | $ (1,082,769) | $ 604,473 |
| Issuance of common stock upon exercises of stock options | — | — | — | — | 61,527 | 1 | 762 | — | — | 763 |
| Issuance of common stock upon vesting of restricted stock units | — | — | — | — | 232 | — | — | — | — | — |
| Share-based compensation expense | — | — | — | — | — | — | 10,844 | — | — | 10,844 |
| Unrealized loss on available-for-sale securities | — | — | — | — | — | — | — | (176) | — | (176) |
| Net loss | — | — | — | — | — | — | — | — | (100,735) | (100,735) |
| Balance as of June 30, 2025 | 134,864 | $ 61,188 | 145,160 | $ 127,697 | 81,651,186 | $ 817 | $ 1,508,902 | $ 69 | $ (1,183,504) | $ 515,169 |
| Issuance of common stock, March 2025 ATM, net of issuance costs of $209 | — | — | — | — | 500,000 | 5 | 9,746 | — | — | 9,751 |
| Issuance of common stock upon exercises of stock options | — | — | — | — | 34,522 | — | 547 | — | — | 547 |
| Issuance of common stock under employee stock purchase plan | | | | | 43,450 | — | 558 | — | — | 558 |
| Share-based compensation expense | — | — | — | — | — | — | 11,250 | — | — | 11,250 |
| Unrealized gain on available-for-sale securities | — | — | — | — | — | — | — | 294 | — | 294 |
| Net loss | — | — | — | — | — | — | — | — | (34,599) | (34,599) |
| Balance as of September 30, 2025 | 134,864 | $ 61,188 | 145,160 | $ 127,697 | 82,229,158 | $ 822 | $ 1,531,003 | $ 363 | $ (1,218,103) | $ 502,970 |

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

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

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2026** | **2025** |
| Cash flows from operating activities: | | |
| Net loss | $ (333,229) | $ (222,246) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Share-based compensation expense | 47,606 | 32,314 |
| Non-cash interest expense | 13,486 | 308 |
| Depreciation and amortization | 581 | 340 |
| Accretion and amortization of available-for-sale securities | (4,864) | (5,005) |
| Non-cash lease expense | (46) | (30) |
| Change in fair value of derivative liability | (8,410) | — |
| Loss on extinguishment of debt | 4,113 | — |
| Changes in operating assets and liabilities: | | |
| Accounts receivable, net | (29,782) | — |
| Inventory | (85) | — |
| Prepaid expenses and other assets | (5,771) | 8,849 |
| Accounts payable | 614 | 7,942 |
| Accrued liabilities | (1,449) | (5,109) |
| Other liabilities | (236) | — |
| Unbilled revenue | (279) | (70,000) |
| Net cash used in operating activities | (317,751) | (252,637) |
| Cash flows from investing activities: | | |
| Purchases of marketable securities | (645,594) | (141,084) |
| Maturities of marketable securities | 527,734 | 443,196 |
| Milestone payment related to licensed intellectual property | (10,000) | — |
| Purchases of property and equipment | (1,699) | (255) |
| Net cash provided by (used in) investing activities | (129,559) | 301,857 |
| Cash flows from financing activities: | | |
| Proceeds from the sale of convertible notes | 250,000 | — |
| Proceeds from the issuance of common stock in offerings | 143,750 | — |
| Proceeds from sale of common stock in at-the-market offerings | — | 14,904 |
| Payments of issuance costs associated with the sale of common stock | (8,778) | (416) |
| Payments of issuance costs associated with the sale of convertible notes | (8,014) | — |
| Proceeds from sale of future revenue | 75,000 | — |
| Prepayment of long-term debt | (54,700) | — |
| Proceeds from the exercise of warrants | — | 1,618 |
| Proceeds from issuance of common stock upon exercises of stock options | 10,560 | 3,607 |
| Proceeds from issuance of common stock under employee stock purchase plan | 1,270 | 1,120 |
| Net cash provided by financing activities | 409,088 | 20,833 |
| Net increase (decrease) in cash, cash equivalents, and restricted cash | (38,222) | 70,053 |
| Cash, cash equivalents, and restricted cash at beginning of period | 212,382 | 99,594 |
| Cash, cash equivalents, and restricted cash at end of period | $ 174,160 | $ 169,647 |
| | | |
| Supplemental disclosure of cash flow information | | |
| Cash paid for interest | $ 2,227 | $ 1,362 |
| Issuance of common stock upon the conversion of convertible preferred stock | $ 34,032 | $ — |
| Purchase of property and equipment included in accounts payable and accrued liabilities | $ 418 | $ 17 |
| Deferred issuance costs included in accounts payable and accrued liabilities | $ — | $ 528 |
| Right-of-use asset obtained in exchange for new lease liability | $ 783 | $ 729 |

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

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

## 1. DESCRIPTION OF THE BUSINESS

Viridian Therapeutics, Inc., a Delaware corporation (the "Company" or "Viridian"), is a biopharmaceutical company focused on discovering, developing and commercializing potentially best-in-class medicines for autoimmune and rare diseases. The Company commercializes veligrotug, trade name Lumvoa™ (veligrotug-vvze), for thyroid eye disease ("TED"). Veligrotug was approved by the U.S. Food and Drug Administration ("FDA") for the treatment of TED in June 2026 and is a differentiated monoclonal antibody targeting insulin-like growth factor-1 receptor ("IGF-1R"), a clinically and commercially validated target for the treatment of TED. The Company's second product candidate for TED, elegrobart, is an extended half-life monoclonal antibody with the same binding domains as veligrotug and designed to be subcutaneously administered via a convenient, low-volume autoinjector. 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. Viridian additionally announced a program targeting the thyroid stimulating hormone receptor ("TSHR") in January 2026 that has the potential to be developed for the treatment of TED and Graves' disease.

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

***Liquidity and Capital Resources***

The Company's unaudited condensed consolidated financial statements have been prepared on the basis of the Company continuing as a going concern and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from any uncertainty related to its ability to continue as a going concern. The Company expects that its cash, cash equivalents and marketable securities as of September 30, 2026 of $955.2 million will enable the Company to fund its planned operations for at least twelve months from the date of issuance of these unaudited condensed consolidated financial statements.

The Company has funded its operations to date principally through proceeds received from the sale of the Company's common stock, Series A convertible preferred stock, Series B convertible preferred stock, and other equity securities, debt financings, and license fees and reimbursements received under collaboration agreements. After receiving marketing approval of veligrotug from the FDA in June 2026, the Company has also funded its operations from sales of veligrotug in the United States. The Company has incurred recurring losses and negative cash flows from operations since inception. As of September 30, 2026, the Company had an accumulated deficit of $1,671.7 million. Substantially all of the Company's operating losses resulted from expenses incurred in connection with its research and development programs and from selling, general and administrative costs associated with its operations. In addition, the Company may continue to incur additional operating losses as a result of planned expenditures for research and development activities, its drug development programs, including clinical trial and manufacturing costs, and the continued build-out of clinical, manufacturing, commercial and compliance capabilities.

The future viability of the Company is dependent on its ability to generate cash from operating activities or to raise additional capital to finance its operations. There can be no assurance that the Company will ever achieve profitability, or if achieved, that profitability will be sustained on a continuing basis. In addition, the Company's nonclinical and clinical development activities, manufacturing activities, and commercialization activities for the Company's product candidates, if approved, may require significant additional capital. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on the Company's financial condition and its ability to develop its product candidates. Changing circumstances may cause the Company to consume capital significantly faster or slower than currently anticipated. If the Company is unable to acquire additional capital or resources, it will be required to modify its operational plans. The estimates included herein are based on assumptions that may prove to be wrong, and the Company could exhaust its available financial resources sooner than currently anticipated.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

***Basis of Presentation and Principles of Consolidation***

The unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"), for interim financial reporting and as required by Regulation S-X, Rule 10-01. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC"), and Accounting Standards Updates ("ASU"), or the Financial Accounting Standards Board ("FASB").

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. 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, 2025, filed with the U.S. Securities and Exchange Commission (the "SEC") on February 26, 2026 (the "2025 Annual Report"). 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.

***Unaudited Interim Condensed Consolidated Financial Information***

In the opinion of management, all adjustments, consisting of normal recurring accruals and revisions of estimates, considered necessary for a fair presentation of the unaudited condensed consolidated financial statements have been included. Interim results for the nine months ended September 30, 2026, are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2026, or any other future period.

During the nine months ended September 30, 2026, there have been no changes to the Company's significant accounting policies as described in the 2025 Annual Report, except as discussed below.

***Cash, Cash Equivalents, and Restricted Cash***

All highly-liquid marketable securities 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. Additionally, the Company administers a patient co-pay assistance program that provides financial support to eligible patients for its approved product, veligrotug. In connection with this program, the Company advances funds to a third-party administrator that processes and settles claims. Amounts advanced are contractually restricted for use solely in connection with the Company's co-pay assistance programs, including the payment of eligible patient claims and related administrative fees, and are not available for general corporate purposes. Accordingly, such amounts are classified as restricted cash within the condensed consolidated balance sheets. As of September 30, 2026, restricted cash totaled $1.3 million, all of which is classified as current due to expected settlement within normal claims processing cycles. As of December 31, 2025, the Company had no restricted cash.

For purposes of the consolidated statements of cash flows, total cash, cash equivalents, and restricted cash consisted of the following as of September 30, 2026 and September 30, 2025:

| | September 30, 2026 | September 30, 2025 |
|---|---|---|
| | (in thousands) | |
| Cash and cash equivalents | $ 172,860 | $ 169,647 |
| Restricted cash | 1,300 | — |
| Total cash, cash equivalents, and restricted cash shown in the condensed consolidated statement of cash flows | $ 174,160 | $ 169,647 |

***Accounts Receivable, Net***

Accounts receivable, net as of September 30, 2026 consisted of $29.8 million of veligrotug product sales. Payment terms are established pursuant to the Company's contractual arrangements with its customers, with standard payment terms of approximately 60 days from the invoice date. Prior to J-code assignment, the Company agreed to extended payment terms of approximately 130 days from the invoice date. The Company periodically reviews accounts receivable for collectability and assesses whether an allowance for doubtful accounts is necessary for amounts that are not expected to be collected based on customer creditworthiness, historical payment experience, the age of outstanding receivables, including past-due amounts, and other relevant facts and circumstances. The Company did not record a reserve for estimated credit losses as of September 30, 2026.

***Inventory***

Prior to receiving marketing approval of veligrotug, costs related to the manufacturing of inventory were recorded as research and development expense on the Company's consolidated statements of operations and comprehensive loss in the period incurred. Following the marketing approval by the FDA of veligrotug in June 2026, the Company subsequently began capitalizing veligrotug inventory costs as it was determined that inventory costs incurred subsequent to the approval had a probable future economic benefit.

Inventory is stated at the lower of cost or estimated net realizable value, with cost determined on a first-in, first-out basis. Inventory costs include raw materials, third-party contract manufacturing, third-party packaging services, freight and overhead. The Company reduces its inventory to net realizable value for potentially excess, dated or obsolete inventory based on a quarterly assessment of the recoverability of its capitalized inventory. The Company periodically reviews inventory levels to identify inventory that may expire prior to expected sale or has a cost basis in excess of its estimated realizable value and writes down such inventories as appropriate as a component of cost of revenues in the consolidated statements of operations and comprehensive loss.

***Milestone and Royalty Payments Under In-licensing and Other Research and Development Agreements***

Under the Company's in-licensing and other research and development agreements, the Company could be required to pay development, regulatory, and sales-based milestone payments if certain substantive milestones are met. The Company generally expenses development milestones as incurred. For regulatory or sales-based milestones that are associated with an approved asset, the Company capitalizes the milestone payments related to the asset purchase as a finite-lived intangible asset provided that the milestone payment is recoverable based on the Company's estimated projected cash flows and if the asset has an alternative future use. Such intangible asset is amortized over its estimated useful life on a straight-line basis. The Company assesses the carrying value of its finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying value may not be fully recoverable. Recoverability of finite-lived intangible assets is measured by comparison of the carrying value of the asset to the future undiscounted cash flows the asset is expected to generate.

The Company could also be required to pay royalties based on actual net sales under in-licensing agreements. Such royalties are expensed in the period of sale of the product.

***Revenue Recognition***

The Company recognizes revenue in accordance with ASC Topic 606 - Revenue from Contracts with Customers ("ASC 606"). Under ASC 606, an entity recognizes revenue when or as performance obligations are satisfied by transferring control of promised goods or services to the customer, in an amount that reflects the consideration which the entity expects to be entitled to in exchange for those goods or services.

To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when (or as) the entity satisfies a performance obligation. At contract inception, the Company assesses the goods or services promised within each contract, determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

***Product Revenue, Net***

Following marketing approval of veligrotug in the United States from the FDA in June 2026, the Company began generating product revenue from sales of veligrotug.

The Company entered into a third-party logistics distribution agreement (the "3PL Agreement") to engage a logistics distribution agent (the "3PL Agent") to distribute the Company's products to its customers. The 3PL Agent provides services to the Company that include storage, distribution, processing product returns, customer service support, logistics support, electronic data interface, and system access support. Revenue is recognized when or as performance obligations are satisfied by transferring control of promised goods to a customer.

As of September 30, 2026, the Company had applied for mandatory distribution licenses that certain states require in order for the Company to sell its product throughout the United States. In order for the Company to execute sales in the United States prior to obtaining such licenses, the Company and an affiliate of the 3PL Agent (the "Title Company") entered into a Temporary Title Model Agreement (the "Temporary Title Model Agreement"), which was an amendment to the 3PL Agreement, so that the Title Company may purchase and take title to the product and sell the product to specialty distributors who have contracted to purchase the product from the Company. Although under the Temporary Title Model Agreement, the Title Company takes title to the product, the economic substance of the transaction provides that the Title Company does not possess the risk of loss or participate in the significant risks and rewards of ownership of the product or have the ability to control, direct the use of, and obtain substantially all of the remaining benefits from the product. Accordingly, the Company does not recognize revenue upon the transfer of the goods at the time of sale to the Title Company and recognizes revenue when the goods are sold from the Title Company to the specialty distributors.

Product revenue is recorded net of applicable reserves for variable consideration, including discounts and allowances.

*Government Rebates*

The Company records accruals for rebates under state Medicaid and Medicare programs as a reduction of sales when the product is shipped into the distribution channel using the expected value method. Until the Company obtains sufficient historical data based on product sales and reimbursement, the Company estimates its provision for government rebates based on industry data and reduces the revenue recognized at the time of the product sale to the customer to account for the estimated government rebates. Once sufficient history has been collected for government rebates, the Company will utilize that history to inform its rebates estimates.

*Chargebacks*

The Company records an estimate for chargebacks for discounts arising from contractual obligations to sell products at discounted prices to certain customers, including purchasers under government pricing programs and commercial agreements. The wholesaler or specialty distributor, charges the Company the difference between the price they paid and the contract price paid to the wholesaler or specialty distributor by the customer. The allowance for chargebacks is made using the expected value method and is based on actual and expected customer utilization of Company's product. Chargebacks could exceed historical experience and the Company's estimates of future customer utilization. Until the Company obtains sufficient historical data, the Company estimates its provision for chargebacks based on industry data and reduces the revenue recognized at the time of the product sale to the customer to account for the estimated chargeback. Once sufficient history has been collected for chargebacks, the Company will utilize that history to inform its chargebacks estimate.

*Co-pay Assistance*

The Company also maintains a co-pay assistance program for eligible patients with commercial insurance in the U.S. The co-pay assistance program assists certain commercially insured patients by reducing each participating patient's financial responsibility for the purchase price, up to a specified dollar amount of assistance.

*Distributor Fees*

The Company pays fees to specialty distributors for distribution and related services. Such fees are recorded as a reduction of revenue, as well as a component of accrued expenses.

*Product Returns*

The Company records an estimate for product returns at the time its customers take control of their product. Return amounts are recorded as a reduction of sales. In the initial sales period, the Company estimates its provision for returns based on industry data and specifically identified anticipated returns due to known business conditions and product expiry dates, and adjusts the transaction price at the time of the product sale to the customer to account for the estimated returns. Once sufficient history has been collected for product returns, the Company will utilize that history to inform its returns estimates.

***Concentrations***

Financial instruments that potentially subject the Company to concentrations of credit risk are receivables and marketable securities. Billings to large pharmaceutical distributors account for the majority of the Company's receivables. To mitigate credit risk, the Company monitors the financial performance and credit-worthiness of its customers. The following represents revenue and receivables from the Company's distributors exceeding 10% of the total in each category as of and for the three months ended September 30, 2026:

| Customer | Accounts Receivable | Total Revenues |
|---|---|---|
| Distributor A | 30 % | 29 % |
| Distributor B | 26 % | 24 % |
| Distributor C | 18 % | 17 % |
| Distributor D | 14 % | 13 % |

The Company holds its interest-bearing marketable securities with major financial institutions and, in accordance with documented investment policies, the Company limits the amount of credit exposure to any one financial institution or corporate issuer. The Company's investment objectives are, first, to ensure liquidity and conservation of capital and, second, to obtain investment income.

***Use of Estimates***

The Company's unaudited condensed consolidated financial statements are prepared in accordance with U.S. GAAP, which requires it to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and contingent liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions reflected in these unaudited condensed consolidated financial statements include, but are not limited to, estimates related to revenue recognition, fair value of marketable securities, accrued research and development expenses, liability related to sale of future revenue, derivative liability, income taxes and share-based compensation. Although these estimates are based on the Company's knowledge of current events and actions it may take in the future, actual results may ultimately differ from these estimates and assumptions.

***Recently Issued Accounting Standard Updates***

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

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

**3. MARKETABLE SECURITIES AND FAIR VALUE MEASUREMENTS**

***Marketable Securities***

The Company's marketable securities consisted of the following as of September 30, 2026 and December 31, 2025:

| (in thousands) | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---|---|---|---|---|
| **September 30, 2026** | | | | |
| U.S. treasury securities | $ 328,341 | $ — | $ (1,196) | $ 327,145 |
| Corporate paper and bonds | 456,183 | 2 | (984) | 455,201 |
| Total | $ 784,524 | $ 2 | $ (2,180) | $ 782,346 |
| | | | | |
| **December 31, 2025** | | | | |
| U.S. treasury securities | $ 223,526 | $ 254 | $ (9) | $ 223,771 |
| Corporate paper and bonds | 438,297 | 241 | (39) | 438,499 |
| Total | $ 661,823 | $ 495 | $ (48) | $ 662,270 |

As of September 30, 2026, the Company considers the unrealized losses in its investment portfolio to be temporary in nature and not due to credit losses. The Company has the intent and ability to hold such investments until their recovery at fair value. The Company did not have any realized gains or losses in its available-for-sale securities during the three and nine months ended September 30, 2026 and 2025. The Company did not have any sales of marketable securities during the three and nine months ended September 30, 2026 and 2025. The contractual maturity dates of the Company's investments are all less than 36 months. While the Company may hold securities with stated maturities greater than one year, all available-for-sale securities are considered available to support current operations, and thus are classified as current assets.

***Fair Value Measurements***

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

| (in thousands) | Quoted Prices in Active Markets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) | Total |
|---|---|---|---|---|
| **September 30, 2026** | | | | |
| Assets: | | | | |
| **Cash equivalents:** | | | | |
| Money market funds | $ 137,946 | $ — | $ — | $ 137,946 |
| Corporate paper and bonds | — | 2,595 | — | 2,595 |
| **Marketable securities:** | | | | |
| U.S. treasury securities | — | 327,145 | — | 327,145 |
| Corporate paper and bonds | — | 455,201 | — | 455,201 |
| Total cash equivalents and marketable securities | $ 137,946 | $ 784,941 | $ — | $ 922,887 |
| | | | | |
| **Liabilities:** | | | | |
| Derivative liability | $ — | $ — | $ 11,620 | $ 11,620 |
| Total liabilities | $ — | $ — | $ 11,620 | $ 11,620 |
| | | | | |
| **December 31, 2025** | | | | |
| Assets: | | | | |
| **Cash equivalents:** | | | | |
| Money market funds | $ 191,308 | $ — | $ — | $ 191,308 |
| Corporate paper and bonds | — | 14,624 | — | 14,624 |
| **Marketable securities:** | | | | |
| U.S. treasury securities | — | 223,771 | — | 223,771 |
| Corporate paper and bonds | — | 438,499 | — | 438,499 |
| Total cash equivalents and marketable securities | $ 191,308 | $ 676,894 | $ — | $ 868,202 |
| | | | | |
| **Liabilities:** | | | | |
| Derivative liability | $ — | $ — | $ 20,030 | $ 20,030 |
| Total liabilities | $ — | $ — | $ 20,030 | $ 20,030 |

The fair value of the Company's Level 1 cash equivalents is based on quoted market prices in active markets with no valuation adjustment. The fair value of the Company's Level 2 cash equivalents and marketable securities, consisting of securities with original maturities of three months or less and 36 months or less, respectively, are determined through third-party pricing services. The amortized cost of cash equivalents approximates the fair value. There have been no impairments of the Company's assets measured and carried at fair value during the three and nine months ended September 30, 2026 and 2025. In addition, there were no changes in valuation techniques or transfers between Level 1, Level 2 and Level 3 financial assets during the three and nine months ended September 30, 2026 and 2025.

For information on the fair value of the derivative liability, see Note 7, *Purchase and Sale of the Revenue Participation Right*.

The Company believes the terms of its liability related to the sale of future revenue, net, which was entered into in October 2025, reflects current market conditions for instruments with similar terms and maturity, therefore, the carrying value approximates its fair value based on Level 3 of the fair value hierarchy.

**4. INTANGIBLE ASSET, NET**

As a result of the approval of veligrotug by the FDA in June 2026, the Company was required to pay AbbVie Inc. (formerly ImmunoGen, Inc., "ImmunoGen") a milestone payment of $10.0 million (see Note 8, *Collaboration and License Agreements*). The gross carrying amount of the intangible asset is $10.0 million, which is being amortized over approximately 12 years from the approval date. The estimated future amortization expense as of September 30, 2026 for the remaining periods in the next five years and thereafter is as follows:

| Years Ending December 31 | (in thousands) |
|---|---|
| 2026 (remaining) | $ 209 |
| 2027 | 833 |
| 2028 | 833 |
| 2029 | 833 |
| 2030 | 833 |
| Thereafter | 6,251 |
| Total | $ 9,792 |

**5. ACCRUED LIABILITIES**

Accrued liabilities consisted of the following:

| | September 30, 2026 | December 31, 2025 |
|---|---|---|
| | (in thousands) | |
| Accrued compensation and related benefits | $ 22,262 | $ 19,657 |
| Accrued outsourced manufacturing | 10,993 | 15,987 |
| Accrued outsourced clinical and nonclinical studies | 10,556 | 8,595 |
| Other accrued liabilities | 7,320 | 2,809 |
| Accrued milestone payment | — | 10,000 |
| Accrued professional fees | 7,118 | 3,827 |
| Accrued interest payable | 1,701 | 385 |
| Operating lease liabilities, short-term | 806 | 753 |
| Total accrued liabilities | $ 60,756 | $ 62,013 |

**6. DEBT**

*Convertible Notes*

In May 2026, the Company completed a public offering of $250.0 million aggregate principal amount of its 1.75% convertible senior notes due 2032 (the "Notes"), including the exercise in full of the underwriters' option to purchase up to an additional $25.0 million aggregate principal amount of the Notes. The Notes were issued pursuant to, and are governed by, an indenture (the "Indenture"), dated as of May 11, 2026, between the Company and U.S. Bank Trust Company, National Association, as trustee.

The Notes are general, unsecured, senior obligations of the Company. The Notes will accrue interest payable semiannually in arrears on May 15 and November 15 of each year, beginning on November 15, 2026, at a rate equal to 1.75% per year. In addition, special interest will accrue on the Notes upon the occurrence of certain events relating to the Company's failure to file certain reports with the SEC as provided in the Indenture. The Notes will mature on May 15, 2032, unless earlier converted, redeemed or repurchased by the Company.

Noteholders may convert their Notes at their option only in the following circumstances: (1) during any calendar quarter (and only during such calendar quarter) commencing after the calendar quarter ending on September 30, 2026, if the last reported sale price per share of the Company's common stock, $0.01 par value per share, exceeds 130% of the conversion price for each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter; (2) during the five consecutive business days immediately after any 10 consecutive trading day period (such 10 consecutive trading day period, the "Measurement Period") in which the trading price per $1,000 principal amount of Notes for each trading day of the Measurement Period was less than 98% of the product of the last reported sale price per share of the common stock on such trading day and the conversion rate on such trading day; (3) upon the occurrence of certain corporate events or distributions on the common stock, as described in the Indenture; (4) if the Company calls such Notes for redemption; and (5) at any time from, and including, February 15, 2032 until the close of business on the scheduled trading day immediately before the maturity date. The Company will settle conversions by paying or delivering, as applicable, cash, shares of common stock or a combination of cash and shares of common stock, at the Company's election, based on the applicable conversion rate. The initial conversion rate is 40.5680 shares of common stock per $1,000 principal amount of Notes, which represents an initial conversion price of approximately $24.65 per share, and is subject to adjustment as described in the Indenture.

