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# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, DC 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 December 31, 2025**
**or**

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

**For the transition period from _____ to _____.**

**Commission File Number: 001-37761**

# VISTAGEN THERAPEUTICS, INC.

*(Exact name of registrant as specified in its charter)*

| **Nevada** | 20-5093315 |
|---|---|
| *(State or other jurisdiction of incorporation or organization)* | *(I.R.S. Employer Identification No.)* |

**343 Allerton Avenue**
**South San Francisco, CA 94080**
*(Address of principal executive offices including zip code)*

**(650) 577-3600**
*(Registrant's telephone number, including area code)*

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, par value $0.001 per share | VTGN | Nasdaq Capital Market |

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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting 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 February 11, 2026, 39,620,317 shares of the registrant's common stock, $0.001 par value, were outstanding.

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**PART I. FINANCIAL INFORMATION**

**Item 1. Condensed Consolidated Financial Statements**

**VISTAGEN THERAPEUTICS, INC.**
**CONDENSED CONSOLIDATED BALANCE SHEETS**
**(in thousands, except share and par value amounts)**

| | December 31, 2025 | March 31, 2025 |
|---|---|---|
| | (unaudited) | |
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 47,371 | $ 67,131 |
| Marketable securities | 14,399 | 13,351 |
| Prepaid expenses and other current assets | 1,475 | 1,594 |
| Total current assets | 63,245 | 82,076 |
| Property and equipment, net | 480 | 476 |
| Right-of-use asset - operating lease | 939 | 1,335 |
| Other assets | 392 | 454 |
| Total assets | $ 65,056 | $ 84,341 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,280 | $ 653 |
| Accrued expenses | 9,254 | 8,810 |
| Note payable | 379 | — |
| Deferred revenue - current portion | 1,999 | 2,588 |
| Operating lease obligation - current portion | 617 | 561 |
| Total current liabilities | 13,529 | 12,612 |
| Deferred revenue - non-current portion | 176 | 391 |
| Operating lease obligation - non-current portion | 431 | 948 |
| Total liabilities | 14,136 | 13,951 |
| Commitments and contingencies (Note 10) | | |
| Stockholders' equity: | | |
| Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2025 and March 31, 2025; no shares outstanding at December 31, 2025 and March 31, 2025 | — | — |
| Common stock, $0.001 par value; 325,000,000 shares authorized at December 31, 2025 and March 31, 2025; 39,624,839 and 29,001,481 shares issued at December 31, 2025 and March 31, 2025, respectively | 40 | 29 |
| Additional paid-in capital | 515,878 | 481,956 |
| Treasury stock, at cost, 4,522 shares of common stock held at December 31, 2025 and March 31, 2025 | (3,968) | (3,968) |
| Accumulated other comprehensive income | 13 | 5 |
| Accumulated deficit | (461,043) | (407,632) |
| Total stockholders' equity | 50,920 | 70,390 |
| Total liabilities and stockholders' equity | $ 65,056 | $ 84,341 |

See accompanying notes to unaudited condensed consolidated financial statements.

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

| | Three Months Ended December 31, | | Nine Months Ended December 31, | |
|---|---|---|---|---|
| | **2025** | **2024** | **2025** | **2024** |
| Revenues: | | | | |
| Sublicense and other revenue | $ 303 | $ 234 | $ 804 | $ 501 |
| Total revenues | 303 | 234 | 804 | $ 501 |
| Operating expenses: | | | | |
| Research and development | 14,223 | 11,305 | 41,914 | $ 29,168 |
| General and administrative | 5,626 | 4,049 | 14,299 | $ 12,811 |
| Total operating expenses | 19,849 | 15,354 | 56,213 | $ 41,979 |
| Loss from operations | (19,546) | (15,120) | (55,409) | $ (41,478) |
| Other income, net: | | | | |
| Interest income, net | 647 | 1,031 | 1,989 | $ 3,702 |
| Other income | — | — | 9 | — |
| Loss before income taxes | (18,899) | (14,089) | (53,411) | (37,776) |
| Income taxes | — | — | — | $ (7) |
| Net loss | $ (18,899) | $ (14,089) | $ (53,411) | $ (37,783) |
| Unrealized gain (loss) on marketable securities | (1) | (11) | 8 | 11 |
| Comprehensive loss | $ (18,900) | $ (14,100) | $ (53,403) | $ (37,772) |
| Basic and diluted net loss per common share | $ (0.45) | $ (0.46) | $ (1.46) | $ (1.23) |
| Weighted average common shares outstanding, basic and diluted | 42,234,405 | 30,711,872 | 36,655,195 | 30,649,384 |