The Notes are not redeemable prior to May 20, 2030. On or after May 20, 2030, the Company may redeem the Notes for cash (subject to certain limitations set forth in the Indenture) if the last reported sale price per share of the common stock exceeds 130% of the conversion price on (i) each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the trading day immediately before the date the Company sends the related redemption notice; and (ii) the trading day immediately before the date the Company sends such notice. However, the Company may not redeem less than all of the outstanding Notes unless at least $75.0 million aggregate principal amount of Notes are outstanding and not called for redemption as of the time the Company sends the related redemption notice.

As of September 30, 2026, the Notes are classified as a long-term liability on the condensed consolidated balance sheets and presented net of unamortized debt discount and issuance costs of $7.5 million. The issuance costs are amortized to interest expense over the contractual term of the Notes. As of September 30, 2026, the effective interest rate of the Notes is 2.25%. The Company recorded interest expense of $1.4 million and $2.2 million during the three and nine months ended September 30, 2026, respectively.

The outstanding balance of the Notes as of September 30, 2026 consisted of the following (in thousands):

| | September 30, 2026 (in thousands) |
|---|---|
| Principal amount | $ 250,000 |
| Unamortized debt discount and issuance costs | (7,539) |
| Convertible notes, net | $ 242,461 |

As of September 30, 2026, the estimated fair value of the Notes was approximately $278.1 million. The fair value was determined based on the quoted price of the Notes in an inactive market on the last trading day of the reporting period and has been classified as Level 2 in the fair value hierarchy.

*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 Borrower with access to a term loan with an aggregate principal amount of up to $75.0 million, in four tranches, including an initial tranche of $25.0 million. Upon signing the Hercules Loan and Security Agreement, the Borrower drew an initial principal amount of $5.0 million. The Borrower was originally obligated to make interest-only payments through April 1, 2024, which was extended to October 1, 2024 upon the achievement of a development milestone in August 2022.

In August 2023, the Borrower executed the first amendment to the Hercules Loan and Security Agreement (the "Hercules First Amendment"). The Hercules First Amendment was determined to substantially alter the Hercules Loan and Security Agreement and therefore was accounted for as a debt extinguishment. Under the Hercules First Amendment, the maturity date was extended to October 1, 2026 and the Lenders provided the Borrower access to an increased term loan with an aggregate principal amount of up to $150.0 million, in four tranches, consisting of (i) an initial tranche of $50.0 million, $25.0 million of which was available through December 15, 2023 and $25.0 million of which was available from July 1, 2024 through December 15, 2024; (ii) a second tranche of $20.0 million, subject to achievement of certain regulatory milestones, which was available through February 15, 2025; (iii) a third tranche of $20.0 million, subject to achievement of certain regulatory milestones, which was available through March 31, 2025; and (iv) a fourth tranche of $60.0 million subject to approval by the Lenders' investment committee(s), which was available through June 15, 2025. Upon execution of the Hercules First Amendment, the Borrower drew an additional principal amount of $15.0 million, increasing the cumulative amount drawn to $20.0 million. The obligations of the Borrower under the Hercules First Amendment agreement were secured by substantially all of the assets of the Borrower, excluding the Borrower's intellectual property.

In October 2025, the Borrower executed a second amendment (the "Hercules Second Amendment") to the Hercules Loan and Security Agreement. Under the Hercules Second Amendment, the term loan facility was amended to extend the maturity date to October 1, 2030 and provide an aggregate principal amount of up to $300.0 million available upon achievement of certain milestones. The obligations of the Borrower under the Hercules Second Amendment were secured by substantially all of the assets of the Borrower. The Borrower did not draw any amounts under the Hercules Facility other than the $50.0 million described above prior to its termination in May 2026, as described below.

In May 2026, using proceeds received from the issuance of the Notes described above, the Company and Hercules entered into a payoff letter for a voluntary prepayment with respect to the Hercules Loan and Security Agreement (the "Payoff Letter"). Pursuant to the Payoff Letter, the Company paid a total of $55.1 million (the "Payoff Amount") to Hercules, representing the outstanding principal, accrued and unpaid interest, fees, costs and expenses due to Hercules under the Hercules Loan and Security Agreement and related loan documents (collectively, the "Hercules Facility"), in repayment of the Company's outstanding obligations and thereby terminated the Hercules Facility. The Company recorded a loss on extinguishment of debt of $4.1 million under "Interest expense" in the Condensed Consolidated Statements of Operations and Comprehensive Loss for the nine months ended September 30, 2026 related to the write-off of the remaining balance of unamortized debt discount. Upon receipt by Hercules of the Payoff Amount on May 27, 2026, all obligations, covenants, debts and liabilities of the Company under the Hercules Facility were satisfied and discharged in full, and the Hercules Facility was terminated.

**7. PURCHASE AND SALE OF THE REVENUE PARTICIPATION RIGHT**

***Liability Related to the Sale of Future Revenue***

In October 2025, the Company and DRI Healthcare Acquisitions LP ("DRI") entered into a Purchase and Sale Agreement of revenue participation right (the "DRI Purchase and Sale Agreement"), pursuant to which DRI purchased rights to certain revenue streams in the U.S. from the Company in exchange for up to $300.0 million in consideration, including $55.0 million paid at signing and conditional payments consisting of: (i) $25.0 million that is payable following the achievement of certain milestones with respect to the Company's elegrobart pivotal phase 3 clinical trials, REVEAL-1 and REVEAL-2, on or before a specified date; (ii) $75.0 million that is payable following receipt of marketing approval for veligrotug from the FDA on or

before a specified date; (iii) $15.0 million that is payable if the events set forth in the foregoing clauses (i) and (ii) are met; (iv) $50.0 million that is payable following receipt of marketing approval for elegrobart from the FDA on or before a specified date; (v) at the Company's election, $50.0 million that is payable following the Company's achievement of net sales of certain products equal to or exceeding $1.1 billion on or before a specified date; and (vi) an additional $30.0 million that may be payable to the Company at a time and pursuant to financial terms agreed upon by the Company and DRI at such time.

The DRI Purchase and Sale Agreement contains customary representations, warranties and indemnities of the Company and DRI and customary covenants on the part of the Company, as well as a limit on the amount of incurrence of certain types of indebtedness, which limit automatically terminates a certain period of time following receipt of marketing approval for veligrotug in the U.S. The DRI Purchase and Sale Agreement requires the Company to pay tiered royalties to DRI based on net sales of veligrotug, elegrobart and certain other related products (the "Net Sales Royalties"). The royalties consist of (i) 7.5% of annual U.S. net sales up to and including $600 million, which royalties could increase to low-double digits if marketing approval for elegrobart is not received prior to a specified date, (ii) 0.8% of annual U.S. net sales above $600 million and up to and including $900 million, (iii) 0.25% of annual U.S. net sales above $900 million and up to $2 billion, and (iv) no royalty owed for annual U.S. net sales in excess of $2 billion. The DRI Purchase and Sale Agreement may only be terminated upon repayment by the Company of a certain multiplier of the consideration paid to the Company by DRI (less payments by the Company to DRI to date) on or prior to a certain date or repayment by an acquirer of the Company of a certain multiplier of the consideration paid by DRI to the Company, less payments by the Company to DRI to date, following a change of control of the Company.

The Company determined that the DRI Purchase and Sale Agreement is considered a sale of future revenues and is treated as a financing liability according to ASC 470, *Debt*, based on the specific facts and circumstances including the Company's significant continuing involvement in the generation of the cash flows due to DRI. The sale of future revenue liability is accounted for as debt and is recorded at cost. After initial recognition of the debt instrument, the Company will use the effective interest method to account for the amount recorded as debt on its balance sheet. The effective interest rate is the rate that equates the present value of the estimated future cash flows with the carrying amount of the liability related to the sale of future revenue. The estimate of future cash flows includes estimated future Net Sales Royalties to be paid to DRI and the receipt of conditional payments from DRI that were deemed probable of achievement at inception. The interest rate on this financing liability may vary during the term of the agreement depending on a number of factors, including the Company's net sales forecast and the probability of achieving certain milestones. The Company evaluates the interest rate used to amortize the liability related to the sale of future revenue quarterly based on its expectations of future net sales and current market conditions using the prospective method. A significant increase or decrease in actual or forecasted net sales or changes in expected achievement of certain milestones may materially impact the liability, interest expense, and the time period for repayment. The conditional payments represent loan commitments that are not treated as freestanding financial instruments and qualify for the derivative scope exception under ASC 815, *Derivatives and Hedging*, and therefore have not been bifurcated and accounted for separately.

Upon receipt of the $55.0 million payment from DRI at the close of the DRI Purchase and Sale Agreement, the Company recorded a liability related to the sale of future revenue of $32.4 million, net of the proportionate debt issuance costs allocated to it and the initial fair value of the bifurcated derivative liability. Following the FDA approval of veligrotug in June 2026, the Company received a $75.0 million milestone payment pursuant to the DRI Purchase and Sale Agreement. The Company accrued $8.0 million and $12.4 million in interest expense during the three and nine months ended September 30, 2026, including Net Sales Royalties of $1.9 million for both the three and nine months ended September 30, 2026. As of September 30, 2026, the net carrying amount of the liability related to the sale of future revenue was $121.6 million. The imputed effective annual interest rate for the liability related to the sale of future revenue was 27.1% as of September 30, 2026. During the first quarter of 2026, the Company did not achieve certain milestones with respect to the Company's elegrobart pivotal phase 3 clinical trials and therefore is not eligible to receive the $25.0 million conditional milestone payment or the additional $15.0 million conditional milestone payment.

The following table summarizes the activity of the liability related to the sale of future revenue for the nine months ended September 30, 2026 (in thousands):

| | | |
|---|---|---|
| Carrying value as of December 31, 2025 | $ | 34,244 |
| Milestone achieved | | 75,000 |
| Interest expense | | 12,364 |
| Carrying value as of September 30, 2026 | $ | 121,608 |

*Derivative Liability*

In the event of a change of control of the Company at, or prior to, January 1, 2035, the DRI Purchase and Sale Agreement provides the Company an option to repurchase, and DRI an option to require the Company to repurchase, the revenue participation right from DRI (the "Put/Call Option"). Upon exercise of the Put/Call Option by the Company or DRI, the DRI Purchase and Sale Agreement will terminate, and the Company will become obligated to pay the applicable multiplier of the consideration paid to the Company by DRI to date, less the payments of Net Sales Royalties paid to DRI by the Company to date.

The Put/Call Option is an embedded derivative pursuant to ASC 815, *Derivatives and Hedging*, that must be bifurcated and measured at fair value initially and at each subsequent reporting period. The Company estimated the fair value of the derivative liability using a "with-and-without" method, which involves determining the fair value of the entire financial liability instrument, inclusive of all terms, features, and conditions, and separately determining the fair value of the financial liability instrument excluding the derivative. The difference between the fair value of the entire financial liability instrument including the derivative and the fair value of the financial liability instrument excluding the derivative represents the fair value of the derivative liability.

The estimated probability and timing of a change in control event that triggers the exercisability of the Put/Call Option, the estimated cash flows and the discount rate used are Level 3 significant unobservable inputs used to determine the fair value of the derivative liability. Management concluded the probability of exercise of the Put/Call Option to be remote. The estimated market yield used to measure the fair value of the derivative was 15.8% and 11.5% as of September 30, 2026 and December 31, 2025, respectively. The initial fair value allocated to the derivative liability as of the close of the DRI Purchase and Sale Agreement was $19.3 million. Issuance costs of $1.8 million allocated to the derivative were recorded to expense as a component of other expense, net in the consolidated statements of operations and comprehensive loss. The derivative liability is subsequently remeasured at fair value each reporting period, with changes in fair value being recorded as a component of other expense, net in the consolidated statements of operations and comprehensive loss. As of September 30, 2026, the fair value of the derivative liability was $11.6 million resulting in recognition of a decrease in fair value of $8.4 million during the nine months ended September 30, 2026.

The following table presents the activity of the derivative liability for the nine months ended September 30, 2026 (in thousands):

| | | |
|---|---|---|
| Carrying value as of December 31, 2025 | $ | 20,030 |
| Change in fair value | | (8,410) |
| Carrying value as of September 30, 2026 | $ | 11,620 |

**8. COLLABORATION AND LICENSE AGREEMENTS**

***License Agreement with Zenas BioPharma, Inc.***

In October 2020, the Company entered into a license agreement with Zenas BioPharma (Cayman) Limited (now Zenas BioPharma, Inc., its successor in interest, "Zenas BioPharma") to license technology comprising certain materials, patent rights, and know-how to Zenas BioPharma. Subsequently, the Company entered into several letter agreements to assist Zenas BioPharma with its development activities and a manufacturing development and supply agreement to manufacture and supply, or to have manufactured and supplied, clinical drug product for Zenas BioPharma's development activities. These agreements (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

throughout the royalty term. The royalty percentage may vary based on different tiers of annual net sales of the licensed products made.

While the Zenas Agreements are in the scope of ASC 808, *Collaborative Arrangements,* the Company applied ASC 606, *Revenue from Contracts with Customers*, to account for certain activities related to 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 when the related sales occur or when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

In January 2025, Zenas BioPharma sublicensed their rights under the license agreement to Zai Lab (Hong Kong) Limited ("Zai Lab") and assigned to them the manufacturing development and supply agreement.

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

Prior to May 2026, the Zenas Agreements were considered related party transactions because Fairmount Funds Management LLC ("Fairmount") beneficially owned more than 5% of the Company's capital stock and a member of Fairmount had a seat on Zenas BioPharma's board of directors. The Side Agreement and MTA with Zai Lab were also considered related party transactions of the Company because Zenas BioPharma determined Zai Lab is its related party. In May 2026, the Fairmount affiliated member ceased serving on Zenas BioPharma's board of directors and Fairmount's beneficial ownership interest in Zenas BioPharma declined below 5%. Accordingly, Zenas BioPharma and Zai Lab were no longer considered related parties beginning in May 2026.

During the nine months ended September 30, 2026, the Company recognized $0.2 million of related party collaboration revenue related to the Zenas Agreements, Side Agreement and MTA. During the three months ended September 30, 2026, the Company did not recognize any related party collaboration revenue related to the Zenas Agreements, Side Agreement and MTA. During the three and nine months ended September 30, 2025, the Company recognized $0.6 million and $0.7 million, respectively, of collaboration revenue related to the Zenas Agreements, Side Agreement and MTA.

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

In January 2022, the Company and Paragon Therapeutics, Inc. ("Paragon") entered into an antibody and discovery option agreement (the "Paragon Research Agreement") under which the Company and Paragon will cooperate to develop one or more proteins or antibodies. Under the terms of the Paragon Research Agreement, Paragon will perform certain development activities in accordance with an agreed upon research plan, and the Company will pay Paragon agreed upon development fees in exchange for Paragon's commitment of the necessary personnel and resources to perform these activities. The Paragon Research Agreement stipulates a final deliverable to the Company consisting 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 for 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 October 2023, the Company entered into a License Agreement with Paragon (the "Paragon License Agreement") as a result of exercising its Option under the Paragon Research Agreement to obtain exclusive licenses to develop, manufacture and commercialize certain antibodies, proteins and associated products.

In September 2024, the Company entered into the Amended and Restated License Agreement with Paragon (the "Amended Paragon License Agreement") which amended and restated the Paragon License Agreement. In consideration for rights granted by Paragon, the Company is obligated to make certain future milestone payments of up to $16.0 million on a program-by-program basis upon the achievement of specified clinical and regulatory milestones, with total milestone payments under all programs not to exceed $40.0 million. Additionally, if the Company develops a product utilizing certain intellectual property rights granted to it under the Amended Paragon License Agreement, the Company is obligated to pay Paragon potential additional future development milestone payments of up to $3.1 million and commercial milestone payments of up to $17.0 million with respect to such product. If the Company successfully commercializes any product candidate subject to the Amended Paragon License Agreement, it is responsible for royalty payments equal to a percentage in the mid-single digits of such product's net sales.

During the nine months ended September 30, 2026, the Company recorded $1.5 million in research and development costs related to the Paragon Research Agreement and Amended Paragon License Agreement (collectively, the "Paragon Agreements"). During the three months ended September 30, 2026, the Company did not record any research and development costs related to the Paragon Agreements. During the nine months ended September 30, 2025, the Company recorded $4.5 million in research and development costs related to the Paragon Agreements. During the three months ended September 30, 2025, the Company did not record any research and development costs related to the Paragon Agreements.

The Paragon Agreements are considered related party transactions because Fairmount beneficially owns more than 5% of the Company's capital stock and beneficially owns more than 5% of Paragon's capital stock, which is a joint venture between Fairmount and FairJourney Biologics, has appointed the sole director on Paragon's board of directors and has the contractual right to approve the appointment of any executive officers.

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

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

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

The term of the Kissei Agreement will continue until expiration of the last to expire payment obligations, unless terminated earlier. Kissei has the right to terminate the Kissei Agreement for convenience with written notice of certain periods. The

Company may terminate the Kissei Agreement under certain conditions. In addition, either party may terminate the Kissei Agreement for the other party's material breach or insolvency.

The Company evaluated the Kissei Agreement in accordance with ASC 606, *Revenue from Contracts with Customers*, and concluded that the contract counterparty, Kissei, is a customer. The Company evaluated the promised goods and services within the Kissei Agreement and determined which goods and services were separate performance obligations. The Company determined the Kissei Agreement had two performance obligations: granting the exclusive licenses to develop and commercialize veligrotug and granting the exclusive license to develop and commercialize elegrobart. The performance obligations were satisfied concurrently at a point in time upon the granting of the license rights at contract inception.

At the inception of the arrangement, the Company evaluated whether the milestones were considered probable of being reached and estimated the amount to be included in the transaction price using the most likely amount method. As it was not probable that a significant revenue reversal would not occur, none of the associated milestone payments were included in the transaction price at contract inception. For the sales-based royalties included in the arrangement, the license was deemed to be the predominant item to which the royalties relate. The Company will recognize royalty revenues at the later of when the related sales occur or when the performance obligation to which some or all of the royalty has been allocated has been satisfied. Under the Kissei Agreement, the Company may manufacture and provide clinical supply to Kissei to use in development and commercialization in the licensed territory for consideration, as defined within the Kissei Agreement. Certain of these provisions were determined to be options to acquire additional goods or services at a price that approximates the stand-alone selling price for that good or service and therefore do not represent material rights, or separate performance obligations, within the context of the Kissei Agreement.

***License Agreement with ImmunoGen, Inc.***

In October 2020, the Company entered into a license agreement (the "ImmunoGen License Agreement") with ImmunoGen, under which the Company obtained an exclusive, sublicensable, worldwide license to certain patents and other intellectual property rights to develop, manufacture, and commercialize certain products for non-oncology and non-radiopharmaceutical indications. In consideration for rights granted by ImmunoGen, the Company is obligated to make certain future development milestone payments of up to $48.0 million upon the achievement of specified clinical and regulatory milestones. Additionally, if the Company successfully commercializes any product candidate subject to the ImmunoGen License Agreement, it is responsible for royalty payments equal to a percentage in the mid-single digits of net sales and commercial milestone payments of up to $95.0 million. The Company is obligated to make any such royalty payments on a product-by-product and country-by-country basis from the first commercial sale of a specified product in each country until the later of (i) the expiration of the last patent claim subject to the ImmunoGen License Agreement in such country, (ii) the expiration of any applicable regulatory exclusivity obtained for each product in such country, or (iii) the 12th anniversary of the date of the first commercial sale of such product in such country. On February 12, 2024, AbbVie Inc. acquired ImmunoGen. The terms of the ImmunoGen License Agreement did not change as a result of this acquisition. For the nine months ended September 30, 2026, a $10.0 million milestone for FDA approval of veligrotug in June 2026 was achieved under the ImmunoGen License Agreement. For the three months ended September 30, 2026 there were no milestone events pursuant to the ImmunoGen License Agreement. Additionally, for both the three and nine months ended September 30, 2025, there were no milestone events pursuant to the ImmunoGen License Agreement. The Company expensed $1.3 million of royalties to ImmunoGen, as cost of revenues, for both the three and nine months ended September 30, 2026.

***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 to the Company an exclusive, royalty-bearing, sublicensable, non-transferable license to develop, commercialize, seek marketing approval for and otherwise use and exploit certain products and make and have made such product solely for such permitted uses. Pursuant to the terms of the Enable License Agreement, the Company granted Enable a non-exclusive, royalty-free, non-sublicensable, non-transferable license. In January 2023, 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 February 2026, the Company and Enable amended the Enable License Agreement to include a second product for additional consideration.

The Company is obligated to make certain future milestone payments of up to $49.0 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. For both the three and nine months ended September 30, 2026, a $5.0 million milestone was met under the Enable License Agreement. Additionally, for both the three and nine months ended September 30, 2025, there were no milestones met pursuant to the Enable License Agreement.

**9. COMMITMENTS AND CONTINGENCIES**

***Manufacturing Agreement***

In May 2026, the Company entered into a commercial manufacturing services agreement with WuXi Biologics (Hong Kong) Limited ("WuXi"), for the non-exclusive commercial manufacture of the Company's veligrotug drug substance and drug product (the "WuXi Commercial Supply Agreement"). The WuXi Commercial Supply Agreement has an initial five-year term and automatically renews for successive five-year periods unless either party provides written notice of non-renewal at least two years prior to the expiration of the then-current term.

Under the WuXi Commercial Supply Agreement, each month the Company is required to provide WuXi with a rolling forecast schedule detailing batch volume requirements for veligrotug drug substance and drug product. The volume requirements are binding for a period of twelve months with respect to drug substance and nine months with respect to drug product. In addition to service fees, the Company is required to pay variable pass-through costs based on costs incurred by WuXi to procure materials in connection with the manufacturing services. As of September 30, 2026, the Company had outstanding non-cancelable purchase commitments of approximately $26.9 million under the agreement.

***Indemnification Agreements***

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to its vendors, lessors, contract research organizations ("CROs"), business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. The Company has not incurred any material costs as a result of such indemnifications and is not currently aware of any indemnification claims.

***Legal Proceedings***

The Company, from time to time, may be party to litigation arising in the ordinary course of business. The Company was not subject to any material legal proceedings during the three months ended September 30, 2026 and, to the best of its knowledge, no material legal proceedings are currently pending or threatened.

***Payments Upon Termination***

The Company enters into contracts in the normal course of business with CROs, contract development and manufacturing organizations ("CDMOs") and other third parties for preclinical studies, clinical trials and manufacturing services. These contracts typically do not contain minimum purchase commitments and are generally cancelable by the Company upon written notice. Payments due upon cancellation consist of payments for services provided or expenses incurred, including noncancelable obligations of the Company's service providers, up to the date of cancellation and, in the case of certain arrangements with CROs and CDMOs, may include noncancelable fees. Under such agreements, the exact amounts owed by the Company in the event of termination will be based on the timing of the termination and the exact terms of the agreement. As of September 30, 2026, the Company has not recognized any amounts related to these contingencies as the amount and timing of such payments are not fixed and estimable.

**10. CAPITAL STOCK**

***Public Offering***

In May 2026, the Company entered into an underwriting agreement with Jefferies LLC ("Jefferies"), Leerink Partners LLC and Goldman Sachs & Co. LLC, relating to the offer and sale of 8,455,883 shares of the Company's common stock, which included 1,102,941 shares of common stock issued in connection with the exercise in full by the underwriters of their option to purchase additional shares at a public offering price of $17.00 per share. The aggregate gross proceeds to the Company were approximately $143.8 million, before deducting underwriting discounts and commissions and other offering expenses payable by the Company.

***ATM Agreement***

In March 2025, the Company entered into an Open Market Sale Agreement℠ (the "March 2025 ATM Agreement") with Jefferies, pursuant to which the Company may offer and sell shares of its common stock having an aggregate offering price of up to $300.0 million from time to time at prices and on terms to be determined by market conditions at the time of offering, with Jefferies acting as its sales agent. Jefferies will receive a commission of up to 3.0% of the gross proceeds of any shares of common stock sold under the March 2025 ATM Agreement. No shares were sold under the March 2025 ATM Agreement during the three and nine months ended September 30, 2026.

**11. SHARE-BASED COMPENSATION**

***Equity Incentive Plans***

The Company has grants outstanding under its amended and restated 2016 Equity Incentive Plan (the "2016 Plan") and its 2020 Equity Incentive Plan (the "2020 Plan" and collectively with the 2016 Plan, the "Equity Incentive Plans"). Additionally, beginning in July 2021, the Company granted stock options and restricted stock units ("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. The 2016 Plan will terminate in April 2035.

As of September 30, 2026, the Company had the following balances by plan:

| | Restricted Stock Units Outstanding | Stock Options Outstanding | Shares Available for Issuance |
|---|---|---|---|
| Inducement Awards | — | 7,109,647 | — |
| 2020 Plan | — | 40,459 | — |
| 2016 Plan | 1,859,298 | 9,365,938 | 6,420,651 |
| Total | 1,859,298 | 16,516,044 | 6,420,651 |

***Restricted Stock Units***

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

A summary of RSU activity is as follows:

| | RSUs | Weighted-Average Grant Date Fair Value Per Share |
|---|---|---|
| Outstanding at December 31, 2025 | 1,064,375 | $15.51 |
| Granted | 1,107,600 | $26.88 |
| Vested | (234,928) | $16.40 |
| Forfeited | (77,749) | $19.48 |
| Outstanding at September 30, 2026 | 1,859,298 | $22.00 |

***Stock Options***

Options granted under the Equity Incentive Plans and the Inducement Awards have an exercise price equal to the market value of the common stock at the date of grant and expire 10 years from the date of grant. Options generally vest 25% on the first anniversary of the vesting commencement date and 75% ratably in equal monthly installments over the remaining 36 months or in equal monthly or quarterly amounts over periods of up to 48 months.

A summary of common stock option activity is as follows:

| | Number of Options | Weighted-Average Exercise Price Per Share | Weighted-Average Remaining Contractual Term (years) | Aggregate Intrinsic Value (in thousands) |
|---|---|---|---|---|
| Outstanding as of December 31, 2025 | 14,468,627 | $16.82 | 8.4 | $ 209,090 |
| Granted | 3,617,196 | $28.28 | | |
| Exercised | (726,298) | $14.54 | | |
| Forfeited | (594,181) | $18.85 | | |
| Expired | (249,300) | $31.40 | | |
| Outstanding as of September 30, 2026 | 16,516,044 | $19.14 | 8.1 | $ 65,158 |
| Exercisable as of September 30, 2026 | 7,321,726 | $17.49 | 7.4 | $ 33,955 |

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the common stock as of the end of the period.

The aggregate intrinsic value of stock options exercised during the nine months ended September 30, 2026 and 2025 was $8.9 million and $1.3 million, respectively. The total fair value of options vested during the nine months ended September 30, 2026 and 2025 was $39.5 million and $31.1 million, respectively. The tax benefit from the exercise of options eligible for a tax deduction realized during the nine months ended September 30, 2026 and 2025 was $1.7 million and $0.3 million, respectively.

***Fair Value Assumptions***

The Company uses the Black-Scholes option pricing model to estimate the fair value of stock options granted under its equity compensation plans. The Black-Scholes model requires inputs for risk-free interest rate, dividend yield, volatility, and expected terms of the options. Because the Company has a limited history of stock purchase and sale activity, expected volatility is based on a blend of historical data from public companies that are similar to the Company in size and nature of operations, as well as the Company's own volatility. The Company will continue to use similar entity volatility information until its historical volatility is relevant to measure expected volatility for option grants. The Company accounts for forfeitures as they occur. The risk-free rate for periods within the contractual life of each option is based on the U.S. Treasury yield curve in effect at the time of the grant for a period commensurate with the expected term of the grant. The expected term (without regard to forfeitures) for options granted represents the period of time that options granted are expected to be outstanding and is derived from the contractual terms of the options granted, and actual and expected option-exercise behaviors. The fair value of the underlying common stock is based on the closing price of the common stock on The Nasdaq Capital Market at the date of grant.

The weighted-average grant-date fair value of options granted during the nine months ended September 30, 2026 and 2025 was $16.77 and $10.43, respectively. The fair value was determined by the Black-Scholes option pricing model using the following weighted-average assumptions:

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2026 | 2025 |
| Expected term (in years) | 4.97 | 5.00 |
| Expected volatility | 68.2% | 84.0% |
| Risk-free interest rate | 3.7% | 4.0% |
| Expected dividend yield | —% | —% |
| Weighted average exercise price | $28.28 | $15.22 |

***Employee Stock Purchase Plan***

In June 2025, the Company's stockholders approved the 2025 Employee Stock Purchase Plan ("2025 ESPP"). The 2025 ESPP allows qualified employees to purchase shares of common stock at a price equal to 85% of the lower of: (i) the closing price on the first day of the offering period or (ii) the closing price on the purchase date. As of September 30, 2026, the Company had 1,907,158 shares available for issuance. There were 92,842 shares issued during the nine months ended September 30, 2026. During the three and nine months ended September 30, 2026, the Company recognized $0.1 million and $0.5 million, respectively, in related share-based compensation expense.

***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 2025 ESPP for the purchase periods active during each respective period is included in the unaudited condensed consolidated statements of operations and comprehensive loss as follows:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 | 2025 |
| | (in thousands) | | (in thousands) | |
| Research and development | $ 7,416 | $ 5,107 | $ 20,586 | $ 16,029 |
| Selling, general and administrative | 9,816 | 6,143 | 27,020 | 16,285 |
| Total share-based compensation expense | $ 17,232 | $ 11,250 | $ 47,606 | $ 32,314 |

As of September 30, 2026, the Company had $115.0 million of total unrecognized share-based compensation costs related to stock options, which the Company expects to recognize over a weighted-average remaining period of 2.67 years. As of September 30, 2026, the Company had $33.9 million of total unrecognized share-based compensation costs related to unvested RSUs, which the Company expects to recognize over a weighted-average remaining period of 3.15 years.

**12. NET LOSS PER SHARE**

The Company computes net loss per share of common stock, Series A convertible preferred stock, and Series B convertible preferred stock using the two-class method required for multiple classes of common stock and other participating securities. The two-class method is an earnings (loss) allocation method under which earnings (loss) per share is calculated for each class of common stock. The Company has determined that the Series A convertible preferred stock and Series B convertible preferred stock do not have preferential rights when compared to the Company's common stock and therefore it must allocate losses to these other classes of stock, as illustrated in the table below.

Basic and diluted net loss per share is computed by dividing the allocated net loss to each share class by the weighted-average number of shares outstanding during the period. For periods in which the Company generated a net loss, the Company does not include potential shares of common stock in diluted net loss per share when the impact of these items is anti-dilutive. The Company has generated a net loss for all periods presented, therefore diluted net loss per share is the same as basic net loss per share since the inclusion of potential shares of common stock would be anti-dilutive.

The following table sets forth the computation of basic and diluted net loss per share of common stock, Series A convertible preferred stock, and Series B convertible preferred stock (in thousands, except share and per share amounts):

| | Three Months Ended September 30, 2026 | | | Nine Months Ended September 30, 2026 | | |
|---|---|---|---|---|---|---|
| | Series A Convertible Preferred Stock | Series B Convertible Preferred Stock | Common Stock | Series A Convertible Preferred Stock | Series B Convertible Preferred Stock | Common Stock |
| Numerator | | | | | | |
| Allocation of net loss | $ (7,160) | $ (2,605) | $ (91,444) | $ (24,605) | $ (12,096) | $ (296,528) |
| Denominator | | | | | | |
| Weighted-average shares outstanding | 133,191 | 48,463 | 113,407,432 | 134,263 | 66,004 | 107,875,408 |
| Net loss per share, basic and diluted | $ (53.76) | $ (53.76) | $ (0.81) | $ (183.26) | $ (183.26) | $ (2.75) |

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

There are no potentially dilutive securities to Series A convertible preferred stock or Series B convertible preferred stock. Potentially dilutive securities to the common stock include the following:

| | September 30, | |
|---|---|---|
| | 2026 | 2025 |
| Series A convertible preferred stock, as converted to shares of common stock | 8,879,843 | 8,991,383 |
| Series B convertible preferred stock, as converted to shares of common stock | 3,231,028 | 9,677,817 |
| Options to purchase common stock | 16,516,044 | 14,503,682 |
| Warrants to purchase common stock | 29,446 | 29,446 |
| Convertible notes, as converted to shares of common stock | 10,142,000 | — |
| Restricted stock units | 1,859,298 | 1,090,439 |
| Total | 40,657,659 | 34,292,767 |

**13. SEGMENT INFORMATION**

The Company manages its operations as one operating segment, focused on discovering, developing and commercializing potential best-in-class medicines for autoimmune and rare diseases. The Company's chief operating decision maker ("CODM") is its Chief Executive Officer. The CODM reviews and evaluates consolidated net loss for purposes of assessing performance, making operating decisions, allocating resources, and planning and forecasting for future periods. Operating expenses are used to monitor budget versus actual results. As the Company's operations comprise of a single reporting segment, the segment assets are reflected on the accompanying consolidated balance sheet as "total assets." All tangible assets are physically located within the United States. Segment asset information is not used by the CODM to allocate resources.

Significant segment expenses, as provided to the CODM, are presented below:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 | 2025 |
| | (in thousands) | | (in thousands) | |
| Product revenue, net | $ 24,671 | $ — | $ 24,671 | $ — |
| License revenue | 125 | 70,000 | 364 | 70,000 |
| Collaboration revenue | 956 | 570 | 1,142 | 717 |
| Total revenues | 25,752 | 70,570 | 26,177 | 70,717 |
| | | | | |
| Segment cost of revenues | 1,527 | — | 1,527 | — |
| Segment research and development expense | 62,606 | 81,106 | 198,539 | 233,544 |
| Segment selling, general and administrative expense | 47,729 | 18,117 | 124,046 | 45,165 |
| Total segment operating expenses | 111,862 | 99,223 | 324,112 | 278,709 |
| | | | | |
| Share-based compensation expense | 17,232 | 11,250 | 47,606 | 32,314 |
| Depreciation expense | 135 | 110 | 373 | 340 |
| Other income, net | 2,268 | 5,414 | 12,685 | 18,400 |
| Net loss | $ (101,209) | $ (34,599) | $ (333,229) | $ (222,246) |

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

*The following discussion and analysis should be read together with our unaudited condensed consolidated financial statements and the related notes thereto included in Part I, Item 1 of this Quarterly Report and our consolidated financial statements and related notes thereto for the year ended December 31, 2025 included in our 2025 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 "Cautionary Note Regarding Forward-Looking Statements" for a discussion of the uncertainties, risks, and assumptions associated with these statements. Actual results and the timing of events could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section entitled "Risk Factors" included elsewhere in this Quarterly Report.*

### Overview and Recent Developments

We are a biopharmaceutical company focused on discovering, developing, and commercializing potentially best-in-class medicines for autoimmune and rare diseases. We target therapeutic areas in which current treatments leave room for improvements in efficacy, safety, and/or dosing convenience. We believe there is significant potential in these areas for better medicines that address unmet needs, improve outcomes, and expand treatment options for patients. We aim to develop differentiated, potential best-in-class medicines that could lead to improved patient outcomes, reduced side effects, improved quality of life, and expanded market access.

Our portfolio targets validated pathways and disease-driving mechanisms in autoimmune and rare diseases. These include our FDA-approved medicine veligrotug and product candidate elegrobart, both directed at IGF-1R for the treatment of TED, our FcRn inhibitors with potential applications across multiple autoimmune disorders, and our TSHR inhibitor program with the potential to be developed for the treatment of TED and Graves' disease. We develop therapeutics through internal research and discovery, as well as through in-licensing opportunities that align with our strategic focus. Our capabilities span protein and antibody discovery and engineering, biologics manufacturing, nonclinical and clinical development, commercial planning, and commercialization in these therapeutic areas.

In June 2026, the FDA approved veligrotug for the treatment of TED under Priority Review. In preparation for the veligrotug launch, we built the infrastructure we believe is required to support a successful transition to a commercial organization. This includes establishing our capabilities in sales and marketing, market access, patient services, and commercial operations functions, and expanding our medical, clinical, regulatory, quality, and supply chain and distribution capabilities. Following approval, we launched veligrotug in the United States under the trade name Lumvoa with commercial launch efforts focused on reaching target prescribers, enabling reliable access for patients, supporting physician offices and infusion centers, and engaging effectively with payors.

Our strategy combines clear scientific, clinical, and commercial rationale with excellence in execution to rapidly discover, develop, and commercialize better medicines for patients. We rely on our scientific, clinical, and commercial expertise to identify opportunities to improve upon existing investigational or approved therapies and to apply these insights to designing, selecting, developing, and commercializing potential best-in-class product candidates. We bring potential improvements to critical areas such as molecular design, dose selection, pharmacokinetics, pharmacodynamics, clinical trial design, trial endpoints, and the selection and recruitment of patients. We believe this strategy enables efficient product development and reduces the risk when developing novel therapeutics.

#### *Development and Commercialization of IGF-1R Therapies to Treat Thyroid Eye Disease (TED)*

We are developing and commercializing therapies for the treatment of TED, a serious and debilitating rare autoimmune disease that causes inflammation within the orbit of the eye that can cause bulging of the eyes, redness and swelling, double vision, pain, and potential blindness. TED significantly impacts quality of life, imposing a high burden on activities of daily living and mental health for patients suffering from the disease. TED is a progressive disease consisting of an initial active phase ("active TED"), followed by a transition to a secondary chronic phase ("chronic TED").

In June 2026, the FDA approved veligrotug under Priority Review. Veligrotug provides a compelling new treatment option for TED in the U.S., in addition to the previously approved Tepezza® (teprotumumab), which is marketed in the United States by

Amgen Inc. (“Amgen”). As of September 30, 2026, more than 100 patients had started therapy with veligrotug in the United States.

The FDA approval of veligrotug was supported by our pivotal phase 3 clinical trials THRIVE and THRIVE-2, which evaluated veligrotug in active and chronic TED, respectively. Both the THRIVE and THRIVE-2 clinical trials met their respective primary and all secondary endpoints, consistently demonstrating statistically significant and clinically meaningful improvements at week 15 across all of the key signs and symptoms of TED. Across both clinical trials, patients received a 12-week course of veligrotug designed to reduce the burden of treatment. Veligrotug demonstrated a rapid onset of clinical benefit, with reductions in proptosis observed as early as three weeks. Veligrotug is the first approved product for TED to show a statistically significant effect in both diplopia response and complete resolution in active and chronic TED. In June 2026, the results from the THRIVE pivotal phase 3 clinical trial in active TED were published in *Ophthalmology*. In September 2026, we initiated an open-label clinical trial of veligrotug in participants with TED who previously responded to teprotumumab.

We have established commercial infrastructure to support the U.S. launch of veligrotug, including sales and marketing, market access, patient services, medical affairs, distribution, supply chain and commercial operations capabilities. Our launch priorities include driving awareness of veligrotug with key stakeholders, including core prescribers, payers, infusion centers, physician offices and patients, differentiating veligrotug through its clinical profile and treatment regimen, and supporting access through payer engagement and patient services. We also established ViridianCares™, a patient support program designed to support patients, physician offices, and infusion centers through the treatment journey for eligible patients.

We are also developing elegrobart, our subcutaneous anti-IGF-1R product candidate currently in pivotal clinical studies in TED, and designed to be administered via a simple autoinjector that patients can self-administer at home. In its phase 1 clinical study in healthy volunteers, elegrobart was shown to have a prolonged half-life of 40 to 50 days, which is four to five times that of veligrotug. Based on this data and the similarities between the veligrotug and elegrobart antibodies, we selected Q4W and Q8W dosing of elegrobart to advance to phase 3 pivotal studies. PK modeling showed Q4W and Q8W subcutaneous elegrobart dosing could achieve the range of modeled veligrotug exposures based on a two-infusion phase 2 TED study at 3 mg/kg and 10 mg/kg IV, once every three weeks. Both dosing regimens of veligrotug showed robust clinical activity. We are conducting a global pivotal program for elegrobart, including evaluating its efficacy and safety in two global well-controlled phase 3 clinical trials, REVEAL-1 and REVEAL-2, for the treatment of active and chronic TED, respectively. Both studies evaluated elegrobart administered subcutaneously every four weeks (“Q4W”) or every eight weeks (“Q8W”) and assessed outcomes versus placebo.

In March 2026, we announced topline data from the REVEAL-1 study, which enrolled 132 patients, randomized 1:1:1 to elegrobart Q4W (n=44), elegrobart Q8W (n=44), and placebo (n=44). REVEAL-1 met its primary endpoint of Q4W proptosis responder rate (“PRR”) with a highly statistically significant treatment effect. Subcutaneous elegrobart given Q4W and Q8W each achieved rapid reductions in proptosis and diplopia, and at the primary analysis at 24 weeks, showed clinically meaningful PRRs of 54% and 63%, respectively, versus 18% placebo. In addition, 51% of patients treated Q4W achieved a complete resolution of diplopia versus 16% placebo.

In May 2026, we announced topline data from the REVEAL-2 study, which enrolled 204 patients, randomized to elegrobart Q4W (n=70), elegrobart Q8W (n=68), and placebo (n=66). REVEAL-2 met its primary endpoint of Q4W PRR and key secondary endpoint of Q8W PRR, each with a highly statistically significant treatment effect. Subcutaneous elegrobart given Q4W and Q8W each achieved rapid reductions in proptosis and diplopia, and at the primary analysis at 24 weeks, showed clinically meaningful PRRs of 50% and 54%, respectively, versus 15% placebo. In addition, at 24 weeks, elegrobart given Q4W achieved a diplopia responder rate of 61% versus 38% placebo. We anticipate submitting a BLA for elegrobart in the first quarter of 2027.

In addition to REVEAL-1 and REVEAL-2, to enable BLA submission for elegrobart, we are conducting a safety study with elegrobart to meet the 300-patient safety database requirement (to also include patients from the REVEAL-1 and REVEAL-2 trials). We enrolled 321 patients in this safety study, exceeding the target enrollment of 284 patients due to demand, and achieved primary study completion in April 2026. Additionally, we conducted an autoinjector study to enable launching elegrobart in an autoinjector device, if approved. We enrolled 87 patients in the autoinjector study, exceeding the target enrollment of 75 patients, and completed the study in May 2026.

***Development of FcRn Inhibitors***

We are also developing a portfolio of engineered FcRn inhibitors, including VRDN-006 and VRDN-008. FcRn inhibitors have the potential to treat a broad array of autoimmune diseases, representing a possible significant commercial market opportunity. Our multi-pronged engineering approach has resulted in a portfolio of FcRn-targeting molecules that leverage the clinically and commercially validated mechanism of FcRn inhibition while potentially addressing the limitations of current agents such as incomplete immunoglobulin G ("IgG") suppression, safety, and inconvenience of dosing. We expect to communicate development plans for our portfolio of FcRn inhibitors in the fourth quarter of 2026.

VRDN-006 is a highly selective Fc fragment that inhibits FcRn and is designed to be a convenient subcutaneous and self-administered option for patients. In non-human primate ("NHP") studies, VRDN-006 demonstrated specificity for blocking FcRn-IgG interactions while not showing decreases in albumin or increases in low-density lipoprotein ("LDL") levels, which are known potential side effects associated with certain full-length anti-FcRn monoclonal antibodies. In our head-to-head NHP studies, VRDN-006 demonstrated comparable potency and IgG reductions to efgartigimod, which is the current standard of care in FcRn inhibition, as well as a similar safety profile. We submitted an IND for VRDN-006 in December 2024, which cleared in January 2025. In September 2025, we announced that data from an ongoing phase 1 clinical trial in healthy volunteers showed that VRDN-006 led to IgG reductions that are consistent with the FcRn inhibitor class, and that VRDN-006 was sparing of albumin and LDL and was generally well-tolerated with no dose-limiting toxicities or serious adverse events.

VRDN-008 is a half-life extended bispecific FcRn inhibitor comprising an Fc fragment and an albumin-binding domain designed to prolong IgG suppression and provide a potentially best-in-class subcutaneous option for patients. In a single, high-dose, head-to-head study in NHPs, VRDN-008 demonstrated three times the half-life of efgartigimod. Additionally, VRDN-008 showed a deeper and more sustained IgG reduction with peak IgG reductions that were 20% deeper than efgartigimod, and IgG levels returned to baseline 35 days after VRDN-008 dosing, more than twice as long as efgartigimod, which returned to baseline 14 days after dosing. VRDN-008 spared albumin and LDL, consistent with efgartigimod. We submitted an IND for VRDN-008 in December 2025 and received IND clearance from the FDA in January 2026. A phase 1 clinical trial assessing VRDN-008 in healthy volunteers is currently ongoing with data on track for the fourth quarter of 2026.

***Development of TSHR Inhibitors***

In January 2026, we announced that we are developing an anti-TSHR candidate with potential use in the treatment of Graves' disease and TED. This product candidate is a half-life extended monoclonal antibody designed to inhibit activation of TSHR. It is being developed for subcutaneous administration via autoinjector, with the goal of enabling extended dosing intervals intended to support patient convenience. We expect to initiate a phase 1 clinical trial of our anti-TSHR antibody, VRDN-292, starting in patients with Graves' disease in the fourth quarter of 2026. We believe inhibiting TSHR has the potential to treat both TED and Graves' disease. TED pathophysiology potentially stems from the activation of the TSHR and IGF-1R signaling complex on orbital fibroblasts, leading to hyaluronan secretion and expansion of orbital fat and muscle. Autoantibodies that stimulate TSHR can activate pathways that promote inflammation, fibroblast proliferation, and tissue remodeling relevant to TED. We believe inhibiting TSHR could complement the inhibition of IGF-1R in the treatment of TED. In addition to TED, we believe blocking TSHR could also be effective to treat Graves' disease. Graves' disease is an autoimmune disease in which autoantibodies form against TSHR, stimulating and activating the receptor. These TSH receptor antibodies can drive a heightened activation of TSHR, resulting in excessive thyroid hormone production and hyperthyroidism. Graves' disease is one of the most prevalent autoimmune conditions, affecting more than 2 million people in the United States, and is the leading cause of hyperthyroidism. Current treatments—including antithyroid drugs, radioactive iodine, and surgery—lower thyroid hormone levels but do not entirely address the underlying autoimmune drivers of the disease and are often associated with relapse or the development of permanent hypothyroidism. Blocking TSHR activation through a TSHR antagonist represents a differentiated therapeutic approach aimed at targeting disease-driving mechanisms in TED and in Graves' disease.

***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 United States' conflict with Iran, ongoing conflicts 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**

***Product Revenue, Net***

In June 2026, we received marketing approval from the FDA for veligrotug in the United States. Product revenue, net consists of product revenue earned on the sales of veligrotug in the United States. Product revenues are recognized net of variable consideration, including discounts and allowances, distributor fees, chargebacks, product returns and other incentives such as co-pay assistance programs.

***License and Collaboration Revenue***

Our license and collaboration 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 entered into a license agreement with Zenas BioPharma. Subsequently, we entered into several letter agreements to assist Zenas BioPharma with certain development activities, including manufacturing. Under the Zenas Agreements, we granted Zenas BioPharma an exclusive license to develop, manufacture, and commercialize certain IGF-1R directed antibody products for non-oncology indications in the greater area of China in exchange for upfront non-cash consideration and non-refundable milestone payments upon achieving specific milestone events during the contract term. In July 2022, Zenas BioPharma announced that it had obtained IND approval in China. 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 throughout the royalty term. The royalty percentage may vary based on different tiers of annual net sales of the licensed products made. In May 2022, we entered into a manufacturing development and supply agreement with Zenas BioPharma to manufacture and supply, or have manufactured and supplied, clinical drug product for development purposes. In January 2025, Zenas BioPharma sublicensed their rights under the license agreement to Zai Lab and assigned the manufacturing development and supply agreement to Zai Lab in connection with the sublicense transaction. In July 2025, we entered into a side agreement with Zai Lab (the "Side Agreement"), with Zenas BioPharma as countersigner, pursuant to which we agreed to provide certain services directly to Zai Lab to support development and commercialization activities. In August 2025, we entered into a material transfer agreement ("MTA") with Zai Lab, to supply certain materials for clinical trial use.

In July 2025, we entered into a Collaboration and License Agreement pursuant to which we granted to Kissei an exclusive license to develop and commercialize products containing veligrotug and elegrobart including for the treatment of TED, in Japan, and, under certain circumstances, a non-exclusive license to manufacture such licensed products worldwide for use in Japan. As consideration for the Kissei Agreement, the transaction price included an upfront cash payment of $70.0 million, which was recognized as revenue during the year ended December 31, 2025. Additionally, we are eligible to receive up to an additional $315.0 million of non-refundable milestone payments upon achieving specific milestone events during the contract term, as well as tiered royalty payments ranging from percentages in the twenties to the mid-thirties based on the annual net sales of any licensed products sold in Japan.

Prior to May 2026, the Zenas Agreements were considered related party transactions because Fairmount Funds Management LLC ("Fairmount") beneficially owned more than 5% of the Company's capital stock and a member of Fairmount had been appointed to Zenas BioPharma's board of directors. The Side Agreement and MTA with Zai Lab were also considered related party transactions of the Company because Zenas BioPharma determined Zai Lab is its related party. In May 2026, the Fairmount affiliated member ceased serving on Zenas BioPharma's board of directors and Fairmount's beneficial ownership interest in Zenas BioPharma declined below 5%. Accordingly, Zenas BioPharma and Zai Lab were no longer considered related parties beginning in May 2026.

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

***Cost of Revenues***

Cost of revenues includes costs associated with veligrotug product sales, including manufacturing materials, third-party manufacturing costs, labor and overhead, amortization of milestone-related intangible assets, and ImmunoGen royalty obligations. Veligrotug manufacturing costs include manufacturing materials, third-party manufacturing costs, packaging costs, tariffs, and shipping costs.