See accompanying notes to unaudited condensed consolidated financial statements.

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

| | Common Stock | | Additional Paid-in Capital | Treasury Stock | Accumulated Other Comprehensive Income | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | | | | | |
| **Balance at March 31, 2024** | 27,029,731 | $ 27 | $ 474,441 | $ (3,968) | $ — | $ (356,214) | $ 114,286 |
| Stock-based compensation expense | — | — | 1,160 | — | — | — | 1,160 |
| Sale of common stock pursuant to 2019 Employee Stock Purchase Plan | 29,898 | — | 88 | — | — | — | 88 |
| Unrealized gain on marketable securities available-for-sale, net | — | — | — | — | 2 | — | 2 |
| Net loss | — | — | — | — | — | (10,733) | (10,733) |
| **Balance at June 30, 2024** | 27,059,629 | $ 27 | $ 475,689 | $ (3,968) | $ 2 | $ (366,947) | $ 104,803 |
| Stock-based compensation expense | — | — | 1,112 | — | — | — | 1,112 |
| Unrealized gain on marketable securities available-for-sale, net | — | — | — | — | 20 | — | 20 |
| Net loss | — | — | — | — | — | (12,961) | (12,961) |
| **Balance at September 30, 2024** | 27,059,629 | $ 27 | $ 476,801 | $ (3,968) | $ 22 | $ (379,908) | $ 92,974 |
| Stock-based compensation expense | — | — | 1080 | — | — | — | 1,080 |
| Sale of common stock pursuant to 2019 Employee Stock Purchase Plan | 44,906 | — | 113 | — | — | — | 113 |
| Unrealized loss on marketable securities available-for-sale, net | — | — | — | — | (11) | — | (11) |
| Issuance of common stock under Open Market Sale Agreement, net of issuance costs | 428,322 | 1 | 1,054 | — | — | — | 1,055 |
| Issuance of common stock upon exercise of Pre-Funded Warrants | 788,359 | — | — | — | — | — | — |
| Net loss | — | — | — | — | — | (14,089) | (14,089) |
| **Balance at December 31, 2024** | 28,321,216 | $ 28 | $ 479,048 | $ (3,968) | $ 11 | $ (393,997) | $ 81,122 |

See accompanying notes to unaudited condensed consolidated financial statements.