***Research and Development Expenses***

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

- employee-related expenses, including salaries, severance, retention, benefits, insurance, and share-based compensation expense;
- expenses incurred under agreements with CROs, investigative sites that conduct our clinical trials, and other clinical trial-related vendors, and consultants;
- the costs of acquiring, developing, and manufacturing and testing pre-commercial and nonclinical materials, including costs incurred under agreements with CDMOs;
- costs associated with nonclinical activities and regulatory operations;
- license fees and milestone payments related to the acquisition and retention of certain licensed technology and intellectual property rights; and
- facilities, depreciation, market research, and other expenses, which include allocated expenses for rent and maintenance of facilities, depreciation of leasehold improvements and equipment, and laboratory supplies.

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

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

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

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

***Selling, General and Administrative Expenses***

Selling, general and administrative expenses consist primarily of salaries and related benefits, including share-based compensation, and severance and retention benefits related to our executive, commercial, finance, 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 required to prepare for and to support 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, interest expense and various items of a non-recurring nature. We earn interest income from interest-bearing accounts, money market funds, and marketable securities. Interest expense consists of cash and non-cash interest expense related to the DRI Purchase and Sale Agreement, the Notes, and the Hercules Loan and Security Agreement.

**Critical Accounting Policies and Estimates**

Our management's discussion and analysis of financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions.

Except as described below, there have been no significant changes in our critical accounting policies and estimates as compared to the critical accounting policies and estimates disclosed in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K filed with the SEC on February 26, 2026. Following the FDA's approval of veligrotug in June 2026, we adopted accounting policies for product revenue, net, including estimates of variable consideration for rebates, chargebacks, returns and other incentives, as well as for inventory and for the capitalization and amortization of the milestone-related intangible asset. See Note 2, Summary of Significant Accounting Policies, to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report for additional information.

**Results of Operations**

**Comparison of the Three Months Ended September 30, 2026 and 2025**

| | Three Months Ended September 30, | | |
|---|---|---|---|
| | 2026 | 2025 | Change |
| | (in thousands) | | |
| Product revenue, net | $ 24,671 | $ — | $ 24,671 |
| License revenue | 125 | 70,000 | (69,875) |
| Collaboration revenue | 956 | 570 | 386 |
| Cost of revenues | $ (1,527) | $ — | (1,527) |
| Research and development expenses | (70,093) | (86,261) | 16,168 |
| Selling, general and administrative expenses | (57,609) | (24,322) | (33,287) |
| Other income, net | 2,268 | 5,414 | (3,146) |
| Net loss | $ (101,209) | $ (34,599) | $ (66,610) |

***Product Revenue, Net***

Product revenue, net was $24.7 million for the three months ended September 30, 2026. There was no product revenue, net for the three months ended September 30, 2025. The $24.7 million increase is the result of product sales in the third quarter of 2026 following the launch of veligrotug.

***License Revenue***

License revenue for the three months ended September 30, 2026 was attributable to services provided under the collaboration and license agreement with Kissei. License revenue for the three months ended September 30, 2025 was attributable to a one-time, non-refundable and non-creditable upfront cash payment of $70.0 million, under the collaboration and license agreement with Kissei.

***Collaboration Revenue***

Collaboration revenue for both the three months ended September 30, 2026 and 2025 was attributable to our collaboration agreement with Zenas BioPharma and the Side Agreement and MTA with Zai Lab.

***Cost of Revenues***

Cost of revenues was $1.5 million for the three months ended September 30, 2026. There was no cost of revenues for the three months ended September 30, 2025. Cost of revenues for the three months ended September 30, 2026 consisted primarily of $1.3 million of royalties to ImmunoGen, as well as amortization of the intangible asset and product related costs.

We began capitalizing our inventory costs in June 2026, after the approval of veligrotug from the FDA and based upon our expectation that these costs would be recoverable through commercialization of veligrotug. Prior to the capitalization of our inventory costs, such costs were recorded as research and development expenses in the period incurred. If product related manufacturing costs incurred before FDA approval had qualified for capitalization, cost of revenues for the three months ended September 30, 2026 would have been higher by an amount that is not material to the condensed consolidated financial statements.

***Research and Development Expenses***

| | Three Months Ended September 30, | | |
|---|---|---|---|
| | 2026 | 2025 | Change |
| | (in thousands) | | |
| Direct research and development expenses | | | |
| TED portfolio | $ 23,860 | $ 55,191 | $ (31,331) |
| FcRn inhibitor portfolio | 15,273 | 11,121 | 4,152 |
| Other research programs and expenses | 7,152 | 1,247 | 5,905 |
| Unallocated expenses | | | |
| Personnel-related (including share-based compensation) | 22,926 | 16,528 | 6,398 |
| Facility and other expenses | 882 | 2,174 | (1,292) |
| Total research and development expenses | $ 70,093 | $ 86,261 | $ (16,168) |

Research and development expenses were $70.1 million during the three months ended September 30, 2026, compared to $86.3 million during the three months ended September 30, 2025. The $16.2 million net decrease in research and development expenses reflected the following changes:

- Direct costs related to the TED portfolio decreased by $31.3 million during the three months ended September 30, 2026 compared to the three months ended September 30, 2025, primarily driven by a decrease in clinical trial and manufacturing associated costs due to the timing and stage of our phase 3 clinical trials for veligrotug and elegrobart.
- Direct costs related to the FcRn inhibitor portfolio increased by $4.2 million during the three months ended September 30, 2026 compared to the three months ended September 30, 2025, primarily driven by an increase in clinical trial and manufacturing associated costs.
- Direct costs related to other research programs and expenses increased by $5.9 million during the three months ended September 30, 2026 compared to the three months ended September 30, 2025, primarily attributable to an increase in nonclinical research and manufacturing associated costs to support the development of the TSHR program.
- Personnel-related costs increased by $6.4 million during the three months ended September 30, 2026 compared to the three months ended September 30, 2025, primarily attributable to increased headcount required to support our ongoing research and development efforts.

***Selling, General and Administrative Expenses***

| | Three Months Ended September 30, | | |
|---|---|---|---|
| | 2026 | 2025 | Change |
| | (in thousands) | | |
| Personnel-related (including share-based compensation) | $ 35,817 | $ 12,651 | $ 23,166 |
| Professional services | 19,307 | 10,558 | 8,749 |
| Facility and other expenses | 2,485 | 1,113 | 1,372 |
| Total selling, general and administrative expenses | $ 57,609 | $ 24,322 | 33,287 |

Selling, general and administrative expenses were $57.6 million during the three months ended September 30, 2026, compared to $24.3 million during the three months ended September 30, 2025. The $33.3 million increase in selling, general and administrative expenses is primarily attributable to the following:

- $23.2 million increase in personnel-related costs, primarily due to an increase in headcount to support commercial activities for veligrotug and our growing organization; and
- $8.7 million increase in professional and consulting fees primarily related to commercial activities supporting veligrotug.

***Other Income, net***

Other income, net was $2.3 million during the three months ended September 30, 2026 compared to $5.4 million during the three months ended September 30, 2025 primarily comprised of interest income earned on cash equivalents and marketable securities and the change in fair value of the derivative liability, partially offset by interest expense related to the DRI Purchase and Sale Agreement and the Notes.

**Comparison of the Nine Months Ended September 30, 2026 and 2025**

| | Nine Months Ended September 30, | | |
|---|---|---|---|
| | 2026 | 2025 | Change |
| | (in thousands) | | |
| Product revenue, net | $ 24,671 | $ — | $ 24,671 |
| License revenue | 364 | 70,000 | (69,636) |
| Collaboration revenue | 1,142 | 717 | 425 |
| Cost of revenues | (1,527) | — | (1,527) |
| Research and development expenses | (219,301) | (249,721) | 30,420 |
| Selling, general and administrative expenses | (151,263) | (61,642) | (89,621) |
| Other income, net | 12,685 | 18,400 | (5,715) |
| Net loss | $ (333,229) | $ (222,246) | $ (110,983) |

***Product Revenue, Net***

Product revenue, net was $24.7 million for the nine months ended September 30, 2026. There was no product revenue, net for the nine months ended September 30, 2025. The $24.7 million increase is the result of product sales in the third quarter of 2026 following the launch of veligrotug.

***License Revenue***

License revenue for the nine months ended September 30, 2026 was attributable to services provided under the collaboration and license agreement with Kissei. License revenue for the nine months ended September 30, 2025 was attributable to a one-time, non-refundable and non-creditable upfront cash payment of $70.0 million, under the collaboration and license agreement with Kissei.

***Collaboration Revenue***

Collaboration revenue for both the nine months ended September 30, 2026 and 2025 was attributable to our collaboration agreement with Zenas BioPharma and the Side Agreement and MTA with Zai Lab.

***Cost of Revenues***

Cost of revenues was $1.5 million for the nine months ended September 30, 2026. There was no cost of revenues for the nine months ended September 30, 2025. Cost of revenues for the nine months ended September 30, 2026 consisted primarily of $1.3 million of royalties to ImmunoGen, as well as amortization of the intangible asset and product related costs.

We began capitalizing our inventory costs in June 2026, after the approval of veligrotug from the FDA and based upon our expectation that these costs would be recoverable through commercialization of veligrotug. Prior to the capitalization of our inventory costs, such costs were recorded as research and development expenses in the period incurred. If product related manufacturing costs incurred before FDA approval had qualified for capitalization, cost of revenues for the nine months ended September 30, 2026 would have been higher by an amount that is not material to the condensed consolidated financial statements.

***Research and Development Expenses***

| | Nine Months Ended September 30, | | |
|---|---|---|---|
| | 2026 | 2025 | Change |
| | (in thousands) | | |
| Direct research and development expenses | | | |
| TED portfolio | $ 91,736 | $ 151,640 | $ (59,904) |
| FcRn inhibitor portfolio | 33,052 | 41,498 | (8,446) |
| Other research programs and expenses | 27,083 | 2,402 | 24,681 |
| Unallocated expenses | | | |
| Personnel-related (including share-based compensation) | 65,013 | 49,352 | 15,661 |
| Facility and other expenses | 2,417 | 4,829 | (2,412) |
| Total research and development expenses | $ 219,301 | $ 249,721 | $ (30,420) |

Research and development expenses were $219.3 million during the nine months ended September 30, 2026, compared to $249.7 million during the nine months ended September 30, 2025. The $30.4 million net decrease in research and development expenses reflected the following changes:

- Direct costs related to the TED portfolio decreased by $59.9 million during the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025, primarily driven by a decrease in clinical trial and manufacturing associated costs due to timing and stage of our veligrotug phase 3 clinical trials that was partially offset by an increase of similar costs associated with elegrobart phase 3 clinical trial advancements.

- Direct costs related to the FcRn inhibitor portfolio decreased by $8.4 million during the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025, primarily driven by a decrease in clinical trial and manufacturing associated costs for our FcRn inhibitor portfolio.

- Direct costs related to other research programs and expenses increased by $24.7 million during the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025, primarily attributable to an increase in nonclinical research and manufacturing associated costs to support the development of the TSHR program.

- Personnel-related costs increased by $15.7 million during the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025, primarily attributable to increased headcount to support our ongoing research and development efforts.

***Selling, General and Administrative Expenses***

| | Nine Months Ended September 30, | | |
|---|---|---|---|
| | 2026 | 2025 | Change |
| | (in thousands) | | |
| Personnel-related (including share-based compensation) | $ 92,475 | $ 33,555 | $ 58,920 |
| Professional services | 51,508 | 25,229 | 26,279 |
| Facility and other expenses | 7,280 | 2,858 | 4,422 |
| Total selling, general and administrative expenses | $ 151,263 | $ 61,642 | 89,621 |

Selling, general and administrative expenses were $151.3 million during the nine months ended September 30, 2026, compared to $61.6 million during the nine months ended September 30, 2025. The $89.6 million increase in selling, general and administrative expenses is primarily attributable to the following:

- $58.9 million increase in personnel-related costs, primarily due to an increase in headcount to support commercial activities for veligrotug and our growing organization; and
- $26.3 million increase in professional and consulting fees primarily related to commercial activities supporting veligrotug and other business activities.

***Other Income, net***

Other income, net was $12.7 million during the nine months ended September 30, 2026 compared to $18.4 million during the nine months ended September 30, 2025 primarily comprised of interest income earned on cash equivalents and marketable securities and the change in fair value of the derivative liability, partially offset by interest expense related to the DRI Purchase and Sale Agreement, the Notes, and the Hercules Loan and Security Agreement, including the loss on the extinguishment of debt.

**Liquidity and Capital Resources**

We have funded our operations to date principally through proceeds received from the sale of our common stock, our Series A convertible preferred stock, our Series B convertible preferred stock and other equity securities, debt financings, license fees, and reimbursements received under collaboration agreements. After receiving approval from the FDA in June 2026, we have also funded our operations from sales of veligrotug. Since our inception and through September 30, 2026, we have generated an accumulated deficit of $1,671.7 million. Substantially all of our operating losses resulted from expenses incurred in connection with our research and development programs and from selling, general and administrative costs associated with our operations.

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

As of September 30, 2026, we had $955.2 million in cash, cash equivalents and marketable securities. We expect that our current cash, cash equivalents and marketable securities will enable us to fund our planned operations for at least twelve months from the date of issuance of the unaudited condensed consolidated financial statements included in this Quarterly Report. Based on our current business plans, we believe that our existing cash, cash equivalents, and marketable securities will be sufficient to fund our planned operations to break even where our anticipated revenues fund our anticipated operating expenses.

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

***Convertible Notes***

In May 2026, we completed a public offering of $250.0 million aggregate principal amount of our 1.75% Convertible Senior Notes due 2032 (the “Notes”), including the exercise in full of the underwriters’ option to purchase up to an additional $25.0 million aggregate principal amount of the Notes. The Notes were issued pursuant to, and are governed by, an indenture (the “Indenture”), dated as of May 11, 2026, between us and U.S. Bank Trust Company, National Association, as trustee.

The Notes are our general, unsecured, senior obligations. The Notes will accrue interest payable semiannually in arrears on May 15 and November 15 of each year, beginning on November 15, 2026, at a rate equal to 1.75% per year. In addition, special

interest will accrue on the Notes upon the occurrence of certain events relating to our failure to file certain reports with the SEC as provided in the Indenture. The Notes will mature on May 15, 2032, unless earlier converted, redeemed or repurchased by us.

Noteholders may convert their Notes at their option only in the following circumstances: (1) during any calendar quarter (and only during such calendar quarter) commencing after the calendar quarter ending on September 30, 2026, if the last reported sale price per share of our common stock, $0.01 par value per share, exceeds 130% of the conversion price for each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter; (2) during the five consecutive business days immediately after any 10 consecutive trading day period (such 10 consecutive trading day period, the "Measurement Period") in which the trading price per $1,000 principal amount of Notes for each trading day of the Measurement Period was less than 98% of the product of the last reported sale price per share of the common stock on such trading day and the conversion rate on such trading day; (3) upon the occurrence of certain corporate events or distributions on the common stock, as described in the Indenture; (4) if we call such Notes for redemption; and (5) at any time from, and including, February 15, 2032 until the close of business on the scheduled trading day immediately before the maturity date. We will settle conversions by paying or delivering, as applicable, cash, shares of common stock or a combination of cash and shares of common stock, at our election, based on the applicable conversion rate. The initial conversion rate is 40.5680 shares of common stock per $1,000 principal amount of Notes, which represents an initial conversion price of approximately $24.65 per share, and is subject to adjustment as described in the Indenture.

The Notes are not redeemable prior to May 20, 2030. On or after May 20, 2030, we may redeem the Notes for cash (subject to certain limitations set forth in the Indenture) if the last reported sale price per share of our common stock exceeds 130% of the conversion price on (i) each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the trading day immediately before the date we send the related redemption notice; and (ii) the trading day immediately before the date we send such notice. However, we may not redeem less than all of the outstanding Notes unless at least $75.0 million aggregate principal amount of Notes are outstanding and not called for redemption as of the time we send the related redemption notice.

***Public Offering***

In May 2026, we entered into an underwriting agreement with Jefferies LLC, Leerink Partners LLC and Goldman Sachs & Co. LLC, relating to the offer and sale of 8,455,883 shares of our common stock, which included 1,102,941 shares of common stock issued in connection with the exercise in full by the underwriters of their option to purchase additional shares at a public offering price of $17.00 per share. The aggregate gross proceeds to us were approximately $143.8 million, before deducting underwriting discounts and commissions and other offering expenses payable by us.

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

In April 2022, we entered into the Hercules Loan and Security Agreement, among the Company, certain of our subsidiaries from time to time party thereto (together with the Company, collectively, the "Borrower"), Hercules and certain other lenders party thereto (the "Lenders"). Under the Hercules Loan and Security Agreement, the Lenders provided us with access to a term loan with an aggregate principal amount of up to $75.0 million, in four tranches, including an initial tranche of $25.0 million. Upon signing the Hercules Loan and Security Agreement, we drew an initial principal amount of $5.0 million. Per the terms of the Hercules Loan and Security Agreement, we were originally obligated to make interest-only payments through April 1, 2024, which was extended to October 1, 2024 upon the achievement of a development milestone in August 2022.

In August 2023, we executed the first amendment to the Hercules Loan and Security Agreement (the "Hercules First Amendment"). The Hercules First Amendment was determined to substantially alter the Hercules Loan and Security Agreement and therefore was accounted for as a debt extinguishment. Under the Hercules First Amendment, the maturity date was extended to October 1, 2026 and the Lenders provided the Borrower access to an increased term loan with an aggregate principal amount of up to $150.0 million, in four tranches, consisting of (i) an initial tranche of $50.0 million, $25.0 million of which was available through December 15, 2023, and $25.0 million of which was available from July 1, 2024 through December 15, 2024; (ii) a second tranche of $20.0 million, subject to achievement of certain regulatory milestones, which was available through February 15, 2025; (iii) a third tranche of $20.0 million, subject to achievement of certain regulatory milestones, which was available through March 31, 2025; and (iv) a fourth tranche of $60.0 million subject to approval by the Lenders' investment committee(s), which was available through June 15, 2025. Upon execution of the Hercules First Amendment, the Borrower drew an additional principal amount of $15.0 million, increasing the cumulative amount drawn to

$20.0 million. The obligations of the Borrower under the Hercules First Amendment agreement were secured by substantially all of the assets of the Borrower, excluding the Borrower's intellectual property.

In October 2025, we executed a second amendment (the "Hercules Second Amendment") to the Hercules Loan and Security Agreement. Under the Hercules Second Amendment, the term loan facility was amended to extend the maturity date to October 1, 2030 and provide an aggregate principal amount of up to $300.0 million, available upon achievement of certain milestones. The obligations of the Borrower under the Hercules Second Amendment were secured by substantially all of the assets of the Borrower. The Borrower did not draw any amounts under the Hercules Facility other than the $50.0 million described above prior to its termination in May 2026, as described below.

In May 2026, using proceeds received from the issuance of the Notes described above, we entered into a payoff letter for a voluntary prepayment with respect to the Hercules Loan and Security Agreement (the "Payoff Letter"). Pursuant to the Payoff Letter, we paid a total of $55.1 million (the "Payoff Amount") to Hercules, representing the outstanding principal, accrued and unpaid interest, fees, costs and expenses due to Hercules under the Hercules Loan and Security Agreement and related loan documents (collectively, the "Hercules Facility"), in repayment of the outstanding obligations and thereby terminated the Hercules Facility. We recorded a loss on extinguishment of debt of $4.1 million under "Interest expense" in the Condensed Consolidated Statements of Operations and Comprehensive Loss for the nine months ended September 30, 2026 related to the write-off of the remaining balance of unamortized debt discount. Upon receipt by Hercules of the Payoff Amount on May 27, 2026, all obligations, covenants, debts and liabilities under the Hercules Facility were satisfied and discharged in full, and the Hercules Facility was terminated.

***Purchase and Sale Agreement with DRI***

In October 2025, we entered into a Purchase and Sale Agreement of revenue participation rights with DRI Healthcare Acquisitions LP ("DRI"), (the "DRI Purchase and Sale Agreement"), pursuant to which DRI purchased rights to certain revenue streams in the U.S. from us in exchange for up to $300.0 million in consideration, including $55.0 million paid at signing and conditional payments of up to $245.0 million, which we will become eligible to receive upon achieving certain regulatory and sales-based milestones.

The DRI Purchase and Sale Agreement contains customary representations, warranties and indemnities of the Company and DRI and customary covenants on the part of the Company, as well as a limit on the amount of incurrence of certain types of indebtedness, which limit automatically terminates a certain period of time following receipt of marketing approval for veligrotug in the U.S. The DRI Purchase and Sale Agreement requires us to pay tiered royalties to DRI based on net sales of veligrotug, elegrobart and certain other related products (the "Net Sales Royalties"). The royalties consist of (i) 7.5% of annual U.S. net sales up to and including $600 million, which royalties could increase to low-double digits if marketing approval for elegrobart is not received prior to a specified date, (ii) 0.8% of annual U.S. net sales above $600 million and up to and including $900 million, (iii) 0.25% of annual U.S. net sales above $900 million and up to $2 billion, and (iv) no royalty owed for annual U.S. net sales in excess of $2 billion. The DRI Purchase and Sale Agreement may only be terminated upon repayment by us of a certain multiplier of the consideration paid to us by DRI (less payments by us to DRI to date) on or prior to a certain date or repayment by an acquirer of us of a certain multiplier of the consideration paid by DRI to us (less payments by us to DRI to date) following a change of control of the Company.

We determined that the DRI Purchase and Sale Agreement is considered a sale of future revenues and is treated as a financing liability according to Accounting Standards Codification ("ASC") 470, *Debt*, based on the specific facts and circumstances including our significant continuing involvement in the generation of the cash flows due to DRI. The sale of future revenue liability is accounted for as debt and is recorded at cost. After initial recognition of the debt instrument, we will use the effective interest method to account for the amount recorded as debt on our balance sheet. The effective interest rate is the rate that equates the present value of the estimated future cash flows with the carrying amount of the liability related to the sale of future revenue. The estimate of future cash flows includes estimated future Net Sales Royalties to be paid to DRI and the receipt of conditional payments from DRI that were deemed probable of achievement at inception. The interest rate on this financing liability may vary during the term of the agreement depending on a number of factors, including our net sales forecast and the probability of achieving certain milestones. We will evaluate the interest rate used to amortize the liability related to the sale of future revenue quarterly based on our expectations of future net sales and current market conditions using the prospective method. A significant increase or decrease in actual or forecasted net sales or changes in expected achievement of certain milestones may materially impact the liability, interest expense, and the time period for repayment. The conditional payments represent loan commitments that are not treated as freestanding financial instruments and qualify for the derivative scope exception under ASC 815, *Derivatives and Hedging*, and therefore have not been bifurcated and accounted for separately.

Upon receipt of the $55.0 million payment from DRI at the close of the DRI Purchase and Sale Agreement, we recorded a liability related to the sale of future revenue of $32.4 million, net of the proportionate debt issuance costs allocated to it and the initial fair value of the bifurcated derivative liability. Following the FDA's approval of veligrotug in June 2026, we received a $75.0 million milestone payment. We accrued $8.0 million and $12.4 million in interest expense during the three and nine months ended September 30, 2026, including Net Sales Royalties of $1.9 million for both the three and nine months ended September 30, 2026. As of September 30, 2026, the net carrying amount of the liability related to the sale of future revenue was $121.6 million. The imputed effective annual interest rate for the liability related to the sale of future revenue was 27.1% as of September 30, 2026. During the first quarter of 2026, we did not achieve certain milestones with respect to our elegrobart pivotal phase 3 clinical trials and therefore are not eligible to receive the $25.0 million conditional milestone payment or the additional $15.0 million conditional milestone payment.

*Derivative Liability*

In the event of a change of control of the Company at, or prior to, January 1, 2035, the DRI Purchase and Sale Agreement provides us an option to repurchase, and DRI an option to require us to repurchase, the revenue participation right from DRI (the "Put/Call Option"). Upon exercise of the Put/Call Option by us or DRI, the DRI Purchase and Sale Agreement will terminate, and we will become obligated to pay the applicable multiplier of the consideration paid to us by DRI to date, less the payments of Net Sales Royalties paid to DRI by us to date.

The Put/Call Option is an embedded derivative pursuant to ASC 815, *Derivatives and Hedging*, that must be bifurcated and measured at fair value initially and at each subsequent reporting period. We estimated the fair value of the derivative liability using a "with-and-without" method, which involves determining the fair value of the entire financial liability instrument, inclusive of all terms, features, and conditions, and separately determining the fair value of the financial liability instrument excluding the derivative. The difference between the fair value of the entire financial liability instrument including the derivative and the fair value of the financial liability instrument excluding the derivative represents the fair value of the derivative liability.

The estimated probability and timing of a change in control event that triggers the exercisability of the Put/Call Option, the estimated cash flows and the discount rate used are Level 3 significant unobservable inputs used to determine the fair value of the derivative liability. Management concluded the probability of exercise of the Put/Call Option to be remote. The estimated market yield used to measure the fair value of the derivative was 15.8% and 11.5% as of September 30, 2026 and December 31, 2025, respectively. The initial fair value allocated to the derivative liability as of the close of the DRI Purchase and Sale Agreement was $19.3 million. Issuance costs of $1.8 million allocated to the derivative were recorded to expense as a component of other expense, net in the consolidated statements of operations and comprehensive loss. The derivative liability is subsequently remeasured at fair value each reporting period, with changes in fair value being recorded as a component of other expense, net in the consolidated statements of operations and comprehensive loss. As of September 30, 2026, the fair value of the derivative liability was $11.6 million resulting in recognition of a decrease in the fair value of $8.4 million during the nine months ended September 30, 2026.

***ATM Agreement***

In March 2025, we entered into an Open Market Sale Agreement℠ (the "March 2025 ATM Agreement") with Jefferies LLC ("Jefferies"), pursuant to which we may offer and sell shares of our common stock having an aggregate offering price of up to $300.0 million from time to time at prices and on terms to be determined by market conditions at the time of offering, with Jefferies acting as our sales agent. Jefferies will receive a commission of up to 3.0% of the gross proceeds of any shares of common stock sold under the March 2025 ATM Agreement. No shares were sold under the March 2025 ATM Agreement during the three and nine months ended September 30, 2026. During both the three and nine months ended September 30, 2025,

we sold 500,000 shares under the March 2025 ATM Agreement at a weighted average price of $19.92 per share, for aggregate net proceeds of approximately $9.8 million, after deducting commissions to Jefferies as sales agent.

Summarized cash flows for the nine months ended September 30, 2026 and 2025 are as follows:

| | Nine Months Ended September 30, | | |
|---|---|---|---|
| | 2026 | 2025 | Change |
| | (in thousands) | | |
| Net cash provided by (used in): | | | |
| Operating activities | $ (317,751) | $ (252,637) | $ (65,114) |
| Investing activities | (129,559) | 301,857 | (431,416) |
| Financing activities | 409,088 | 20,833 | 388,255 |
| Net increase (decrease) in cash, cash equivalents, and restricted cash | $ (38,222) | $ 70,053 | $ (108,275) |

***Operating Activities***

Net cash used in operating activities was $317.8 million for the nine months ended September 30, 2026, and primarily consisted of a net loss of $333.2 million, adjusted for non-cash items of $52.5 million (primarily share-based compensation of $47.6 million), and changes in operating assets and liabilities of $37.0 million, primarily driven by a $29.8 million increase in accounts receivable, net following the launch of veligrotug.

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

***Investing Activities***

Net cash used in investing activities was $129.6 million during the nine months ended September 30, 2026, and consisted primarily of net purchases of marketable securities and a $10.0 million milestone payment pursuant to the ImmunoGen License Agreement, following FDA approval of veligrotug in June 2026.

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

***Financing Activities***

Net cash provided by financing activities was $409.1 million during the nine months ended September 30, 2026, and consisted of net proceeds from the sale of the Notes of $242.0 million, net proceeds from the issuance of common stock in our May 2026 public offering of $135.0 million, proceeds of $75.0 million from the DRI Purchase and Sale Agreement, and $10.6 million in proceeds from the exercise of stock options, offset by cash outflows related to the debt extinguishment of $54.7 million.

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

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

There were no material changes to our market risks in the nine months ended September 30, 2026, when compared to the disclosures in Item 7A of our 2025 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

Except for new controls implemented related to product revenues and inventory, there were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

# PART II. OTHER INFORMATION

## ITEM 1. LEGAL PROCEEDINGS

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

## ITEM 1A. RISK FACTORS

*Our business, financial condition, and operating results may be affected by a number of factors, whether currently known or unknown, including but not limited to those described below. Any one or more of such factors could directly or indirectly cause our actual results of operations and financial condition to vary materially from past or anticipated future results of operations and financial condition. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, results of operations, and stock price. The following information should be read in conjunction with the other information contained in this Quarterly Report on Form 10-Q, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the unaudited condensed consolidated financial statements and related notes.*

### Risks Related to Our Financial Condition and Capital Requirements

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

We are a commercial stage biopharmaceutical company with a limited operating history. We have historically incurred net losses. During the nine months ended September 30, 2026 and 2025, our net loss was $333.2 million and $222.2 million, respectively. As of September 30, 2026, we had an accumulated deficit of $1,671.7 million and cash, cash equivalents and marketable securities of $955.2 million.

We may need to secure substantial additional capital to continue to fund our operations in the future. The amount and timing of our future funding requirements will depend on many factors, including the pace, results and costs of our clinical development efforts, our ability to generate revenues from sales of veligrotug and, if elegrobart is approved, elegrobart, 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 identifying, acquiring and developing our product candidates, including conducting clinical trials and providing selling, general and administrative support for our operations. To date, we have financed our operations primarily through the sale of equity securities, convertible promissory notes, convertible senior notes, the Hercules Loan and Security Agreement, the Kissei Agreement, and the DRI Purchase and Sale Agreement. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to generate sufficient product revenue and obtain funding through equity, debt financings or other non-dilutive sources of capital, or strategic collaborations. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We expect our losses to increase as our product candidates continue advancing through clinical development and as new product candidates enter clinical trials and then advance through clinical development. 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.

Our future revenue will depend upon market acceptance and commercial sales of veligrotug, obtaining regulatory approval to market our additional product candidates, the size of any markets in which our product candidates may receive approval, and our ability to establish and maintain a commercial supply chain in each market, achieve sufficient market acceptance, pricing, coverage, and adequate reimbursement from third-party payors, and adequate market share for our current product and product candidates, including veligrotug, and additional products we may develop in the future. 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 veligrotug and our product candidates or increase volumes manufactured by third parties;
- continue to advance our programs into large, expensive clinical trials;
- initiate additional nonclinical studies or clinical trials for our product candidates;
- seek regulatory and marketing approvals, pricing, and reimbursement for our product candidates;
- establish and maintain a sales, marketing, and supply chain and distribution infrastructure to commercialize any products for which we may obtain marketing approval and market ourselves;
- seek to identify, assess, acquire, and/or develop other product candidates;
- make milestone, royalty, or other payments under third-party license agreements or enter into additional third-party license agreements;
- seek to maintain, protect, and expand our intellectual property portfolio;
- seek to attract and retain skilled personnel; and
- experience any delays or encounter issues with the development and potential for regulatory approval of our clinical and product candidates such as safety issues, manufacturing delays, clinical trial accrual delays, longer follow-up for planned studies or trials, additional major studies or trials, or supportive trials necessary to support marketing approval.

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

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

As of September 30, 2026, we had $955.2 million of cash, cash equivalents and marketable securities. We expect that our current cash, cash equivalents and marketable securities will enable us to fund our planned operations for at least twelve months from the date of issuance of the consolidated financial statements included in this Quarterly Report. We may need to secure additional capital to continue to fund our operations and service our obligations in the future. If we are unable to secure additional capital when needed, we may not be able to continue as a going concern.

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

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

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

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

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

***We have a limited history of generating revenue from product sales and we may never be profitable.***

Veligrotug is our only product approved for sale and it is only approved in the United States. Prior to approval of veligrotug, we had not generated revenue from product sales. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaborators, to successfully complete the development of, obtain regulatory and marketing approvals for, and build and maintain a commercial supply chain necessary to commercialize, veligrotug or one or more of our product candidates in development. 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 veligrotug and 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 veligrotug or our product candidates, if approved;
- establishing and maintaining a commercial supply chain for our product candidates in the countries or regions in which we obtain regulatory approval for them, including establishing sufficient shelf-life for our product candidates in multiple regions, receipt and maintenance of necessary licenses, permits, or similar permissions, either directly or with a collaborator or distributor;
- marketing, launching, and commercializing veligrotug and product candidates for which we obtain regulatory and marketing approval, either directly or with a collaborator or distributor;
- gaining market acceptance of veligrotug and our product candidates as treatment options;
- addressing any competing products;
- developing, protecting and enforcing our intellectual property rights, including patents, trade secrets, and know-how;
- our ability to avoid or defend third-party patent infringement claims;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- obtaining coverage and adequate reimbursement from third-party payors and receiving and maintaining pricing for veligrotug and our product candidates that supports profitability; and
- attracting, hiring, and retaining qualified personnel.

We have incurred and expect to continue to incur significant costs associated with commercializing veligrotug and any other product candidates, if approved. 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 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 sufficient revenue from the sale of veligrotug or any other products once approved, 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 veligrotug or our other product candidates, we expect to finance our cash needs primarily through a combination of equity offerings, debt financings, and license and development agreements. To the extent that we raise additional capital through the sale of equity securities or convertible debt securities, or other sources of capital, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, making additional product acquisitions, or declaring dividends.

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

To the extent that we raise additional capital through the sale of equity, including pursuant to any sales under our March 2025 ATM Agreement with Jefferies LLC (“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 the DRI Purchase and Sale Agreement, may include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, making additional product acquisitions, or declaring dividends.

We cannot be assured that we will be able to obtain additional funding, if and when necessary, to fund our entire portfolio of product candidates to meet our projected plans. If we are unable to obtain funding on a timely basis, we may be required to limit our commercialization efforts for veligrotug in additional markets, 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.

***Servicing our 1.75% convertible senior notes due 2032 (the "2032 Notes") requires a significant amount of cash, and we may not have sufficient cash flow to pay our debt.***

In May 2026, we issued $250.0 million aggregate principal amount of the 2032 Notes, pursuant to an indenture dated as of May 11, 2026, between us as issuer, and U.S. Bank Trust Company, National Association, as trustee. Our ability to make scheduled payments of the principal of, to pay interest on, or to refinance our indebtedness, including the 2032 Notes, depends on our future performance, which is subject to many factors, including, economic, financial, competitive and other, beyond our control. If our business does not generate cash flow from operations sufficient to service our debt and make necessary capital expenditures, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance the 2032 Notes, which mature in 2032, will depend on the capital markets and our financial condition at such times. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations, and limit our flexibility in planning for and reacting to changes in our business.

***We may not have the ability to raise the funds necessary to repurchase the 2032 Notes as required upon a fundamental change or event of default, and our future debt may contain limitations on our ability to repurchase the 2032 Notes.***

Holders of the 2032 Notes will have the right to require us to repurchase their 2032 Notes for cash upon the occurrence of a fundamental change at a fundamental change repurchase price equal to 100% of the principal amount of the 2032 Notes to be repurchased, plus accrued and unpaid interest, if any. A fundamental change may also constitute an event of default or prepayment under, and result in the acceleration of the maturity of, our then-existing indebtedness. We may not have sufficient financial resources, or be able to arrange financing, to pay the fundamental change repurchase price in cash with respect to any 2032 Notes surrendered by holders for repurchase upon a fundamental change. In addition, restrictions under our then existing credit facilities or other indebtedness, if any, may not allow us to repurchase the 2032 Notes upon a fundamental change. Our failure to repurchase the 2032 Notes upon a fundamental change when required would result in an event of default with respect to the 2032 Notes which could, in turn, constitute a default under the terms of our other indebtedness, if any. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the 2032 Notes.

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

Our operations, and those of our third-party research institution collaborators, contract research organizations ("CROs"), contract manufacturing operations ("CDMOs"), and other contractors and consultants, could be subject to acts of war, wildfires, earthquakes, power shortages, information technology and telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, governmental actions, medical pandemics or epidemics, and other natural or man-made disasters or business interruptions, for which we are partly uninsured. Shortages and governmental restrictions resulting from pandemics or other public health crises may disrupt the ability of or increase the cost for our clinical trial sites and other CROs to procure items that are essential for our research and development activities, including animals that are used for nonclinical studies. In addition, we rely or may rely in the future on our third-party research institution collaborators for conducting research and development of our product candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could significantly disrupt the timing of clinical trials, harm our operations and financial condition and increase our costs and expenses.

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

In October 2025, we entered into the Purchase and Sale Agreement with DRI. In addition to the $55.0 million we received at signing, the agreement made available to us up to an additional $245.0 million in milestone payments at signing. However, these additional milestone payments are subject to satisfaction of certain conditions related to certain elegrobart clinical trials and regulatory approvals or commercial sales of veligrotug and elegrobart on or prior to a certain date. Should we not satisfy the conditions of the applicable milestones, or if we fail to meet our obligations or default under this agreement, the actual amount of additional milestone payments to us could be substantially less than the maximum amounts available thereunder. Based on our operations to date, we have achieved a milestone payment of $75.0 million and up to an additional $130.0 million in milestone payments remains available to us. In the event of a change of control on or prior to a certain date, we have the option to repurchase, and DRI may require us to repurchase, the revenue participation right from DRI for the multiplier amount, less payments to date.

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

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

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

- inability to generate satisfactory nonclinical, toxicology, or other in vivo or in vitro data or diagnostics to support the initiation or continuation of clinical trials;
- delays in reaching agreement on acceptable terms with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, clinical trial sites, and in countries or regions where our trials are conducted;
- delays in obtaining required approvals from institutional review boards or independent ethics committees at each clinical trial site;
- failure to permit the conduct of a clinical trial by regulatory authorities;
- delays in or inability to recruit a sufficient number of eligible patients and/or subjects in our clinical trials;
- failure by clinical sites, CROs, or other third parties to adhere to clinical trial requirements or to perform their obligations related to the clinical development of our product candidates;
- failure of CDMOs, shipping logistics providers or other third parties to deliver necessary clinical material;
- failure by our clinical sites, CROs, or other third parties to perform in accordance with current good clinical practice (“cGCP”), current good laboratory practice (“cGLP”), current good manufacturing practice (“cGMP”) or other applicable requirements of the FDA or applicable foreign regulatory authorities;
- patients and/or subjects dropping out of our clinical trials;
- adverse events or tolerability or animal toxicology issues significant enough in our studies, in studies of third parties, or as reported for marketed products for the FDA or other regulatory agencies to put any or all clinical trials on hold, require us to change how we conduct our IND-enabling studies or our ongoing or future trials, including amending or submitting new clinical protocols or additional safety monitoring or measurements;
- occurrence of adverse events associated with our product candidates;
- changes in regulatory requirements or guidance that require amending or submitting new clinical protocols;

- geopolitical unrest and adverse regulatory or other actions taken against us, or third parties on whom we rely, by foreign governments or entities, including in Israel and China, where we have current or planned clinical trial operations;
- significant costs of clinical trials of our product candidates, including manufacturing activities;
- negative or inconclusive results from our clinical trials or the trials of third parties with related or similar product candidates, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development programs in 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;
- 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; and
- delays in or failure to obtain required approvals from the FDA or other regulators based on objections to our manufacturing processes.

We are conducting a global pivotal program for elegrobart, where we expect that the REVEAL-1 and REVEAL-2 phase 3 clinical trials, together with a safety database comprising at least 300 treated patients (safety database inclusive of REVEAL-1 and REVEAL-2 patients), will support global health authority registration for elegrobart for marketing approval in both active and chronic TED, respectively. The FDA or other regulatory authorities may require additional patients in this safety database or may require us to take other additional steps. Additionally, we conducted an autoinjector PK study for elegrobart to bridge bioequivalence from the vial/syringe used in the REVEAL-1 and REVEAL-2 trials and the autoinjector, with which we plan to launch commercially. However, the results may not show bioequivalence and/or global health authorities may not agree with the methodologies employed to support bioequivalence. If either of these occur, our BLA for elegrobart and/or its marketing approval may be significantly delayed or abandoned. Additionally, regulatory authorities outside of the United States may require us to conduct additional studies in order to support marketing approval of elegrobart in countries outside of the United States.

We may be required to take other additional steps in the course of development and regulatory interaction regarding veligrotug and our product candidates, including elegrobart, and our pipeline product candidates. Such additional steps may include, without limitation, initiating new trials, starting at an earlier phase of clinical trial, conducting bridging studies, enrolling more patients, amending trial protocols, or requiring us to assess additional parameters related to safety or efficacy. For example, we may make adjustments to the elegrobart clinical trial designs as a result of additional data or feedback from regulatory authorities. These additional requirements or steps could increase the cost of development of our product candidates, negatively affect our anticipated timelines, delay our time to market with our product candidates, if approved, and could harm our business.

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

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market, or product recalls;
- fines, warning letters, or holds on post-approval clinical studies;
- refusal of the FDA or other regulatory authorities to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA or other regulatory authorities to permit the import or export of products; or

- injunctions or the imposition of civil or criminal penalties.

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

***We remain subject to ongoing regulatory oversight.***

We are subject to ongoing regulatory oversight and requirements for veligrotug with respect to manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing clinical trials, 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. If any of our other product candidates are approved, we will also remain subject to these ongoing regulatory requirements with respect to such product candidates.

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 are required to report adverse reactions and production problems, if any, to the FDA, EMA, and any relevant comparable foreign regulatory authorities. Any new legislation could result in delays in product development or commercialization, or increased costs to ensure compliance. If our original marketing approval for a product candidate was granted accelerated approval by the FDA, we could be required to conduct a successful post-marketing clinical trial in order to confirm the clinical benefit of our products. Other regulatory authorities outside of the U.S. may have similar requirements. An unsuccessful post-marketing clinical trial or failure to complete such a trial or failure to comply with other post-marketing obligations could result in the withdrawal of marketing approval. We and any of our suppliers or collaborators, including our CDMOs, are subject to periodic inspections by the FDA, EMA, and, as applicable, comparable foreign regulatory authorities to monitor compliance with cGMPs and other FDA, EMA, and, as applicable, any comparable foreign regulatory requirements. Application holders must further notify the FDA, and any comparable foreign regulatory authorities, as applicable, and depending on the nature of the change, obtain FDA pre-approval or pre-approval from other comparable foreign regulatory authorities, as applicable, for product and manufacturing changes.

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

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

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

In connection with the advancement of our clinical programs and before we can commercialize any of our current or future product candidates, we must obtain marketing approval from regulatory authorities. We may not be able to receive approval to

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

The FDA and other regulatory authorities have substantial discretion in the approval process, including determining when or whether regulatory approval will be obtained for a product candidate. Even if we believe the data collected from clinical trials are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority or such authorities may request additional information that may be difficult to generate or provide. Further, following approval, the FDA or other regulatory authorities may conduct additional inspections and, based on the results of such inspections, deem the inspected manufacturing facilities to be deficient, suspending our ability to manufacture our product candidates until we can secure satisfactory alternative manufacturing facilities. Additionally, the ability of the FDA to review and approve new products, to provide feedback on clinical trials and development programs, to meet with sponsors and to otherwise review regulatory submissions can be affected by a variety of factors, including government budget and funding levels; the ability to hire and retain key personnel and accept the payment of user fees; and statutory, regulatory, and policy changes, among other factors. Average review times have fluctuated in recent years as a result. Delays at the FDA as a result of these or other factors could impact the FDA's ability to act on any of the regulatory submissions that we may make.

In addition to the U.S., we anticipate seeking regulatory approval to commercialize our product candidates in Europe and, in January 2026, we submitted an MAA to the EMA to seek regulatory approval to commercialize veligrotug in Europe. We also anticipate that our partners (or their sublicensees) to whom we have licensed our anti-IGF1R antibodies will seek regulatory approval to commercialize our product candidates in their territories, including in Greater China and Japan. While the scope of regulatory approval is similar in many countries, to obtain separate regulatory approval in multiple countries will require us and our partners to comply with numerous and varying regulatory requirements of each such country or jurisdiction regarding safety, efficacy and quality, and governing, among other things, clinical trials, commercial sales, pricing and distribution, and we cannot predict success in any such jurisdictions, even if we were to receive approval in the U.S.

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

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

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

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

***There is substantial uncertainty as to the potential impacts of a prolonged U.S. federal government shutdown and as to whether and to what extent measures implemented by the current presidential administration in the U.S. will impact the FDA. Our business could be negatively impacted by disruptions at the FDA or other government agencies.***

Since the start of the current presidential administration in 2025, U.S. policy changes have been implemented at a rapid pace and additional changes are likely. The administration and federal government could adopt legislation, regulations, policies, or guidance that adversely affect our business or negatively impact the development, approval, and commercialization of our products, including creating a more challenging or costly environment in which to work. A federal government shutdown may result in the furlough of federal employees, reduced availability of government services, and suspension or delay of activities by key agencies that regulate, fund, or interact with our business, including the FDA, the Department of Health and Human Services, and the U.S. Patent and Trademark Office.

The ability of the FDA and foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including the current presidential administration; government budget and funding levels; statutory, regulatory and policy changes; the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees; and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years including from October 1, 2025 to November 12, 2025, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. Following the reopening of the U.S. government on November 12, 2025, there was a backlog of regulatory submissions which could delay the ability of the FDA to review our regulatory submissions. Any such delays could have a material adverse effect on our business, such as delaying the FDA's review and oversight of our product candidates and impact FDA's ability to provide timely feedback on our development programs, including through Type C or Type D meetings or informal interactions. Additionally, reductions in workforce or other disruptions to the agency, particularly in the review or inspection divisions, could extend BLA review timelines, delay or prevent pre-approval inspections, and limit opportunities for FDA feedback on pending applications. Further, FDA may pursue legislative, regulatory, or policy changes regarding the standards or processes for approving our product candidates that we may be unable to satisfy.

In addition, the current U.S. presidential administration has issued certain policies and certain Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine operations. A significant reduction in FDA's workforce or FDA's budget, or other disruptions at FDA, could materially impact FDA's ability to engage in a variety of activities that may affect our business, including routine regulatory and oversight activities. Changes in FDA personnel under the current presidential administration may also lead to further changes in the regulations, policies, and operations of the FDA, which may impact our clinical development plans. Any of these actions could adversely affect the development and approval of our product candidates. Any of these actions may delay or limit our ability to obtain FDA approval and commercialize our product candidates.

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

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

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

- regulatory authorities may withdraw approvals of such products;

- regulatory authorities may require additional warnings on the drug labeling or narrow approved indications;
- 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 and the commercial success of our products may suffer.

Clinical trials by their nature utilize a sample of the potential patient population. 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 and whether the real world safety and effectiveness of a product candidate will be consistent with the safety and effectiveness profile seen in clinical studies. Such rare and severe side effects may only be uncovered with a significantly larger number of patients or subjects exposed to the drug. New data relating to veligrotug, including from adverse events reports and any potential post-marketing requirements, and from other ongoing clinical studies, including those of our partners, may result in changes to the product labeling and may adversely affect sales, or result in withdrawal of veligrotug from the market. The FDA and other regulatory authorities may also consider the new data in reviewing veligrotug's marketing applications for additional indications and/or in other jurisdictions. If any of these actions were to occur, it could result in significant expense and delay and/or limit our ability to generate sales revenues.

Further, if such safety problems occur or are identified after our product candidates reach the market, we could be subject to costly and time-intensive post-marketing review and regulation. The FDA or other regulatory authorities may require that we amend the labeling of the product, implement a REMS, recall the product, conduct a post-approval study or studies, implement surveillance measures, or may even withdraw approval for the product. Later discovered undesirable side effects could further result in reduced market acceptance and utilization of our product or potential product liability claims. Any of these occurrences may materially harm our business, financial condition, results of operations and prospects.

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

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

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

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

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

We will have to conduct well-controlled trials in our proposed indications to support any regulatory submissions for further clinical development. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles despite promising results in earlier, smaller clinical trials. Larger

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

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

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

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

From time to time, we publish preliminary data from our clinical trials. In December 2023, we reported clinical data from our phase 1 clinical study in healthy volunteers and announced the selection of elegrobart as our lead subcutaneous product candidate for TED. In March 2026, we announced topline data from the phase 3 REVEAL-1 trial of elegrobart in patients with active TED and in May 2026, we announced topline data from the phase 3 REVEAL-2 trial of elegrobart in patients with chronic TED. In the REVEAL-1 trial, elegrobart dosed every four weeks and every eight weeks achieved clinically meaningful 54% and 63% proptosis responder rate versus 18% placebo at week 24. In the REVEAL-2 trial, elegrobart dosed every four weeks and every eight weeks achieved clinically meaningful 50% and 54% proptosis responder rate versus 15% placebo at week 24.

Based on the comparable pharmacology of elegrobart to veligrotug, we believe elegrobart has the potential to maintain the clinical response of veligrotug by delivering a clinical benefit while significantly increasing patient convenience. However, we are conducting a global pivotal program for elegrobart in patients with TED, and the final results of any clinical trials conducted in TED patients with elegrobart may not demonstrate safety or efficacy comparable to veligrotug or at all.

In March 2026, we announced topline data from the phase 3 REVEAL-1 trial of elegrobart in patients with active TED and in May 2026, we announced topline data from the phase 3 REVEAL-2 trial of elegrobart in patients with chronic TED. This data may not be fully reflective of the final results for these trials. If final results from these trials are not positive or favorable, it could negatively impact or alter the development of elegrobart and could materially harm our business prospects. If clinical data from any future veligrotug trials are not positive or favorable, it could negatively impact or alter the development of elegrobart and could materially harm our business prospects. Similarly, negative or unfavorable clinical data from our elegrobart product candidate could negatively impact veligrotug and could materially harm our business prospects.

Topline or preliminary data from our clinical trials that we announce or publish from time to time, including the data from our phase 1 clinical trials in healthy volunteers, the data for our product candidates from our ongoing trials, and topline data, may change as more patient data become available and we become subject to audit and verification procedures that could result in material changes in the final data. The final results of clinical trials may include additional outcome measurements made throughout the duration of the clinical trial. This creates a risk that the final results could be materially different from the preliminary results reported, including those reported to date, and may include additional outcome measurements made throughout the duration of the clinical trial that are not positive or favorable. Additionally, differences in patient populations across our clinical trials may lead to inconsistent or unrepresentative data.