| | Common Stock | | Additional Paid-in Capital | Treasury Stock | Accumulated Other Comprehensive Income | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | | | | | |
| **Balance at March 31, 2025** | 29,001,481 | $ 29 | $ 481,956 | $ (3,968) | $ 5 | $ (407,632) | $ 70,390 |
| Stock-based compensation expense | — | — | 916 | — | — | — | 916 |
| Sale of common stock pursuant to 2019 Employee Stock Purchase Plan | 95,037 | — | 161 | — | — | — | 161 |
| Issuance of common stock under Open Market Sale Agreement, net of issuance costs | 190,067 | — | 397 | — | — | — | 397 |
| Unrealized loss on marketable securities available-for-sale, net | — | — | — | — | (4) | — | (4) |
| Net loss | — | — | — | — | — | (15,095) | (15,095) |
| **Balance at June 30, 2025** | 29,286,585 | $ 29 | $ 483,430 | $ (3,968) | $ 1 | $ (422,727) | $ 56,765 |
| Stock-based compensation expense | — | — | 1,096 | — | — | — | 1,096 |
| Issuance of common stock under Open Market Sale Agreement, net of issuance costs | 9,608,772 | 10 | 27,872 | — | — | — | 27,882 |
| Issuance of common stock upon exercise of stock options | 211 | — | — | — | — | — | — |
| Unrealized gain on marketable securities available-for-sale, net | — | — | — | — | 13 | — | 13 |
| Net loss | — | — | — | — | — | (19,417) | (19,417) |
| **Balance at September 30, 2025** | 38,895,568 | $ 39 | $ 512,398 | $ (3,968) | $ 14 | $ (442,144) | $ 66,339 |
| Stock-based compensation expense | — | — | 1,096 | — | — | — | 1,096 |
| Sale of common stock pursuant to 2019 Employee Stock Purchase Plan | 122,747 | — | 70 | — | — | — | 70 |
| Unrealized loss on marketable securities available-for-sale, net | — | — | — | — | (1) | — | (1) |
| Issuance of common stock under Open Market Sale Agreement, net of issuance costs | 604,405 | 1 | 2,307 | — | — | — | 2,308 |
| Issuance of common stock upon exercise of stock options | 2,119 | — | 7 | — | — | — | 7 |
| Net loss | — | — | — | — | — | (18,899) | (18,899) |
| **Balance at December 31, 2025** | 39,624,839 | $ 40 | $ 515,878 | $ (3,968) | $ 13 | $ (461,043) | $ 50,920 |

See accompanying notes to unaudited condensed consolidated financial statements.

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

| | Nine Months Ended December 31, | |
|---|---|---|
| | **2025** | **2024** |
| **Cash flows from operating activities:** | | |
| Net loss | $ (53,411) | $ (37,783) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 147 | 110 |
| Stock-based compensation | 3,108 | 3,352 |
| Amortization of operating lease right-of-use asset | 396 | 359 |
| Non-cash interest expense | 1 | — |
| Accretion on marketable securities | (412) | (261) |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | 119 | 125 |
| Other assets | (46) | 190 |
| Operating lease liability | (461) | (407) |
| Deferred revenue, net of deferred contract acquisition costs | (748) | (446) |
| Accounts payable and accrued expenses | 1,071 | 2,726 |
| Net cash used in operating activities | (50,236) | (32,035) |
| **Cash flows from investing activities:** | | |
| Purchases of laboratory and other equipment | (151) | (103) |
| Sales and maturities of marketable securities | 16,000 | 7,497 |
| Purchases of marketable securities | (16,627) | (21,069) |
| Net cash used in investing activities | (778) | (13,675) |
| **Cash flows from financing activities:** | | |
| Net proceeds from sale of common stock under Open Market Sale Agreement, net of offering costs | 30,638 | 1,058 |
| Net proceeds from sale of common stock under 2019 Employee Stock Purchase Plan | 231 | 201 |
| Issuance of note payable for insurance policy | 1,020 | — |
| Net proceeds from option exercises | 7 | — |
| Repayment of notes payable | (642) | — |
| Net cash provided by financing activities | 31,254 | 1,259 |
| Net change in cash and cash equivalents | (19,760) | (44,451) |
| Cash and cash equivalents at beginning of period | 67,131 | 119,166 |
| Cash and cash equivalents at end of period | $ 47,371 | $ 74,715 |
| **Supplemental disclosure of noncash activities:** | | |
| Non-cash investing and financing activities: | | |
| Cash paid for interest | $ 28 | $ — |

See accompanying notes to unaudited condensed consolidated financial statements.

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

## 1. Description of Business

Vistagen Therapeutics, Inc., a Nevada corporation (*Vistagen, the Company, we, our, or us*), is a late clinical-stage biopharmaceutical company leveraging a deep understanding of nose-to-brain neurocircuitry to develop and potentially commercialize a new class of non-systemic intranasal product candidates called pherines. Our clinical-stage neuroscience pipeline currently consists of five clinical-stage pherine product candidates, each with a novel proposed mechanism of action (*MOA*) and at least one positive clinical study involving our targeted patient population. Pherines rapidly, specifically and selectively bind to peripheral receptors in human nasal chemosensory neurons, and are designed to rapidly activate nose-to-brain neurocircuits believed to regulate brain areas without requiring systemic absorption or uptake into the brain to achieve desired therapeutic benefits.