Negative or unfavorable additional outcome measurements made throughout the duration of a clinical trial or significant adverse differences between preliminary data and final, audited and verified data could negatively affect the prospect of regulatory approval for our product candidates and could materially harm our reputation and business prospects.

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

Because we have limited financial and human resources, we may forgo or delay the pursuit of opportunities with some programs or product candidates or for other indications, that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or more profitable market opportunities.

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

***We may face liability for our approved products 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 product or product candidates harm patients or subjects, or is perceived to harm patients or subjects even when such harm is unrelated to our approved product or product candidates, our regulatory approvals 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 veligrotug and any other products for which we may obtain marketing approval expose us to the risk of potential product liability claims. There is a risk that our approved product or 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 and sale of commercial products, for up to $20.0 million per occurrence, up to an aggregate limit of $20.0 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 or additional products we may commercialize in the future. There is no way to know if we will be able to continue to obtain product liability coverage and obtain expanded coverage, if we require it, in sufficient amounts to protect us against losses due to liability, on acceptable terms, or at all. We may not have sufficient resources to pay for any liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage. Where we have provided indemnities in favor of third parties under our agreements with them, there is also a risk that these third parties could incur liability and bring a claim under such indemnities. An individual may bring a product liability claim against us alleging that one of our product candidates causes, or is claimed to have caused, an injury or is found to be unsuitable for consumer use. Any such product liability claims may include allegations of defects in manufacturing, defects in design, failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. Any product liability claim brought against us, with or without merit, could result in:

- inability to recruit clinical trial volunteers, investigators, patients or subjects, or trial sites;
- withdrawal of clinical trial volunteers, investigators, patients or subjects, or trial sites, or limitations on approved indications;
- delay in the development of product candidates;
- the inability to commercialize, or if commercialized, decreased demand for, our product candidates;
- if commercialized, product recalls, labeling, marketing or promotional restrictions, or the need for product modification;

- initiation of investigations by regulators;
- loss of revenue;
- substantial costs of litigation, including monetary awards to patients or other claimants;
- liabilities that substantially exceed our product liability insurance, which we would then be required to pay ourselves;
- an increase in our product liability insurance rates or the inability to maintain insurance coverage in the future on acceptable terms, if at all;
- the diversion of management's attention from our business; and
- damage to our reputation and the reputation of our products and our technology.

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

**Risks Related to Commercialization of Our Product and Product Candidates**

***Our business operations and market access arrangements are subject to applicable healthcare regulatory laws, which, if not properly adhered to, could expose us to penalties.***

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute veligrotug and any future products, if approved. In the U.S., these laws include, but are not limited to the following, which apply with respect to the marketing approval for veligrotug and each product candidate we may develop in the future:

- federal false claims, false statements, and civil monetary penalties laws prohibiting, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false statement to get a false claim paid;
- the federal anti-kickback law, which prohibits, among other things, persons from offering, soliciting, receiving, or providing remuneration, directly or indirectly, to induce either the referral of an individual for, or the purchasing or ordering of, a good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- HIPAA, which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the FDCA, which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing products prior to approval or for off-label use and regulates the distribution of samples;
- federal laws that require pharmaceutical manufacturers to calculate, report and certify product prices and other data to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs, which data may be used in the calculation of reimbursement and/or discounts on approved products;
- the federal Open Payments (or federal "sunshine" law), which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with certain healthcare providers to CMS within the U.S. Department of Health and Human Services for re-disclosure to the public, as well as ownership and investment interests held by physicians and their immediate family members;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous state laws and regulations, including state anti-kickback and false claims laws, consumer protection and unfair competition laws and laws governing privacy, security and breaches of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- state laws that require pharmaceutical companies to comply with specific compliance standards, restrict financial interactions between pharmaceutical companies and healthcare providers, report drug product pricing information, financial interactions with healthcare providers, or marketing expenditures and/or require the registration of pharmaceutical sales representatives.

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

Ensuring compliance with these laws is time-consuming and costly and we have had to expand and evolve our compliance efforts in connection with commercialization of veligrotug to address laws that are newly applicable to our business. Given the breadth of the laws and regulations, limited guidance for certain laws and regulations and evolving government interpretations of the laws and regulations, governmental authorities may possibly conclude that our business practices are non-compliant. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our business, financial condition, results of operations, and prospects.

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

To successfully commercialize veligrotug and any additional products we may develop in the future, we will need to continue to invest in and develop our commercialization capabilities, including commercial manufacturing, sales and marketing capabilities, or establish and maintain arrangements with collaborators to commercialize veligrotug or any additional products. Any failure or delay in the timely development of our internal commercialization capabilities, or in entering into agreements with third parties to market or sell our product candidates could adversely impact the potential for the launch and success of our products. If commercialization collaborators do not commit sufficient resources to commercialize veligrotug and we are unable to develop the necessary capabilities on our own, we will be unable to generate sufficient product revenue to sustain or grow our business. We currently compete and may be required in the future to compete with companies that currently have extensive and well-funded manufacturing, 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, but we may not be able to do so, which may cause us to alter our development and commercialization plans. Even where we have entered into a collaboration, it may not be successful.***

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 where we have entered into a license agreement or other form of collaboration regarding the development or commercialization of our products or product candidates, including those with Zenas BioPharma or Kissei, 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 products or product candidates could delay the development or commercialization of our products or 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 our products to market and our business may be materially and adversely affected.

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

The development and commercialization of new drug products is highly competitive, particularly in the treatment of TED and FcRn inhibitor therapeutics. We face competition from major pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, universities, and other research institutions worldwide with respect to veligrotug and our product candidates. We are aware that the following companies, among others, have therapeutics marketed or in development for TED: Amgen, Roche Holdings AG, Novartis AG, Minghui Pharmaceutical, Lassen Therapeutics, and Sling Therapeutics, Inc. Other companies such as Kriya Therapeutics, Inc., Septerna, Yarrow Bioscience, Inc., Ethyreal Bio, 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. Veligrotug competes and elegrobart, if approved, will also compete against generic medications, such as corticosteroids, and surgical procedures that are prescribed for the treatment of TED. We are also aware that the following companies, among others, may have anti-FcRn therapeutics marketed or in development: Argenx, UCB S.A., Johnson & Johnson and Immunovant, Inc. Moreover, there are more than 20 indications announced or in development across the FcRn class. Depending on the indications in which we choose to develop our FcRn inhibitor product candidates, there may be further competition from marketed and in-development therapeutics targeting other mechanisms such as complement inhibition, T-cell inhibitors, anti-IL-6 and other mechanisms of action.

Our product candidates may demonstrate inferior efficacy and safety profiles as compared to currently approved drugs, or product candidates currently in development by our competitors. Our competitors may succeed in developing, acquiring, or licensing technologies and drug products that are more effective or less costly than our product candidates that we are currently developing or that we may develop, which could render our product candidates obsolete and noncompetitive. Our competitors may also adopt a similar licensing and development strategy as ours with regard to the development of an existing IGF-1R monoclonal antibody for the treatment of TED. If any competitor is able to effect this strategy in a more efficient manner, there may be less demand for veligrotug or our product candidates, if 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. Veligrotug may be priced at a significant premium over other competitive products. This may make it difficult for veligrotug or any other future products to compete with generic 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, Amgen is a large biotechnology company in the competitive landscape for clinical trials and therapeutics for TED. Large pharmaceutical companies, in particular, have extensive expertise in developing and commercializing drugs, including nonclinical and clinical testing, and in obtaining regulatory approvals, pricing and reimbursement for drugs. In addition, academic institutions, government agencies, and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies. These organizations may also establish exclusive collaborative or licensing relationships with our competitors. If our product candidates fail to compete effectively against established treatment options or future products currently in development, this would harm our business, financial condition, results of operations and prospects.

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

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

- our ability to demonstrate to the clinicians and payors the clinical efficacy, effectiveness and safety of our products as the prescription products of choice for their respective indications;
- the effectiveness of our sales and marketing organizations and distribution networks;
- the ability of patients or providers to be adequately reimbursed for our products in a timely manner from government and private payors;
- the actual and perceived efficacy and safety profile of our products, particularly if unanticipated adverse events related to our products' treatment arise and create safety concerns among potential patients or prescribers or if new data and analyses we obtain for our products do not support, or are interpreted by some parties to not support, the efficacy of our products; and
- the efficacy and safety of therapies developed by our competitors.

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

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

The pricing, as well as the coverage, and reimbursement of veligrotug and any other products that may be approved in the future 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, private insurers, managed care plans, and other organizations, are essential for most patients to be able to afford expensive treatments. Sales of veligrotug and other products that may be approved in the future will depend substantially, both domestically and abroad, on the extent to which the costs will be paid for or reimbursed by third-party payors. Government authorities and other third-party payors decide which products they will cover and establish reimbursement levels for those products. Such payors may attempt to control costs by restricting coverage, controlling utilization and limiting the amount of reimbursement for particular medications. Third party payors may take action to encourage use of other products perceived to be clinically superior or more cost effective which may limit demand for veligrotug or any additional products that may be approved in the future. Our ability to commercialize veligrotug and our product candidates, if approved, successfully may also be adversely affected by discounts or rebates that we are required to provide in order to ensure coverage of our products and compete in the marketplace. If coverage and adequate reimbursement are not available, or are available only in limited amounts we may not be able to successfully commercialize veligrotug or our product candidates, if approved, which would adversely affect our business and financial condition.

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

Outside the U.S., international operations are generally subject to extensive governmental price controls and other price-restrictive regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, and other countries has and will continue to put pressure on the pricing and usage of products. In many countries, the prices of products are subject to varying price control mechanisms as part of national health systems. Price controls or other changes in pricing

regulation could restrict the amount that we are able to charge for our products, if any. Accordingly, in markets outside the U.S., the potential revenue may be insufficient to generate commercially reasonable revenue and profits.

Within the U.S., the current presidential administration has sought and is likely to continue to seek to implement "most favored nation" pricing for drugs and biologics covered under government programs. In May 2025, President Trump issued an Executive Order that directed government agencies and officials to identify most-favored nation pricing targets for prescription drugs. In the wake of these policy pronouncements, federal agencies are developing new drug pricing pilot programs, such as proposed Medicare Part B and Part D pilot models. On October 2, 2026, CMS released a final rule for the Global Benchmark for Efficient Drug Pricing ("GLOBE") Model. A companion Medicare Part D Guarding U.S. Medicare Against Rising Drug Costs ("GUARD") Model has also been proposed. If these models become effective as planned, they will replace existing inflation-based Medicare rebates with rebates determined on the basis of international prices, for drugs and patients subject to each applicable model. If "most favored nation" pricing is implemented under the law, payment for our products and our business results could be adversely affected, although the full impact of any such actions cannot be predicted. Additionally, since 2025, 26 pharmaceutical manufacturers have entered into voluntary agreements with the U.S. government related to drug pricing through CMS's GENErating cost Reductions for U.S. Medicaid ("GENEROUS") Model, a voluntary most favored nation framework for manufacturers participating in the Medicaid Drug Rebate Program. Voluntary agreements under the GENEROUS Model may increase the likelihood that other companies in the industry will enter into similar agreements or accept similar terms.

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

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

We created the organizational infrastructure we believe we need to support the commercial success of veligrotug. Factors that may inhibit our efforts to maintain and further develop commercial capabilities include:

- an inability to retain an adequate number of effective commercial personnel and hire additional commercial personnel in the future;
- an inability to train sales personnel, who may have limited experience with our company or our products, to deliver a consistent message regarding our products and be effective in educating clinicians on how to prescribe our products;
- an inability to equip sales personnel with compliant and effective materials, including medical and sales literature to help them educate physicians and other healthcare providers regarding our products and their proper administration and educate payors on the safety, efficacy and effectiveness profile of our products to support favorable coverage decisions;
- unforeseen costs and expenses associated with maintaining and further developing an independent sales and marketing organization; and
- an inability to timely develop effective commercial, sales and marketing infrastructure to support new product launches.

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

In addition, the FDA may implement regulatory, policy, or enforcement changes that materially limit our ability and that of our third-party contractors to promote our products to consumers, which could materially impact our business. In September 2025, the FDA stated that it intends to more aggressively enforce requirements for direct-to-consumer, or DTC, drug advertising and sent more than 100 warning or untitled letters to companies for allegedly deceptive prescription drug advertising, which represents a dramatic increase in such actions as compared to prior years. FDA also announced plans to expand its oversight of

digital and social media advertising and to initiate a rulemaking that would call for drug companies to disclose additional safety information in DTC broadcast advertisements. The nature and extent of changes to FDA's regulations and enforcement approach are unclear but may impact pharmaceutical marketing efforts across the industry, including ours, which could in turn impact our sales and operations.

In the future, we may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or as an alternative to our own sales force and distribution systems. To the extent that we enter into co-promotion or other licensing arrangements, our product revenue may be lower than if we directly marketed or sold any approved products. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third parties, which may not be successful and are generally not within our control. If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize any approved products. If we are not successful in commercializing any approved products, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

***The size of the potential market for our product and product candidates is difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for our product or product candidates may be different than our estimates. If the market opportunities for our product or any product candidates we develop are smaller than we believe they are, our potential revenues may be adversely affected, and our business may suffer.***

The potential market opportunities for veligrotug and our product candidates are difficult to estimate and will depend in part on the success of competing therapies and therapeutic approaches. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on estimates. Our estimates of the potential market opportunities and existing market penetration are predicated on many assumptions, which may include industry knowledge and publications, third-party research reports, and other surveys. Although we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain, and their reasonableness has not been assessed by an independent source. These estimates may prove to be incorrect and new studies may change the estimated incidence or prevalence of these diseases. The number of patients in the United States, Europe, and elsewhere may turn out to be lower than expected, and patients may not be amenable to treatment with veligrotug or other products that we may develop in the future. If any of the assumptions proves to be inaccurate, the actual markets for veligrotug or other future products could be smaller than our estimates of the potential market opportunities.

**Risks Related to Our Reliance on Third Parties**

***We rely on third parties to conduct our nonclinical development activities and clinical trials, manufacture our commercial product and 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 maintain our commercial operations and our business could be substantially harmed.***

We have relied upon and plan to continue to rely upon third parties, including CROs and other vendors, to conduct, monitor, manage and support nonclinical and clinical programs. Adding or changing CROs or other vendors 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 and other vendors 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 development. If we or any of our CROs or other vendors fail to comply with applicable and evolving laws, regulations, and guidelines, the results generated in our clinical trials may be deemed insufficient or unreliable, and the FDA, EMA, or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. For example, we are aware of certain instances of non-compliance with GCP regulations. We cannot be assured that our CROs, clinical sites, and other vendors will fully remediate any deficiencies and will meet these requirements on an ongoing basis, or that upon inspection by any regulatory authority, such regulatory authority will determine that efforts, including any of our clinical trials, comply with applicable requirements. Any non-compliance with these laws, regulations and guidelines may negatively impact the integrity of the data collected in our clinical trials and may prevent approval or require us to repeat clinical trials or add patients to ongoing clinical trials, which would be costly and delay the regulatory submission and/or approval process.

If any of our relationships with these third-party CROs or other vendors terminate, we may not be able to enter into arrangements with alternative CROs or other vendors in a timely manner or do so on commercially reasonable terms. In

addition, our CROs may not prioritize our clinical trials relative to those of other customers, and any turnover in personnel or delays in the allocation of CRO employees by the CRO may negatively affect our clinical trials. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, our clinical trials may be delayed or terminated, and we may not be able to meet our current plans with respect to our product candidates. For example, our first in human or early clinical studies for a product candidate may be done at a single site. A disruption of operations at the single site could delay or terminate our clinical trial, and we may not be able to enter into arrangements with alternative CROs in a timely manner or do so on commercially reasonable terms. If this happens, we may not be able to meet our current plans with respect to our product candidates. CROs may also involve higher costs than anticipated, which could negatively affect our financial condition and results of operations.

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 veligrotug or any of our product candidates on a clinical or commercial scale without the use of third-party manufacturers. We rely, and plan to continue to rely, on third-party manufacturers whose responsibilities include purchasing from third-party suppliers the materials necessary to produce our product candidates for our clinical trials and regulatory approval. There are expected to be a limited number of suppliers for the active ingredients and other materials, including devices and device components, that we expect to use to manufacture and deliver our product candidates, including those of our product candidates that are anticipated to be combination products. We may not be able to identify alternative suppliers to prevent a possible disruption of the manufacture of veligrotug for commercial sale or our product candidates for our clinical trials. Although we generally do not expect to begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the trial, any significant delay or discontinuity in the supply of a product candidate, or the active ingredient or other material components in the manufacture or administration of the product candidate, could delay completion of our clinical trials and potential timing for regulatory approval of our product candidates, which would harm our business and results of operations.

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

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

Even minor variations in starting reagents and materials, deviations from normal manufacturing processes, changing a manufacturer, or changing a manufacturing location could result in reduced production yields, product shortages, product defects, manufacturing failure, changes in product characteristics and other supply disruptions. If microbial, viral, or other contaminations are discovered in our product candidates or in any of the manufacturing facilities in which products or other materials are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Any failure or difference 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 commercial or clinical product supplies, including Chinese manufacturer WuXi Biologics (Hong Kong) Limited ("WuXi"), for drug substance and drug product, and other third parties for devices and device components. If we are unable to source these supplies on a timely basis, at sufficient quantities, or at acceptable quality or prices, establish longer-term contracts with our suppliers, or if our third-party manufacturers fail to comply with applicable regulatory requirements, the commercialization of veligrotug and the development and, if approved, commercialization of our other product candidates could be stopped, delayed, or made less profitable.***

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

We do not currently have, nor do we currently plan to establish, the capability to manufacture veligrotug on a commercial scale without the use of third-party manufacturers. Any significant delay or discontinuity in the supply of veligrotug could negatively impact our ability to generate revenues from sales of veligrotug, which would harm our business and results of operations. We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing of all of the product candidates in our pipeline, including those in nonclinical and early clinical research, and our current cost to manufacture our drug products may not be commercially feasible. Additionally, the actual cost to manufacture our product candidates could materially and adversely affect the commercial viability of our product candidates. As a result, we may never be able to develop a commercially viable product.

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

- We may be unable to identify additional manufacturers of our product candidates, including combination product candidates, on acceptable terms or at all.
- Our third-party manufacturers might be unable to timely formulate and manufacture our products or produce the quantity and quality required to meet our clinical and commercial needs.
- Contract manufacturers may not be able to execute our manufacturing process or procedures appropriately.
- Our future third-party manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our commercial products.
- Our reliance on single-sourced manufacturing with our CDMOs increases the risk that any problems or delays with a CDMO could materially, negatively affect the development of our product candidates or their commercialization.
- Manufacturers are subject to ongoing periodic unannounced inspection by the FDA, applicable foreign regulatory authorities and some state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.
- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates.
- Our third-party manufacturers could breach or terminate their agreement with us.

- Our third-party manufacturers' performance, available capacity and ability to manufacture clinical or commercial products may be impacted by mergers and/or acquisitions.
- We or our third-party manufacturers may experience labor disputes or shortages, raw material shortages or manufacturing capacity shortages, including from the effects of health emergencies (such as novel viruses or pandemics) and natural disasters.
- We and our third-party manufacturers may be impacted by global conflicts, including any potential conflict involving China and Taiwan, and any resulting trade sanctions or regulatory actions.
- We are heavily reliant on third-party manufacturing operations in China, and any regional or geopolitical disruption, including as a result of the escalation of tariffs or other trade restrictions, could negatively impact our clinical trials and development or commercialization of our product candidates, which would harm our business.
- Foreign third-party manufacturers may be subject to U.S. legislation, regulatory actions, or investigations, including legislation similar to the BIOSECURE Act, trade restrictions and other U.S. or foreign regulatory requirements, which could increase the cost or reduce the supply of material available to us, delay or prevent the procurement or supply of such material, delay clinical trials, delay commercial launch, affect the ability to transfer to different manufacturers or have an adverse effect on our ability to secure commitments from governments to purchase our potential therapies.

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

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

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

The manufacture of drug products, including combination products that comprise a biological drug product and a device, is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques, process controls and product testing methods. Manufacturers of medical products often encounter difficulties in production, particularly in scaling up and validating initial production and absence of contamination. These problems include difficulties with raw material supply, production costs and yields, quality control, stability of the product, quality assurance testing, operator error, shortages of qualified personnel, logistical problems or delays encountered when using multiple sites for manufacturing and testing, as well as compliance with strictly enforced federal, state, and foreign regulations. These problems may be more likely, or worse, in cases where the product candidates being manufactured are combination products, like certain of our product candidates, due to the increased complexity in their manufacture and associated supply chain. If we cannot source sufficient materials, we may stock out, fail to meet patient demand, experience regulatory delays or be forced to effect a recall, any of which could adversely affect our business and financial condition. 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. Failure to effectively manufacture material with sufficient stability could materially affect our ability to commercialize our product candidates. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes, shortages, including from the effects of health emergencies (such as novel viruses or pandemics), natural disasters, or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our product candidates to patients or subjects in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the initiation or completion of clinical trials, increase the costs associated with

initiating or maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

We currently rely on WuXi and other CDMOs to develop and manufacture veligrotug and our product candidates, and will likely continue to rely on them in the future. There has been increased governmental focus in the U.S. on the role of Chinese companies in the life sciences industry. In December 2025, the BIOSECURE Act was enacted into law as part of the National Defense Authorization Act for FY 2026. The BIOSECURE Act prohibits U.S. federal executive agencies from contracting with any entity where the biotechnology equipment or services of a "biotechnology company of concern" would be used in the performance of that contract. Generally, a "biotechnology company of concern" is a biotechnology company that is subject to the jurisdiction, direction, control, or operates on behalf of a foreign adversary's government and poses a risk to the national security of the U.S. The BIOSECURE Act has the potential to severely restrict our ability to purchase services or products from, or otherwise collaborate with, certain Chinese "biotechnology companies of concern" without losing the ability to contract with, or otherwise receive funding from, the U.S. government. We do business with companies in China, including WuXi, and it is possible some of our contractual counterparties could be impacted by the legislation described above in the future and alternative arrangements may need to be made. While WuXi is not currently a biotechnology company of concern under the BIOSECURE Act, they may be deemed a biotechnology company of concern in the future. For example, in June 2026, WuXi AppTec was 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), and the Department of Defense may add additional companies to the Chinese Military Companies List in the future. Our reliance on Chinese-based contract research organizations, such as WuXi, may also cause us to face additional risks due to geopolitical tensions between the U.S. and China and related legal and regulatory restrictions and requirements, including measures directly affecting WuXi.

We currently rely on certain foreign manufacturers to manufacture our drug substance and drug product. The current presidential administration imposed increased tariffs, including on pharmaceuticals, though the full effect that any such actions would have on us or our industry remains unclear. Any unfavorable tariffs will make it more difficult for us to manufacture veligrotug or our product candidates, increase the cost of, and affect the demand for, veligrotug or our product candidates, if approved, which could have an adverse effect on our business.

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

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

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

If it becomes necessary to shift our operations away from reliance upon WuXi or other non-U.S. based CROs and CDMOs, we will need to find suitable replacements for their services. We may encounter significant difficulty in finding suitable replacement partners and vendors, difficulties in transferring our programs or processes from one CRO or CDMO to another, and such parties may have limited capacity due to the influx of demand from other companies, including other biotechnology and biopharmaceutical companies in a position similar to ours. Inability to find suitable replacements for these necessary services could increase the cost or reduce or eliminate the supply of material available to us, delay or prevent the procurement or supply of such material, delay or impact the availability of our product candidates, delay or impact clinical trials, availability

of commercial supply, or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies. Any of the foregoing outcomes could adversely affect our financial condition and business prospects.

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

We have entered into collaborations to develop and commercialize products containing veligrotug and elegrobart with Zenas BioPharma in Greater China and Kissei Pharmaceuticals in Japan. We may enter into additional collaborations or partnerships for these product candidates as well as future product candidates. For our current collaborations, there is no guarantee that the collaboration will be successful and no guarantee if we are successful in entering into additional future collaborations with respect to the development and/or commercialization of one or more product candidates. Collaborations may pose a number of risks, including:

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

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

**Risks Related to Our Intellectual Property**

***We rely on patent rights, trade secret protections and confidentiality agreements to protect the intellectual property related to our products, 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, products and product candidates. Our success depends in large part on our ability to obtain regulatory exclusivity and our and our licensors' ability to maintain patent and other intellectual property protection in the U.S. and in other countries with respect to our proprietary technologies, products and product candidates. Regulatory exclusivity rules may be amended by legislative action, such as through the recently adopted "Pharma Package" in the EU in December 2025.

We have sought to protect our proprietary position by filing and licensing the rights to patent applications in the U.S. and abroad related to our technologies, products 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 products or product candidates in the U.S. or in other foreign countries. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our products and 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 products and product candidates, including compositions of matter and their methods of use. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent, or whether any issued patents will be found invalid and unenforceable or unpatentable following a challenge by third parties. Any successful post-grant review proceeding or litigation with respect to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

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

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

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

Patent term extensions ("PTEs") under the Hatch-Waxman Act in the U.S. and under supplementary protection certificates in Europe may be available to extend the patent exclusivity terms of our products and 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 products or product candidates for an extended period after regulatory approval, 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 products or product candidates, our business and results of operations will be adversely affected.

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

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

The USPTO has issued subject matter eligibility guidance instructing USPTO examiners on the ramifications of the Supreme Court rulings in Mayo Collaborative Services v. Prometheus Laboratories, Inc. and Association for Molecular Pathology v.

Myriad Genetics, Inc., and applied the Myriad ruling to natural products and principles including all naturally occurring molecules. In addition, the USPTO continues to provide updates to its guidance. The USPTO guidance may make it impossible for us to obtain similar patent claims in future patent applications. Currently, our patent portfolio contains claims of various types and scope, including methods of medical treatment. The presence of varying types of claims in our patent portfolio significantly reduces, but may not eliminate, our exposure to potential validity challenges.

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

An important change introduced by the Leahy-Smith Act is that, as of March 16, 2013, the U.S. transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either: (i) file any patent application related to our products or 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 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 impact on our business prospects in Russia. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have predominately primary place of business or profit-making activities in the U.S. and other countries that Russia has deemed unfriendly without consent or compensation. Consequently, we would not be able to prevent third parties from practicing its inventions in Russia or from selling or importing products made using its inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, operations and prospects may be adversely affected.

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

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

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

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

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

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

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

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

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

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

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

We currently have rights to certain intellectual property, through licenses from third parties and under technology and patents that we do not own, to develop and commercialize our products and product candidates. Because our programs may require the use of proprietary rights held by third parties, the growth of our business depends 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 products or 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 products or product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license their patent rights to us. Even if we are able to license or acquire third-party intellectual property rights that are necessary for our product candidates, there can be no assurance that they will be available on favorable terms.

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

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

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

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

The USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent prosecution and post grant or issuance. We employ reputable law firms and other professionals to help us comply. Additionally, periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or patent applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or patent applications. We rely on our outside counsel or our agents to pay these fees when due. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to

official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If such an event were to occur, it could have a material adverse effect on our business. In addition, we may be responsible for the payment of patent fees for patent rights that we license from third parties. If any licensor of these patents does not itself elect to make these payments, and we fail to do so, we may be liable to the licensor for any costs and consequences of any resulting loss of patent rights. If we or our existing or future licensors fail to maintain the patents and patent applications covering our products or product candidates, our competitors might be able to enter the market, which would have an adverse effect on our business.

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

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

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

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

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

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

***We may be subject to claims that our employees, consultants, or independent contractors are failing to comply with obligations to former employers or other third parties, including having wrongfully used or disclosed confidential information of former employers or third parties, that our employees have wrongfully used or disclosed alleged trade secrets of their former employers or third parties, or in connection with claims that our employees, consultants, or independent contractors are soliciting employees or business from prior 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. We may also be subject to claims in connection with claims that our employees, consultants, or independent contractors are otherwise failing to comply with obligations to former employers or other 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, or our employees' ability to perform their jobs could be limited for a period of time, 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, which could adversely impact our business.

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

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arising from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

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

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

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

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

The Biologics Price Competition and Innovation Act of 2010 (the "BPCIA") was enacted as part of the Affordable Care Act of 2010 (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 veligrotug and any of the product candidates we develop that is approved in the U.S. as a biological product under a BLA should qualify for the current 12-year period of exclusivity provided by law. However, there is a risk that this exclusivity could be shortened in the future due to congressional action or otherwise, that the FDA will not consider approval of a product candidate to be a "first licensure" that gives rise to an exclusivity period, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

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

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

We may seek orphan drug designation for veligrotug in indications other than TED and/or territories outside of the U.S. or for our other product candidates in various indications and/or territories subject to meeting the local requirements for orphan designation.

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

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

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

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

by data from our clinical development program. Fast Track or Breakthrough Therapy designation alone does not guarantee qualification for the FDA's priority review procedures.

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

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

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

***Any product candidates for which we may obtain approval would be subject to extensive and ongoing regulatory oversight. If we fail to comply with continuing U.S. and foreign requirements, any approvals we may receive for our product candidates could be limited or withdrawn, we could be subject to other penalties, and in any such case our business would be seriously harmed.***

Veligrotug is, and any additional product candidates for which we may ultimately receive marketing authorization would be, subject to ongoing regulatory requirements governing the testing, manufacturing, labeling, packaging, storage, advertising, promotion, sale, distribution, import, export, recordkeeping, and reporting. Ongoing FDA requirements include, among other things, submission of safety and other post-marketing information and reports, registration and listing, continued compliance with cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians, and GCP requirements for any clinical trials that we conduct post-approval. In addition, we intend to seek approval to market veligrotug and our product candidates in jurisdictions outside of the U.S., and therefore would also be subject to, and must comply with, regulatory requirements in those jurisdictions.

Any product candidates for which we may receive approval, including veligrotug, will be subject to continuing regulatory oversight following approval, including the review of adverse drug experiences and clinical results that are reported after our drug products are made commercially available. This includes results from any post-marketing studies or surveillance to monitor the safety and efficacy of our approved products or other products required as a condition of approval or otherwise agreed to by us. Products are more widely used by patients once approval has been obtained and therefore side effects and other problems may be observed after approval that were not seen or anticipated, or were not as prevalent or severe, during pre-

approval clinical trials or nonclinical studies. The subsequent discovery of previously unknown or underestimated problems with a product could result in:

- sales of our approved products may be lower than originally anticipated;
- regulatory approvals for our approved products may be restricted or withdrawn;
- we may decide, or be required, to send product warning letters or field alerts to physicians, pharmacists and hospitals;
- additional nonclinical studies or clinical trials, changes in labeling, adoption of a REMS plan, or changes to manufacturing processes, specifications and/or facilities may be required; and/or
- government investigations or lawsuits, including class action suits, may be brought against us.

Any of the above occurrences could reduce or eliminate sales of our approved products, increase our expenses and impair our ability to successfully commercialize one or more of these products.

If we or our collaborators, CDMOs or other service providers fail to comply with applicable continuing regulatory requirements in the U.S. or a foreign jurisdiction in which we seek to market our products, we or they may be subject to, among other things, fines, warning or untitled letters, holds on clinical trials, refusal by the FDA or foreign regulatory authorities to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, refusal to permit the import or export of products, operating restrictions, fines, injunctions, civil penalties and criminal prosecution.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any product candidates for which we may obtain approval and any product candidates we may develop and adversely affect our business, financial condition, results of operations and prospects.

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

In the U.S., there have been and continue to be a number of executive, legislative, and regulatory initiatives to contain healthcare costs and reexamine drug pricing and payment models. Heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products has resulted in several recent Congressional inquiries, and proposed and enacted federal and state legislation and executive initiatives designed to, among other things, bring more transparency to product pricing, and reform government program reimbursement methodologies for products. For example, in March 2010, the ACA was passed, which was intended to substantially change the way healthcare is financed by both governmental and private insurers, and significantly impact the U.S. pharmaceutical industry. In 2022, Congress passed the Inflation Reduction Act of 2022 (the "IRA"), which, among other provisions, included a number of changes intended to address rising prescription drug prices in Medicare Parts B and D. These changes included caps on Medicare Part D out-of-pocket costs, Medicare Part B and Part D drug price inflation rebates, a new Medicare Part D manufacturer discount drug program (replacing the previous coverage gap discount program) and a drug price negotiation program for certain high-spend Medicare Part B and D drugs. The IRA has had and will likely continue to have a significant impact on the pharmaceutical industry. Some legal challenges to the IRA remain underway.

Drug pricing and payment is a current focus of significant activity. In 2025, President Trump issued two Executive Orders with multiple directives aimed at lowering drug prices, including refining the Medicare drug price negotiation program established by the IRA; accelerating competition for high-cost prescription drugs; facilitating drug importation; and identifying most-favored-nation target pricing for prescription drugs and making such pricing available to government health benefit programs and patients. In the wake of these Executive Orders and related executive initiatives, a number of pharmaceutical manufacturers have announced direct-to-consumer offerings with discounted prices and/or reached agreement with the federal government regarding pricing for drugs, including prices for Medicaid drugs and newly launched products. A website sponsored by the federal government offering pharmaceutical direct-to-consumer channels was launched in February 2026. Federal agencies are developing new Medicare and Medicaid drug pricing pilot programs. Many of these reform initiatives would require additional legal and/or administrative action to implement and may be subject to legal challenge. There have also been other reform efforts affecting access to healthcare or funding of healthcare as well as more general actions affecting federal budgets and tariffs. There is uncertainty regarding the nature or impact of any drug, broader healthcare, or other reform implemented at the federal or state level, and the extent to which any such action will be subject to legal challenges, including litigation, or other

challenges. It is unclear how any such healthcare reform measures will impact our business. Ongoing efforts to contain or reduce costs of healthcare and/or impose price controls may adversely affect the demand for our products, our revenues, and our ability to achieve or maintain profitability.

***We are subject, directly or indirectly, to a wide range of domestic and foreign healthcare and other 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 are subject to a wide range of domestic and foreign laws, including fraud and abuse laws, such as the federal Anti-Kickback Statute, the federal civil False Claims Act, and, the UK Bribery Act 2010, privacy laws, such as Physician Payments Sunshine Act, the European General Data Protection Regulation 2016/679, and other regulations. These laws may impact, among other things, our interactions with healthcare professionals and patients, and influence our proposed promotional activities. In addition, we may be required to adopt certain compliance standards and may be required to certify to them. Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation, and may make it challenging for us to ensure compliance.

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 our obligations under the Medicaid Drug Rebate program, other governmental pricing or reporting programs, including state pricing reporting requirements, we could be subject to penalties and sanctions, which could have a material adverse effect on our business, financial condition, results of operations, and future prospects.***

We participate in the Medicaid Drug Rebate program, the Public Health Service's 340B program, the VA Federal Supply Schedule pricing program, the Tricare Retail Pharmacy Program, and particular other federal and state government pricing programs. Such programs often require us to provide discounts and/or pay rebates to certain government payors and/or private purchasers. These programs may require participating drug manufacturers to report product and pricing data that determine the discounts and/or rebates available through them. Pricing and rebate calculations vary across such products and programs, are complex, and are often subject to interpretation by the government, which interpretation can change and evolve over time. If we become aware of an inaccuracy in our reported product or pricing data, we are generally obligated to resubmit our reporting and correct the federal program discounts and/or rebates accordingly. Any determination by governmental agencies that we have failed to comply with our reporting and payment obligations could subject us to penalties and sanctions, which could have a material adverse effect on our business, financial condition, results of operations, and future prospects.

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

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

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

We may collect, use, transfer, or otherwise process proprietary, confidential, and sensitive information, including personal information and health-related data, which subjects us to numerous evolving and complex data privacy and security obligations, including various laws, regulations, guidance, and industry standards. Regulation of personal information processing is evolving, as federal, state, and foreign governments continue to adopt new, or modify existing, laws and regulations addressing data privacy and security, and the collection, processing, storage, transfer, and use of such data. We, our collaborators, and our service providers may be subject to current, new, or modified federal, state, and foreign data protection laws and regulations (e.g., laws and regulations that address data privacy and data security, including, without limitation, health data). These new or proposed laws and regulations are subject to differing interpretations and may be inconsistent among jurisdictions, and guidance on implementation and compliance practices is 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.

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

Outside of the U.S., data protection laws, including the GDPR, which also forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018, and as amended by the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019 (SI 2019/419) ("UK GDPR"), also apply to some of our operations. The GDPR and UK GDPR increase our obligations with respect to the processing of personal data in relation to clinical trials conducted in the member states of the EEA and the UK, including by expanding the definition of personal data to include coded (pseudonymized) data and requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators. In addition, the GDPR and the UK GDPR increase the scrutiny that clinical trial sites located in the EEA and UK should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection. The GDPR and UK GDPR impose substantial fines for breaches of data protection requirements, which can be up to four percent of global revenue or 20 million Euros (£17.5 million in the UK), whichever is greater, and they also confer a private right of action on data subjects for breaches of data protection requirements. Compliance with these laws is a rigorous and time-intensive process that requires review and updates

that may increase our cost of doing business, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm in connection with our European and UK activities. Other governmental authorities around the world are considering and, in some cases, have enacted, similar privacy and data security laws.

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

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

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

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

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

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

**Risks Related to Our Business Operations**

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

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends greatly upon our ability to attract and retain highly qualified managerial, scientific, medical and commercial 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.

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

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

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

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

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

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions at various points over the last few decades, including, among other things, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates, increased trade tariffs and trade disputes with other countries, and uncertainty about economic stability. The Federal Reserve has raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates,

coupled with reduced government spending and volatility in financial markets, and the potential for increased U.S. trade tariffs and trade disputes with other countries may increase economic uncertainty, increase operating costs, and affect consumer spending. Similarly, the ongoing global military conflicts 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.

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

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

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

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

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

In addition, security incidents or breaches affecting us or our current or future collaborators or third-party service providers could result in the unauthorized access to, or disclosure or loss of information, including information that we process. This, in

turn, could require notification under applicable data privacy regulations or contracts, and could lead to financial losses, litigation, governmental audits, investigations, fines, penalties, and other possible liability, damage our relationships with our collaborators, trigger indemnification and other contractual obligations, cause us to incur investigation, mitigation and remediation expenses, have a negative impact on our ability to conduct clinical trials, and cause reputational damage. For example, the loss of clinical trial data for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

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

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

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

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

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

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

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

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

We are subject to taxation in numerous U.S. states and territories and non-U.S. jurisdictions. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements,

we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors including the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes, and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

**Risks Related to Ownership of our Common Stock**

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

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

In addition, the Certificate of Designation of our Series A convertible preferred stock may delay or prevent a change in control of our company. At any time while at least 30% of the originally issued Series A convertible preferred stock remains issued and outstanding, we may not consummate a Fundamental Transaction (as defined in the Certificate of Designation of the Series A convertible preferred stock) or any merger or consolidation of the Company with or into another entity or any stock sale to, or other business combination in which the stockholders of the Company immediately before such transaction do not hold at least a majority of the capital stock of the Company immediately after such transaction, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series A convertible preferred stock. As of September 30, 2026, all of the then outstanding shares of Series A convertible preferred stock were held by entities affiliated with one stockholder. This provision of the Certificate of Designation may make it more difficult for us to enter into any of the aforementioned transactions.

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

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

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

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

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

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

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

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

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

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

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

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

**General Risk Factors**

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

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

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

- changes in the possible market size, or perceived market size, for our product candidates;
- failure to meet or exceed analyst revenue estimates for veligrotug or any of our future products, if approved;
- 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 our business, we and our directors and officers may become involved in various legal proceedings, including commercial, employment, intellectual property, and other litigation and claims, as well as governmental and other regulatory investigations and proceedings. Such matters can be time-consuming, divert management's attention and resources and cause us to incur significant expenses. Litigation is inherently unpredictable and 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.

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

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

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

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION**

*Rule 10b5-1 Trading Arrangements*

During the three months ended September 30, 2026, the following directors or officers of the Company adopted or terminated a "Rule 10b5-1 trading arrangement," as defined in Item 408 of Regulation S-K:

| Name and Title | Plan Action | Plan Adoption Date | Expiration Date | Number of Shares to be Sold under Plan |
|---|---|---|---|---|
| Thomas Beetham, Chief Operating Officer | Adoption | 8/12/2026 | 12/17/2027 | 60,000 |
| Seth Harmon, Chief Financial Officer | Adoption | 8/21/2026 | 8/18/2027 | 67,574 |
| Stephen Mahoney, Chief Executive Officer | Adoption | 8/12/2026 | 6/15/2027 | 70,000 |
| Jennifer Tousignant, Chief Legal Officer | Adoption | 8/19/2026 | 8/31/2027 | 21,132* |

*In addition to the listed number of shares to be sold, the Rule 10b5-1 trading arrangement also includes an undetermined number of shares that may be purchased by Ms. Tousignant under the Company's 2025 ESPP.

During the three months ended September 30, 2026, none of the Company's officers or directors adopted or terminated any "non-Rule 10b5-1 trading arrangement," as 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 | |
| 10.1 | Seventh Amendment to Lease, dated as of September 25, 2026, between Watch City Ventures MT LLC and Viridian Therapeutics, Inc. | | | | x |
| 31.1 | Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities 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 Exchange Act, as amended. | | | | x |
| 32.1* | Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | | | | x |
| 101.INS | XBRL Instance Document | | | | x |
| 101.SCH | XBRL Taxonomy Extension Schema Document | | | | x |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document | | | | x |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document | | | | x |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document | | | | x |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document | | | | x |
| 104 | Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101) | | | | x |

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

x Filed/furnished herewith.

**SIGNATURES**

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

**VIRIDIAN THERAPEUTICS, INC.**

Date: November 4, 2026

By: /s/ Stephen Mahoney

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

Date: November 4, 2026

By: /s/ Seth Harmon

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

# SEVENTH AMENDMENT TO LEASE

This **SEVENTH AMENDMENT TO LEASE** (this "**Amendment**") is made as of the 25th day of September, 2026 (the "**Effective Date**") by and between **WATCH CITY VENTURES MT LL**C, a Massachusetts limited liability company, having an address at c/o Berkeley Investments, Inc., One International Place, Suite 1120, Boston, Massachusetts 02110 ("**Landlord**"), and **VIRIDIAN THERAPEUTICS, INC.**, a Delaware corporation, having an address at 221 Crescent Street, Suite 103A, Waltham, Massachusetts 02453 ("**Tenant**"), as successor in interest to Viridian, LLC, a Massachusetts limited liability company ("**Viridian LLC**").

**REFERENCE** is made to a certain Lease, dated January 13, 2020 by and between Landlord and Viridian LLC as Tenant's predecessor in interest, pursuant to that certain Assignment and Consent Agreement entered into between the Landlord, Tenant and Viridian, LLC, dated September 27, 2020, as amended by that certain First Amendment to Lease dated July 6, 2021, as further amended by that certain Second Amendment to Lease dated April 13, 2022, as further amended by that certain Third Amendment to Lease dated July 29, 2022, as further amended by that certain Fourth Amendment to Lease dated April, 2024, as further amended by that certain Fifth Amendment to Lease dated September 19, 2024, and as further amended by that certain Sixth Amendment to Lease dated September 8, 2025 (as amended, the "**Lease**") for certain premises consisting of **(a)** approximately 10,427 rentable square feet on the first (1st) floor of Buildings #18 and #19, as shown as Suite 103A on the plan attached to the Lease as Exhibit A-1.4 (the "**Suite 103A Premises**"), **(b)** approximately 2,788 rentable square feet on the first (1st) floor of Building #20, as shown as Suite 103B on the plan attached to the Lease as Exhibit A-1.5 (the "**Suite 103B Premises**"), **(c)** approximately 2,737 rentable square feet located on the first (1st) floor of Building #4 , and shown as Suite 110 on the plan attached to the Lease as Exhibit A-1.7 (the "**Suite 110 Premises**"), and **(d)** approximately 2,503 rentable square feet located on the first (1st) floor of Building #4, and shown as Suite #111 on the plan attached to the Lease as Exhibit A-1.7 (the "**Suite 111 Premises**" and together with the Suite 103A Premises, the Suite 103B Premises, and Suite 110 Premises, collectively, the "**Original Premises**").

**WHEREAS**, Tenant has requested, and Landlord has agreed, to lease an additional approximately 12,167 rentable square feet on the fourth (4th) floors of Buildings #4, #21, and #25, and more particularly shown as Suite 403 on the plan attached hereto as **Exhibit A-1.9** (the "**Suite 403 Premises**" or the "**New Premises**");

**WHEREAS**, the rent commencement date for the New Premises shall be the later to occur of (a) delivery of the New Premises to Tenant, and (b) October 1, 2026 (the "**Suite 403 Premises Rent Commencement Date**"), subject to the Suite 403 Base Rent Abatement described below;

**WHEREAS,** Tenant has agreed to accept the Suite 403 Premises in its current "as is" condition, and Landlord shall not be obligated to construct any improvements on behalf of Tenant or to alter, remodel, improve, renovate, repair or decorate the Suite 403 Premises, the Building, or any part thereof, or to provide any allowance for such purposes, except with respect to the Tenant New Premises Phase I Improvement Allowance (defined below);

**WHEREAS**, Tenant has requested and Landlord has agreed to grant to Tenant an ongoing right of first refusal solely with respect to space located on the fourth (4th) floor of Building #21, #24, and #25 (the "**4th Floor ROFR Expansion Premises**"), subject to the rights of existing tenants or occupants at the Watch Factory Complex to lease all or any portion of the 4th Floor ROFR Expansion Premises, including without limitation, the pre-existing expansion rights of existing tenants at the Watch Factory Complex to lease all

or any portion of the 4th Floor ROFR Expansion Premises, and all in accordance with the terms of this Amendment;

**WHEREAS**, the current Term of the Lease is scheduled to expire as of July 31, 2029, and Tenant has requested and Landlord has agreed to continue to recognize Tenant's existing right to extend the Term of the Lease for one (1) period of three (3) years, commencing on August 1, 2029, all in accordance with the terms of Section 2.6 of the Lease, as amended by the Fourth Amendment to Lease; and

**WHEREAS**, Landlord and Tenant desire to amend the Lease to (i) add the New Premises to the Premises, (ii) adjust the Base Rent, (iii) adjust the number of parking spaces available to Tenant, (iv) adjust Tenant's Proportionate Share, (v) provide Tenant with an allowance to complete the Tenant's New Premises Phase I Work (defined below), and (vi) provide Tenant with an ongoing right of first refusal with respect to the 4th Floor ROFR Expansion Premises (defined below), all in accordance with the terms and provisions as hereinafter set forth.

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

1. Capitalized terms used herein and not otherwise defined shall have the meaning ascribed thereto in the Lease.

2. The following definitions shall be added to Article 1 (Definitions) of the Lease:

***Suite 403 Premises***: Approximately 12,167 rentable square feet on the fourth (4th) floors of Buildings #4, #21, and #25, and more particularly shown as Suite 403 on the plan attached hereto as **Exhibit A-1.9**.

***Suite 403 Premises Commencement Date ("S403PCD")***: The Suite 403 Premises Delivery Date. See Section 2.1.8 below.

***Suite 403 Premises Rent Commencement Date ("S403PRCD")***: The later to occur of (a) the Suite 403 Premises Delivery Date, or (b) October 1, 2026, subject to the Suite 403 Base Rent Abatement described below.

***Suite 403 Premises Base Rent***:

| Period | RSF Paying Rent On | Base Rent | Yearly Base Rent | Monthly Base Rent |
|---|---|---|---|---|
| | | | | |
| S403PRCD – 9/30/2027 | 12,167 | $44.00/RSF | $535,348.00 | $44,612.33* |
| 10/1/2027 – 9/30/2028 | 12,167 | $45.00/RSF | $547,515.00 | $45,626.25 |
| 10/1/2028 – 7/31/2029 (ten (10) months) | 12,167 | $46.00/RSF | $559,682.00 | $46,640.17 |

* The monthly Suite 403 Premises Base Rent for Month 1, Month 2, and Month 4 of the Suite 403 Premises Term is hereby abated in full (the "**Suite 403 Base Rent Abatement**"). The Suite 403 Base Rent Abatement shall not apply to Tenant's obligation to pay Base Rent for the Original Premises or Additional Rent for the entire Premises as set forth in the Lease, as specifically modified hereby. By way of example only, in the event the Suite 403

Premises Rent Commencement Date occurs on October 1, 2026, the Suite 403 Base Rent Abatement shall apply to the months of October and November, 2026, and January, 2027.

***Suite 403 Premises Term:*** The period commencing on the Suite 403 Premises Commencement Date and ending at 11:59 P.M. on the Termination Date, unless sooner terminated or extended as provided in this Lease.

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

"**(a)** with respect to the Suite 103A Premises and the Suite 103B Premises, Tenant's Proportionate Share (as defined below) of the cost of any **(i)** reasonable and customary operating expenses for the Buildings, the Common Areas and the Property (as defined below) as reasonably determined by Landlord (including, without limitation, gas, heat, air conditioning, electricity, water, sewer, cleaning, trash collection, snow removal and sanding, and insurance, as applicable) (the "**Operating Expenses**") in excess of the Operating Expenses for Calendar Year 2024; and **(ii)** real estate taxes for the Property (as defined below) and the Buildings in excess of the real estate taxes imposed against the Property and the Buildings for Fiscal Year 2024 (July 1, 2023 – June 30, 2024); **(b)** with respect to the Suite 110 Premises and the Suite 111 Premises, Tenant's Proportionate Share (as defined below) of the cost of any **(i)** Operating Expenses in excess of the Operating Expenses for Calendar Year 2026; and **(ii)** real estate taxes for the Property (as defined below) and the Buildings in excess of the real estate taxes imposed against the Property and the Buildings for Fiscal Year 2026 (July 1, 2025 – June 30, 2026); and **(c)** with respect to the Suite 403 Premises, Tenant's Proportionate Share (as defined below) of the cost of any **(i)** Operating Expenses in excess of the Operating Expenses for Calendar Year 2026; and **(ii)** real estate taxes for the Property (as defined below) and the Buildings in excess of the real estate taxes imposed against the Property and the Buildings for Fiscal Year 2027 (July 1, 2026 – June 30, 2027)."