## 2. Basis of Presentation, Principles of Consolidation and Summary of Significant Accounting Policies

### Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (*U.S. GAAP*) applicable to interim financial information and pursuant to the instructions of the Securities and Exchange Commission (*SEC*) on Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. Further, the results of our operations for any interim periods are not necessarily indicative of the results that may be expected for any other interim period or the full fiscal year. In the opinion of management, all normal and recurring adjustments considered necessary for a fair presentation have been included. The condensed consolidated balance sheet at March 31, 2025, has been derived from our audited consolidated financial statements but does not include all disclosures required by U.S. GAAP. Because all of the disclosures required by U.S. GAAP for complete financial statements are not included herein, these unaudited condensed consolidated financial statements and the accompanying notes should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended March 31, 2025 (*Annual Report*), filed with the SEC on June 17, 2025.

Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP as found in the Accounting Standards Codification (*ASC*) and Accounting Standards Updates (*ASU*) promulgated by the Financial Accounting Standards Board (*FASB*).

The accompanying unaudited condensed consolidated financial statements include the accounts of Vistagen and its subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

### *Liquidity and Going Concern*

In order to complete the development of our neuroscience product candidates and to expand our infrastructure and operations in a manner we believe will be necessary to commercialize our product candidates, if approved, on our own or with one or more collaborators, we will require substantial additional capital. Until we can generate a sufficient amount of revenue from the commercialization of our product candidates, we will seek to raise any necessary additional capital through equity and/or debt financings, loans or other capital sources, which could include income from collaborations, partnerships or other marketing, distribution, licensing or other strategic arrangements with third parties. Because of the numerous risks and uncertainties associated with research, development and commercialization of our product candidates, we are unable to estimate the exact amount and timing of our capital requirements. We do not expect to generate any meaningful revenue unless and until we obtain regulatory approval of and commercialize any of our product candidates, and we do not know when, or if, that will occur.

We have incurred significant losses and negative cash flows from operations since inception. As of December 31, 2025, we had an accumulated deficit of $461.0 million, and cash used in operations for the nine months ended December 31, 2025 was $50.2 million. We expect that our operating losses and negative cash flows will continue for the foreseeable future as we continue to develop and, if approved, commercialize our product candidates.

In accordance with Accounting Standards Codification (*ASC*) 205-40, Going Concern, we evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year from the date these consolidated financial statements in this Report are issued. This evaluation initially does not take into consideration the potential mitigating effects of management's plans that have not yet been fully

implemented as of the date the consolidated financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effects of its plans sufficiently alleviates substantial doubt about our ability to continue as a going concern. The mitigating effects of management's plans, however, are only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the consolidated financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. In performing its analysis, management excluded certain elements of its operating plan that cannot be considered probable. Under ASC 205-40, the future receipt of potential funding from future equity and/or debt issuances and other potential sources such as partnerships cannot be considered probable at this time because these plans are not entirely within our control nor have these plans been approved by the Board as of the date of these consolidated financial statements.

As of December 31, 2025, we had cash, cash equivalents, and marketable securities of $61.8 million. As of February 12, 2026, the issuance date of the condensed consolidated financial statements as of and for the three and nine months ended December 31, 2025 in this Report, there is uncertainty about whether our combined cash, cash equivalents, and marketable securities will be sufficient to fund operations beyond twelve months from the issuance date of these condensed consolidated financial statements and therefore we concluded that substantial doubt exists about our ability to continue as a going concern.

When necessary and/or advantageous, we will seek additional capital to fund our planned operations through (i) sales of our equity and/or debt securities in one or more public offerings and/or private placements, including, but not limited to sales of our securities under our Open Market Sale Agreement with Jefferies LLC, (ii) non-dilutive government grants and research awards and/or (iii) non-dilutive strategic partnering collaborations to advance development and commercialization of one or more of our product candidates. However, no assurance can be provided that any such sales of our securities, awards, agreements or collaborations will occur in the future. While we may make additional sales of our equity and/or debt securities, we do not have an obligation to do so.

Our future working capital requirements will depend on many factors, including, without limitation, potential impacts related to adjustments in the size of our staff or other actual and/or planned adjustments to our operations, the scope and nature of opportunities related to our success or failure in nonclinical and clinical trials, including the development and commercialization of our current product candidates, and the availability of, and our ability to enter into financing transactions and research, development and commercialization collaborations on terms acceptable to us. In the future, to further advance the nonclinical and clinical development of our product candidates, as well as support our operating activities, we plan to seek additional financing, including both equity-based and/or debt-based capital and potentially from non-dilutive sources other than debt-based capital, and continue to carefully manage our operating costs, including, but not limited to, our clinical and nonclinical programs.

There can be no assurance that future financings will be available to us in sufficient amounts, in a timely manner, or on terms acceptable to us, if at all, or that any current or future development and commercialization collaborations will generate revenue from future potential milestone payments or otherwise. Further, on February 3, 2026, we received a letter from the Listing Qualifications Staff of The Nasdaq Stock Market, LLC (*Nasdaq*) indicating that, based upon the closing bid price of our common stock for the previous 30 consecutive business days, we are not currently in compliance with the requirement to maintain a minimum bid price of $1.00 per share for continued listing on the Nasdaq Capital Market. While the letter has no immediate effect on the listing of our common stock on the Nasdaq Capital Market, failure to meet applicable Nasdaq continued listing standards by August 3, 2026, the expiration of the 180-day period in which to regain compliance, unless extended, could potentially result in a delisting of our common stock, which could materially reduce the liquidity of our common stock, result in a further reduction in the price of our common stock, require us to implement our stockholder-authorized reverse stock split to maintain our listing, and/or impair our ability to raise capital through alternative financing sources on terms acceptable to us, or at all. If we do not regain compliance by August 3, 2026, an additional 180 days may be granted to regain compliance, so long as we meet the Nasdaq Capital Market continued listing requirements (except for the bid price requirement) and notify Nasdaq in writing of our intention to cure the deficiency during the second compliance period. If we are unable to regain timely compliance with the Nasdaq continued listing standards and/or obtain additional financing on a timely basis when needed, our business, financial condition, and results of operations may be harmed, the price of our common stock may decline, we may be required to reduce, defer, or discontinue certain of our research and development activities, and we may not be able to continue as a going concern.

The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

***Use of Estimates***

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Estimates made in the accompanying condensed consolidated financial statements include, but are not limited to, those relating to stock-based compensation, revenue recognition, research and development expense, determination of right-of-use assets under lease transactions and related lease obligations, and the assumptions used to value common stock purchase warrants. Although these estimates are based on our knowledge of current events, historical experiences, actions we may undertake in the future and on various other assumptions we believe are reasonable, actual results may materially differ from these estimates and assumptions.

***Fair Value Measurements***

We measure cash equivalents and available-for-sale debt securities at fair value. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. A framework is used for measuring fair value utilizing a three-tier hierarchy that prioritizes the inputs to valuation techniques used to measure fair value.

Level 1—Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2—Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability.

Level 3—Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e. supported by little or no market activity).

Money market funds are highly liquid investments and are classified as Level 1. The pricing information for these assets is readily available and can be independently validated as of the measurement date. Available-for-sale debt securities are valued using observable inputs from similar assets, or from observable data in markets that are not active. These assets are classified as Level 2.