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

***Lease Year***: With respect to the Suite 103A Premises, the first "Lease Year" shall be the period commencing on the Suite 103A Premises Commencement Date and ending on the last day of the calendar month in which the first anniversary of the Suite 103A Premises Rent Commencement Date occurs if the Suite 103A Premises Rent Commencement Date is other than the first day of a calendar month. If the Suite 103A Premises Rent Commencement Date is the first day of a calendar month, then the first "Lease Year" with respect to the Suite 103A Premises shall be the period commencing on the Suite 103A Premises Commencement Date and ending on the day (last of the calendar month) immediately prior to the first (1st) anniversary of the Suite 103A Premises Rent Commencement Date. With respect to the Suite 103B Premises, the first "Lease Year" shall be the period commencing on the Suite 103B Premises Commencement Date and ending on the last day of the calendar month in which the first anniversary of the Suite 103B Premises Rent Commencement Date occurs if the Suite 103B Premises Rent Commencement Date is other than the first day of a calendar month. If the Suite 103B Premises Rent Commencement Date is the first day of a calendar month, then the first "Lease Year" with respect to the Suite 103B Premises shall be the period commencing on the Suite 103B Premises Commencement Date and ending on the day (last of the calendar month) immediately prior to the first (1st) anniversary of the Suite 103B Premises Rent Commencement Date. With respect to the Suite 110 Premises, the first "Lease Year" shall be the period commencing on the Suite 110 Premises Commencement Date and ending on July 31, 2026. With respect to the Suite 111 Premises, the first "Lease Year" shall be the period commencing on the Suite 111 Premises Commencement Date and ending on July 31,

2026, it being the intention of the parties that the first "Lease Year" with respect to both the Suite 110 Premises and the Suite 111 Premises, be co-terminus. With respect to the Suite 403 Premises, the first "Lease Year" shall be the period commencing on the Suite 403 Premises Commencement Date and ending on the last day of the calendar month in which the first anniversary of the Suite 403 Premises Rent Commencement Date occurs if the Suite 403 Premises Rent Commencement Date is other than the first day of a calendar month. If the Suite 403 Premises Rent Commencement Date is the first day of a calendar month, then the first "Lease Year" with respect to the Suite 403 Premises shall be the period commencing on the Suite 403 Premises Commencement Date and ending on the day (last of the calendar month) immediately prior to the first (1st) anniversary of the Suite 403 Premises Rent Commencement Date. In either case of the Suite 103A Premises, the Suite 103B Premises, the Suite 110 Premises, the Suite 111 Premises, or the Suite 403 Premises, each succeeding twelve (12) month period thereafter, as the case may be, shall be a Lease Year, with the final Lease Year of each of the Suite 103A Premises, the Suite 103B Premises, the Suite 110 Premises, the Suite 111 Premises, and the Suite 403 Premises, all ending on the Termination Date.

***Parking***: From and after the date hereof, Tenant shall have the non-exclusive right, in common with Landlord and others, to use and occupy during the remainder of the Term up to one hundred two (102) parking spaces in the parking lots serving the Buildings as shown on **Exhibit A-2**, attached hereto, ("**Parking Facilities**"), all at no additional fee or cost, but subject to the reasonable rules and regulations established by Landlord from time to time of uniform application to all users, and of which Tenant has received prior notice. Tenant acknowledges and agrees that the forty (40) parking spaces allocable to the Suite 403 Premises, shall be located in the Cherry Street Lot of the Parking Facilities. Landlord reserves the right in its sole discretion, from time to time, to modify, reconfigure, or relocate the Parking Facilities within reasonable proximity to the Parking Facilities as shown on **Exhibit A-2** attached hereto.

***Security Deposit:*** Landlord is currently holding a security deposit in the amount of **$73,308.00**, as provided in the Third Amendment to Lease. Said deposit shall continue to be held by Landlord in accordance with the Lease.

***Tenant's Proportionate Share***: **(a)** with respect to the Suite 103A Premises during the Suite 103A Premises Term, Six and Forty-Four One Hundredths percent (6.44%), **(b)** with respect to the Suite 103B Premises during the Suite 103B Premises Term, One and Seventy-Two One Hundredths percent (1.72%), **(c)** with respect to the Suite 110 Premises during the Suite 110 Premises Term, One and Sixty-Nine One Hundredths percent (1.69%), **(d)** with respect to the Suite 111 Premises during the Suite 111 Premises Term, One and Fifty-Five One Hundredths percent (1.55%), and (e) with respect to the Suite 403 Premises during the Suite 403 Premises Term, Seven and Fifty-Two One Hundredths percent (7.52%) which percentages have been determined by dividing the total number of rentable square feet in the Suite 103A Premises, Suite 103B Premises, the Suite 110 Premises, the Suite 111 Premises, and the Suite 403 Premises respectively, by the Total Building Rentable Square Footage (161,790) and multiplying the resulting quotient by one hundred (100).

***Term***: **(a)** with respect to the Suite 103A Premises, the period commencing on the Suite 103A Premises Commencement Date and ending at 11:59 p.m. on the Termination Date, **(b)** with respect to the Suite 103B Premises, the period commencing on the Suite 103B Premises Commencement Date and ending at 11:59 p.m. on the Termination Date, **(c)** with respect to the Suite 110 Premises, the period commencing on the Suite 110 Premises Commencement Date and ending at 11:59 p.m. on the Termination Date, **(d)** with respect to the Suite 111 Premises, the period commencing on the Suite 111 Premises Commencement Date and ending at 11:59 p.m. on the Termination Date, and **(e)** with respect to the Suite 403 Premises, the period commencing on the

Suite 403 Premises Commencement Date and ending at 11:59 p.m. on the Termination Date, it being the intention of the parties that the Term with respect to the Suite 103A Premises, the Suite 103B Premises, the Suite 110 Premises, the Suite 111 Premises, and the Suite 403 Premises, be co-terminus.

5. The following shall be added as new Section 2.1.8:

**2.1.8 Suite 403 Premises**: Landlord hereby leases to Tenant the Suite 403 Premises for the Suite 403 Premises Term, subject to the terms and conditions set forth herein. For the purposes of this Lease, the "**Suite 403 Premises Delivery Date**" shall be deemed to have occurred on the later to occur of (a) the full execution and delivery of this Amendment, and (b) the date Landlord has made the Suite 403 Premises available to Tenant. Tenant acknowledges that the term of the lease with Landlord's existing tenant occupying the Suite 403 Premises, ConnectRN, Inc. ("**ConnectRN**") is scheduled to expire as of September 30, 2026 and Landlord's obligations under this Amendment are expressly contingent upon ConnectRN vacating the Premises in accordance with the terms of its lease. In no event shall Landlord be liable to Tenant for any claims, damages, loss, costs or expenses in the event Landlord is unable to deliver the Suite 403 Premises to Tenant on or before any particular date and the Suite 403 Premises Delivery Date, the Suite 403 Premises Commencement Date, and the Suite 403 Premises Rent Commencement Date shall be extended accordingly until Landlord shall be able to deliver the Suite 403 Premises to Tenant in the condition required hereunder.

6. The following shall be added as new Section 2.2.8:

**2.2.8 Acceptance of Suite 403 Premises.** Tenant acknowledges and agrees that Tenant is accepting the Suite 403 Premises in its "as is" condition and Landlord shall not be obligated to construct any improvements on behalf of Tenant; *provided however*, Landlord shall deliver the Suite 403 Premises to Tenant free of other occupants and personal property (except with respect to the existing FF&E located in the Suite 403 Premises which Tenant shall purchase directly from the former tenant, ConnectRN, Inc.) and in broom clean condition with all systems serving the Building and Suite 403 Premises in good working condition. Landlord has no obligation and has made no promises to alter, remodel, improve, renovate, repair or decorate the Suite 403 Premises, the Building, or any part thereof, or to provide any allowance for such purposes, except for the Tenant's New Premises Phase I Improvement Allowance (defined below), and that no representations respecting the condition of the Original Premises, the Suite 403 Premises, or the Building have been made by Landlord to Tenant (except as otherwise specifically set forth herein). Upon expiration or earlier termination of the Term, Tenant shall not be required to remove or restore any alterations or additions to the New Premises that exist on the New Premises as of the Suite 403 Premises Delivery Date.

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

**2.7. Expansion; Right of First Refusal**. Tenant shall have an on-going right, strictly in accordance with this Section 2.7, and subject to the rights of any of Landlord's other tenants in the Buildings existing as of the Effective Date, to renew or extend its existing lease (with or without Landlord's consent) with respect to all or any portion of the 4th Floor ROFR Expansion Premises, and further subject to any pre-existing expansion rights of any of Landlord's other existing tenants in the Building, to lease all or any portion of the 4th Floor ROFR Expansion Premises, consisting of the suites located on the fourth (4th) floor of Building #21, #24, and #25 (the "**4th Floor ROFR Expansion Premises**") on the following terms and conditions: (i) Landlord shall notify Tenant in

writing that Landlord has received a signed offer to lease one or more of the suites within the 4th Floor ROFR Expansion Premises which Landlord is prepared to accept and the basic terms and conditions of such offer ("**Landlord's ROFR Notice**"); (ii) Tenant shall be entitled to lease the applicable 4th Floor ROFR Expansion Premises upon the same terms and conditions as contained in Landlord's ROFR Notice; (iii) there shall remain not less than eighteen (18) months remaining in the unexpired initial Term of this Lease, or if there shall remain less than eighteen (18) months remaining in the initial Term of this Lease, Landlord's ROFR Notice shall include Landlord's determination of Prevailing Market Rate (for the then existing Premises) in accordance with Section 2.6 above and Tenant's election to lease the 4th Floor ROFR Expansion Premises shall be conditioned upon Tenant exercising its option to extend the Term of this Lease for the Extended Term, pursuant to Section 2.6 hereof; (iv) Tenant shall have ten (10) business days from receipt of Landlord's ROFR Notice, time being of the essence, to notify Landlord in writing that Tenant elects to lease the 4th Floor ROFR Expansion Premises on such terms and conditions as are set forth in Landlord's ROFR Notice, and otherwise as set forth herein, or that Tenant disputes Landlord's calculation of Prevailing Market Rate, in which case Landlord and Tenant shall proceed with the appraisal procedure set forth in Section 2.6 above, and Tenant's failure to so timely notify Landlord shall be deemed a waiver of the right to lease the 4th Floor ROFR Expansion Premises in accordance with this Section 2.7 and Landlord shall be entitled to lease the 4th Floor ROFR Expansion Premises (or such applicable portion of the 4th Floor ROFR Expansion Premises included in Landlord's ROFR Notice) free and clear of any rights of Tenant; provided however, if Landlord subsequently reduces the economic terms set forth in Landlord's ROFR Notice by 10% or more, Landlord shall again offer the 4th Floor ROFR Expansion Premises to Tenant pursuant to the terms of this Section 2.7; (v) the 4th Floor ROFR Expansion Premises shall be leased in its then "as is" condition except as set forth in Landlord's ROFR Notice; (vi) Tenant may utilize any furniture located within the ROFR Expansion Premises until Tenant provides Landlord with a one-time written notice to Landlord within sixty (60) days of taking possession of the ROFR Expansion Premises, of Tenant's election to have Landlord remove such existing furniture, in which event Landlord shall promptly remove such furniture from the 4th Floor ROFR Expansion Premises at Landlord's sole cost and expense, and (vii) within ten (10) business days of Tenant's receipt from Landlord of an amendment to this Lease solely reflecting Tenant's exercise of its option for the 4th ROFR Expansion Premises and reflecting the modification of only the applicable terms of the Lease which relate to Tenant's exercise of its option for the 4th Floor ROFR Expansion Premises including, without limitation, the Base Rent and Additional Rent, time being of the essence, Tenant shall execute such amendment and return same to Landlord. Tenant's failure to timely comply with any of the above conditions, time being of the essence, shall be deemed Tenant's waiver of the rights contained in this Section 2.7 to lease such portion of the 4th Floor ROFR Expansion Premises included in Landlord's ROFR Notice), and thereafter Tenant shall have no further rights with respect to such portion of the 4th Floor ROFR Expansion Premises included in Landlord's ROFR Notice. At Landlord's option, Tenant's exercise of its option for the 4th Floor ROFR Expansion Premises shall be effective only if, at the time of Tenant's notice and through the date on which Landlord is to deliver the 4th Floor ROFR Expansion Premises to Tenant, there is no default under this Lease, or condition which would be a default with the passage of time and/or the giving of notice. Notwithstanding anything contained in this Section 2.7 to the contrary, (i) Tenant's right to lease the 4th Floor ROFR Expansion Premises, or any portion thereof, shall expire on the date which is nine (9) months prior to the expiration of the initial Term, unless Tenant has exercised its right to extend the Term of this Lease for the Extended Term in accordance with Section 2.6 hereof, (ii) in the event Tenant has exercised its right to extend the Term of this Lease for the Extended Term in accordance with Section 2.6 hereof, Tenant's right to lease the 4th Floor ROFR Expansion Premises, or any portion thereof, shall expire on the date which is eighteen (18) months prior to the expiration of the Extended Term. Upon Tenant's waiver or deemed waiver of its rights to lease any portion of the 4th Floor ROFR Expansion Premises, such portion shall be deemed removed from the 4th Floor

ROFR Expansion Premises and Tenant shall have no further rights under this Section 2.7 with respect to such portion of 4th Floor ROFR Expansion Premises so removed.

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

**3.1. Base Rent and Additional Rent**. From and after (i) the Suite 103A Premises Rent Commencement Date with respect to the Suite 103A Premises, (ii) the Suite 103B Premises Rent Commencement Date with respect to the Suite 103B Premises, (iii) the Suite 110 Premises Rent Commencement Date with respect to the Suite 110 Premises, (iv) the Suite 111 Premises Rent Commencement Date with respect to the Suite 111 Premises, and (v) the Suite 403 Premises Rent Commencement Date with respect to the Suite 403 Premises, Tenant agrees to pay the Suite 103A Base Rent, with respect to the Suite 103A Premises, the Suite 103B Base Rent, with respect to the Suite 103B Premises, the Suite 110 Base Rent, with respect to the Suite 110 Premises, the Suite 111 Base Rent, with respect to the Suite 111 Premises, the Suite 403 Base Rent, with respect to the Suite 403 Premises, and the Additional Rent in lawful money of the United States in advance on the first day of each and every calendar month during the Term of this Lease, at the Payment Address or at such other place as Landlord may from time to time designate by notice. Landlord may, from time to time, (but not more frequently than once for each calendar year) provide Tenant with an estimate of the Additional Rent for the coming year and such estimated Additional Rent shall be payable by Tenant to Landlord in accordance with the provisions of the preceding sentence in 12 equal monthly installments. The Suite 103A Premises Base Rent, the Suite 103B Premises Base Rent, the Suite 110 Premises Base Rent, the Suite 111 Premises Base Rent, the Suite 403 Premises Base Rent, and Additional Rent for any partial month shall be prorated on the basis of a 30 day month.

9. **Early Access.** Tenant acknowledges that the term of the lease with Landlord's existing tenant occupying the Suite 403 Premises, ConnectRN, is scheduled to expire as of September 30, 2026. Subject to ConnectRN vacating the Suite 403 Premises as set forth above, Tenant shall have the right to enter the Suite 403 Premises prior to the Suite 403 Premises Commencement Date, unless otherwise approved by Landlord in writing, during normal business hours and without payment of rent, solely for the purpose of (i) installing furniture, fixtures and equipment, (ii) installing cabling and other data and telecommunications systems and equipment, (iii) taking measurements and showing the Premises to architects and contractors, and (iv) commencing the Tenant's New Premises Phase I Work (defined below), provided that Tenant's entrance onto the Premises does not materially interfere with, or delay, the delivery of the Suite 403 Premises by Landlord. In the event Tenant desires to enter the Suite 403 Premises prior to October 1, 2026, Tenant shall be required to obtain the prior written consent (which may be via email) of ConnectRN in connection with any such early entry. Such right of entry shall be deemed a license from Landlord to Tenant, and any entry thereunder shall be at the risk of Tenant; provided, however, that Tenant has not begun operating its business from the Premises, and subject to all of the terms and conditions of the Lease (other than the obligation to pay rent), the foregoing activity shall not constitute the delivery of possession of the Premises to Tenant and the term of the Lease shall not commence as a result of said activities. Tenant shall indemnify and save harmless Landlord against and from all liabilities, damages, penalties, costs, and expenses, including reasonable attorneys' fees, that may be imposed upon or incurred by or asserted against Landlord as a result of such entry.

10. **Tenant New Premises Phase I Improvement Allowance ; Tenant's New Premises Work**. Tenant shall be entitled to a tenant improvement allowance in an amount equal to the reasonable costs incurred by Tenant solely in connection with completing the Tenant's New Premises Phase I Work (defined below) (the "**Tenant New Premises Phase I Improvement Allowance**"). The Tenant New Premises Phase I Improvement Allowance shall be used by Tenant solely for the purpose of (a) re-painting the Suite 403 Premises using building standard paint in building standard colors, as reasonably approved by Landlord,

and (b) having the carpets in the Suite 403 Premises professionally cleaned using customary commercial carpet cleaning methods as reasonably approved by Landlord ("**Tenant's New Premises Phase I Work**"), to be completed during any Early Access as set forth in Paragraph 9 above or after the Suite 403 Premises Commencement Date. The Tenant New Premises Phase I Improvement Allowance shall be payable directly to Tenant following the Suite 403 Premises Rent Commencement Date, and within thirty (30) days of submission to Landlord of (i) invoices from Tenant's contractor(s) performing such work; (ii) lien waivers from Tenant's contractors indicating payment for all services and materials relating to such work; and (iii) such other documents as Landlord may reasonably request. Tenant shall not be permitted to submit more than one (1) such request for reimbursement from the Tenant New Premises Phase I Improvement Allowance. Any costs incurred by Tenant to complete such work in excess of the Tenant New Premises Phase I Improvement Allowance shall be borne solely by Tenant and Tenant shall pay the cost therefor in accordance with the provisions of Section 4.3. In addition to Tenant's New Premises Phase I Work, Landlord hereby approves, subject to the terms and conditions of Section 4.3 of the Lease, the following work which Tenant intends to complete following the Suite 403 Premises Commencement Date: (i) constructing two (2) private offices, and (ii) one (1) conference room (the "**Tenant's New Premises Phase II Work**"). Tenant's New Premises Phase II Work shall be at Tenant's sole cost and expense, and subject to all of the terms and conditions of the Lease, including without limitation, Section 4.3 thereof. Prior to commencing Tenant's New Premises Phae II Work, Tenant shall provide Landlord with plans and specifications for Tenant's New Premises Phase II Work, for Landlord's approval, not to be unreasonably withheld, conditioned, or delayed. No portion of the Tenant New Premises Phase I Improvement Allowance shall be available for the cost of Tenant's New Premises Phase II Work.

11. **Suite 110 Premises / Suite 111 Premises Base Rent Abatement**. Subject to Tenant accepting and taking possession of the Suite 403 Premises as set forth herein, the monthly Suite 110 Premises Base Rent and the monthly Suite 111 Premises Base Rent for the month of January, 2027 is hereby abated in full (the "**Suite 110/111 Base Rent Abatement**"). The Suite 110/111 Base Rent Abatement shall not apply to Tenant's obligation to pay Base Rent for the Suite 103A Premises, the Suite 103B Premises, the Suite 403 Premises (subject to the Suite 403 Base Rent Abatement), or Additional Rent for the entire Premises as set forth in the Lease, as specifically modified hereby.

12. **Exhibit A-1.9** attached hereto showing the Suite 403 Premises shall be added as new **Exhibit A-1.9** of the Lease.

13. **Exhibit A-1.8** of the Lease is hereby deleted in its entirety.

14. Tenant and Landlord each represent and warrant to the other that it has not directly or indirectly dealt, with respect to the leasing of office space in the Building, including without limitation, the Suite 403 Premises with any broker or had its attention called to the Premises, the Suite 403 Premises or other space to let in the Building by anyone other than Newmark and Cresa. Landlord assumes sole responsibility for compensating such brokers. Notwithstanding the foregoing, if Tenant fails to take occupancy of the Suite 403 Premises, due to Tenant's fault, Tenant shall reimburse Landlord for any amounts that Landlord has or will pay to any brokers.

15. From and after the S403PCD, all references appearing in the Lease to the Premises shall be amended and read hereafter to be references to the Original Premises, and the Suite 403 Premises, unless specifically set forth in this Amendment to the contrary.

16. From and after the S403PCD, all references appearing in the Lease to the Rent shall be amended and read hereafter to include, without limitation, the Suite 403 Premises Base Rent.

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

18. All references appearing in the Lease and in any related instruments shall be amended and read hereafter to be references to the Lease as amended by this Amendment.

19. This Amendment shall have the effect of an agreement under seal and shall be binding upon and inure to the benefit of the parties hereto and their respective heirs, executors, administrators, successors and assigns.

20. Except as otherwise specifically provided herein, all of the terms and conditions of the Lease shall remain in full force and effect for the extended Lease term and this Amendment is effective as of the date first set forth above.

21. This Amendment may be executed in multiple counterparts, each of which shall be deemed an original, and all of which shall constitute one and the same agreement. This Amendment (and any further amendments to the Lease and any other instruments relating to the transactions contemplated hereby, other than any instruments to be recorded, witnessed and/or notarized) may be electronically signed by the parties by the use of DocuSign, which will be treated as an original copy as though ink-signed by officers or other duly authorized representatives of such party. Ink-signed or electronically signed executed copies hereof may be delivered by telecopier or email and upon receipt will be deemed originals and binding upon the parties hereto.

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

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

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

By: Berkeley Watch MM LLC, its Managing Member

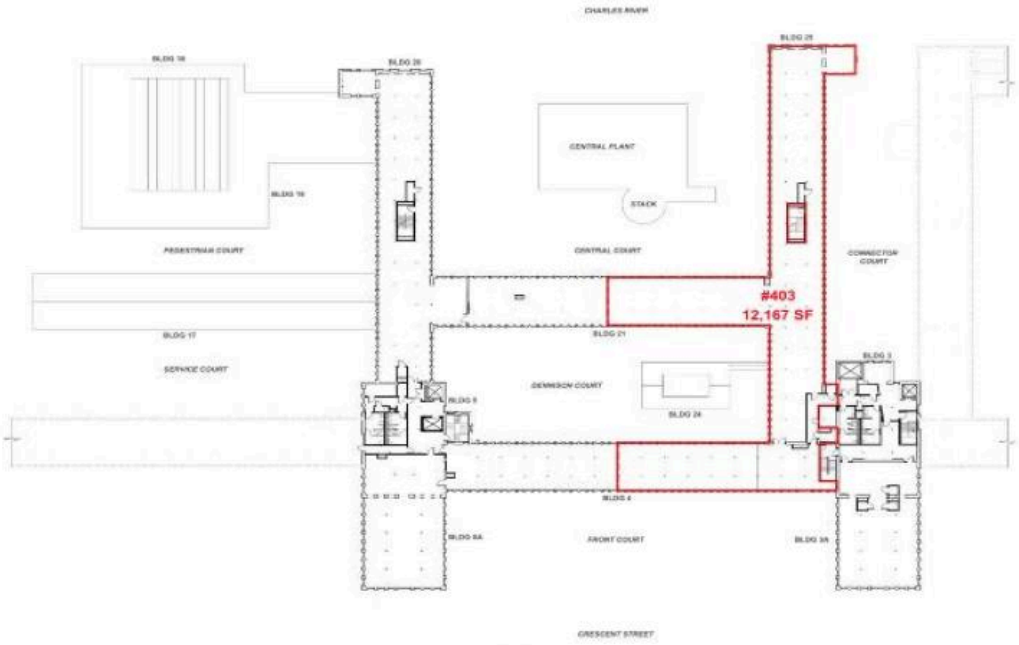
By: /s/ Young Park
Name: Young Park
Its: Authorized Signatory
(hereunto duly authorized)

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

By: /s/ Steve Mahoney
Name: Steve Mahoney
Title: Chief Executive Officer

By: /s/ Thomas Beetham
Name: Thomas Beetham
Title: Chief Operating Officer

**EXHIBIT A-1.9**
**PLAN SHOWING SUITE 403 PREMISES**




**FOURTH FLOOR**

**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: November 4, 2026

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: November 4, 2026

By: /s/ Seth Harmon

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

**Exhibit 32.1**

**SECTION 1350 CERTIFICATION**

Each of the undersigned, Stephen Mahoney, Chief Executive Officer of Viridian Therapeutics, Inc., a Delaware corporation (the "Company"), and Seth Harmon, Chief Financial Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge (1) the Quarterly Report on Form 10-Q of the Company for the quarterly period ended September 30, 2026, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Stephen Mahoney

Stephen Mahoney
President, Chief Executive Officer and Director
(Principal Executive Officer)
Date: November 4, 2026

/s/ Seth Harmon

Seth Harmon
Chief Financial Officer
(Principal Financial Officer; Principal Accounting Officer)
Date: November 4, 2026

*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.*