***Marketable Securities***

Marketable securities consist of U.S. treasury securities. These securities are classified as available-for-sale, as the sale of such securities may be required prior to their maturity. Available-for-sale securities are recorded at fair value, with the related unrealized gains and losses included in accumulated other comprehensive income or loss and included as a separate component of stockholders' equity. Our marketable debt securities are classified as cash equivalents if the original maturity, from the date of purchase, is 90 days or less, and as marketable securities if the original maturity, from the date of purchase, is in excess of 90 days. Our cash equivalents are generally composed of U.S. treasury securities and money market funds. The amortized cost of available-for-sale securities reflects amortization of premiums and accretion of discounts to maturity. Premiums and discounts on debt securities are amortized into interest and other income, net. The Company classifies investments in marketable debt securities as current assets, regardless of the stated maturity date, which may be beyond one year from the current balance sheet date. Short-term classification reflects management's view that the entire portfolio is available, and the Company may use the proceeds from sale of these investments to fund current operations, as necessary.

***Recently Issued Accounting Pronouncements***

There were no significant updates not already disclosed in the Company’s audited consolidated financial statements for the years ended March 31, 2025, and 2024 to the recently issued accounting standards, for the nine months ended December 31, 2025.

***Issued Accounting Pronouncements Not Yet Adopted***

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (*Topic 740*): Improvements to Income Tax Disclosures. ASU 2023-09 requires disaggregated information about a reporting entity’s effective tax rate reconciliation as

well as information on income taxes paid. ASU 2023-09 is effective for public entities with annual periods beginning after December 15, 2024, with early adoption permitted. We are currently evaluating the impact of this guidance on our financial statements.

In November 2024, the FASB issued ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (*Subtopic 220-40*): Disaggregation of Income Statement Expenses (*ASU 2024-03*), which requires disaggregated disclosure of certain expenses to provide enhanced transparency into the 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 periods within annual reporting periods beginning after December 15, 2027, with early adoption permitted. ASU 2024-03 may be adopted on a prospective or retrospective basis. We are currently evaluating the impact of this guidance on our financial statements.

In September 2025, the FASB issued ASU 2025-06, Intangibles — Goodwill and Other Internal-Use Software (*Subtopic 350-40*): Targeted Improvements to the Accounting for Internal-Use Software. This guidance modernizes the accounting framework for internal-use software by providing clearer criteria for capitalization, including the requirement to assess whether significant development uncertainty exists. ASU 2025-06 is effective for annual reporting periods beginning after December 15, 2027, and interim reporting periods within those annual reporting periods, with early adoption permitted. We are currently evaluating the impact of this guidance on our financial statements.

In December 2025, the FASB issued ASU 2025-11, Interim Reporting (Topic 270): Narrow Scope Improvements, which provides clarity on the required interim disclosures under Topic 270 by providing a comprehensive list of required interim disclosures, and clarifies the applicability of Topic 270. ASU 2025-11 is effective for annual reporting periods beginning after December 15, 2027, and interim reporting periods within annual reporting periods beginning after December 15, 2028, with early adoption permitted. ASU 2025-11 may be adopted on a prospective or retrospective basis. We are currently evaluating the impact of this guidance on our financial statements.

**3. Fair Value Measurements**

The following tables show our cash, cash equivalents and marketable securities at fair value as of December 31, 2025 and March 31, 2025 (in thousands):

| | December 31, 2025 | | | |
|---|---|---|---|---|
| | **Level 1** | **Level 2** | **Level 3** | **Total** |
| Assets: | | | | |
| Cash and cash equivalents: | | | | |
| Cash and money market funds | $ 47,371 | $ — | $ — | $ 47,371 |
| Marketable securities | | | | |
| U.S. treasury securities | — | 14,399 | — | 14,399 |
| Total | $ 47,371 | $ 14,399 | $ — | $ 61,770 |

| | March 31, 2025 | | | |
|---|---|---|---|---|
| | **Level 1** | **Level 2** | **Level 3** | **Total** |
| Assets: | | | | |
| Cash and cash equivalents: | | | | |
| Cash and money market funds | $ 67,131 | $ — | $ — | $ 67,131 |
| Marketable securities | | | | |
| U.S. treasury securities | — | 13,351 | — | 13,351 |
| Total | $ 67,131 | $ 13,351 | $ — | $ 80,482 |

The carrying amounts of our prepaid expenses and other current assets, accounts payable, accrued expenses, and the note payable approximate fair value due to their short maturities. We had no financial liabilities measured at fair value on a recurring basis at December 31, 2025 or March 31, 2025. There were no transfers between Levels 1, 2 or 3 for any of the periods presented.

We did not record any impairment charges related to our marketable debt securities during the three and nine months ended December 31, 2025 or 2024.

The following tables summarizes our marketable securities as of December 31, 2025 and March 31, 2025 (in thousands):

| | | December 31, 2025 | | | |
|---|---|---|---|---|---|
| | Maturity (in years) | Amortized Cost | Unrealized Gains | Unrealized Losses | Fair Value |
| U.S. treasury notes | Less than 1 | $ 14,386 | $ 13 | $ — | $ 14,399 |
| Total | | $ 14,386 | $ 13 | $ — | $ 14,399 |

| | | March 31, 2025 | | | |
|---|---|---|---|---|---|
| | Maturity (in years) | Amortized Cost | Unrealized Gains | Unrealized Losses | Fair Value |
| U.S. treasury notes | Less than 1 | $ 13,346 | $ 5 | $ — | $ 13,351 |
| Total | | $ 13,346 | $ 5 | $ — | $ 13,351 |

**4. Notes Payable**

In May 2025, we executed a 6.54% promissory note in the principal amount of $1.0 million in connection with certain insurance policy premiums. The note is payable in monthly installments of approximately $0.1 million, including principal and interest, through April 2026. As of December 31, 2025, the outstanding balance related to the premium financing was $0.4 million. Interest accrued related to the premium financing arrangement was immaterial as of December 31, 2025.

**5. Capital Stock**

**Common Stock**

***October 2023 Public Offering***

On October 2, 2023, we completed an underwritten public offering (the *October 2023 Public Offering*), whereby we offered and sold, for gross proceeds of approximately $100 million, a total of 15,010,810 shares of our common stock and a total of 3,577,240 pre-funded warrants to purchase up to 3,577,240 shares of common stock (the *Pre-Funded Warrants*). Each share of common stock and each Pre-Funded Warrant was issued together with a ratably allocated portion of warrants to purchase up to 9,294,022 shares of common stock with an exercise price of $5.38 per share (the *T1 Warrants*) and warrants to purchase 11,265,086 shares of common stock with an exercise price of $8.877 per share (the *T2 Warrants*). The net proceeds to us from the October 2023 Public Offering were approximately $93.5 million, after deducting related expenses, including commissions, legal expenses and other offering costs.

The Pre-Funded Warrants, T1 Warrants and T2 Warrants (collectively, the *Warrants*) are fully exercisable, only at the option of the holder. Holders may also exercise the T1 Warrants and T2 Warrants for Pre-Funded Warrants at their option. We may not effect the exercise of any Warrants, and a holder will not be entitled to exercise any portion of any of the Warrants, which, upon giving effect to such exercise, would cause the aggregate number of shares of common stock beneficially owned by the holder of such Warrant (together with its affiliates) to exceed 9.99% of the number of shares of common stock outstanding immediately after giving effect to the exercise. However, any holder may increase or decrease such percentage to any other percentage (not to exceed 19.99% if exceeding such percentage would result in a change of control under Nasdaq Listing Rule 5636(b) or any successor rule) upon at least 61 days' prior notice from the holder to us subject to the terms of the respective Warrant agreement.

We evaluated the terms of the Warrants issued and determined that they should be classified as equity instruments within additional paid-in capital. The Warrants are equity classified because they (i) are freestanding financial instruments that are legally detachable and separately exercisable from the other equity instruments, (ii) are immediately exercisable, (iii) do not embody an obligation for the Company to repurchase its shares, (iv) permit the holders to receive a fixed number of shares of common stock upon exercise, (v) are indexed to the Company's common stock and (vi) meet the equity classification criteria. In addition, such Warrants do not provide any guarantee of value or return.

***Open Market Sale Agreement***

In May 2021, we entered into an Open Market Sale Agreement (the *Sales Agreement*) with Jefferies LLC (*Jefferies*) as sales agent, with respect to an at-the-market offering program under which we were permitted, at our option, to offer and sell, from time to time, shares of our common stock having an aggregate offering price of up to $75.0 million. In February 2024, the aggregate offering price available under the Sales Agreement was increased to up to $100 million, and in June 2025, the aggregate offering price available under the Sales Agreement was increased to up to $175 million. As of December 31, 2025, shares of common stock with an aggregate offering price of approximately $140.5 million remained available for offer and sale under the Sales Agreement.

During the three and nine months ended December 31, 2025, we sold 604,405 and 10,403,244 shares of our common stock in at-the-market transactions under the Sales Agreement, resulting in net cash proceeds of approximately $2.3 million and $30.6 million after sales agent commissions, respectively. During the three and nine months ended December 31, 2024, we sold 428,322 shares under the Sales Agreement, resulting in net cash proceeds of approximately $1.1 million, after sales agent commissions. We pay Jefferies a commission of up to three percent (3.0%) of the aggregate gross proceeds from any sales under the Sales Agreement.

***Common Stock Warrants***

At December 31, 2025, the following common stock warrants were outstanding:

| Number of Common Shares Underlying Warrants | Exercise Price Per Share | Expiration Date |
|---|---|---|
| 2,788,620 | $0.001 | N/A |
| 9,294,022 | $5.380 | (a) |
| 11,265,086 | $8.877 | 10/4/2028 |

(a) The warrants will expire 60 days after the later of (i) the date on which the Company first publicly discloses, whether by press release or Current Report on Form 8-K, the top-line results of its PALISADE-3 Phase 3 clinical trial and (ii) the date on which the Company first publicly discloses, whether by press release or Current Report on Form 8-K, the top-line results of its PALISADE-4 Phase 3 clinical trial.

The weighted average exercise price of all outstanding warrants at December 31, 2025 is $6.42 per share. No outstanding warrant is subject to any down-round anti-dilution protection feature. All outstanding warrants are exercisable by the holders only by payment in cash of the stated exercise price per share, except the Pre-Funded Warrants and the T2 Warrants issued in connection with the October 2023 Public Offering, which may be exercised through a cashless exercise, via exchange of a portion of warrants to cover the exercise price. In October 2024, Pre-Funded Warrants to purchase 788,620 shares of common stock were exercised on a cashless basis, resulting in the issuance of 788,359 shares of common stock. In December 2024, 33,334 warrants to purchase common stock, with an exercise price of $15.00 per share, expired. In July 2025, 12,352 warrants to purchase common stock with an exercise price of $21.90 per share, expired.

**6. Stock-Based Compensation**

A summary of our stock option activity for the period ended December 31, 2025 is as follows (in thousands, except share and per share data and years):

| | Options | Weighted-Average Exercise Price | Weighted-Average Remaining Contractual Term (Years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding at March 31, 2025 | 3,239,642 | $ 10.32 | 8.4 | $ 8 |
| Granted | 1,861,827 | $ 2.13 | | |
| Exercised | (2,330) | $ 3.32 | | |
| Forfeited | (235,909) | $ 2.55 | | |
| Expired | (7,192) | $ 84.30 | | |
| Outstanding at December 31, 2025 | 4,856,038 | $ 7.51 | 7.8 | $ — |
| Exercisable at December 31, 2025 | 2,232,281 | $ 12.96 | 6.6 | $ — |
| Vested and expected to vest as of December 31, 2025 | 4,856,038 | $ 7.51 | 7.8 | $ — |

**Stock-Based Compensation Expense**

The fair value of stock options granted was estimated using the following assumptions:

| | Nine Months Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Risk-free interest rate | 3.64% - 4.19% | 3.48% - 4.43% |
| Expected term (years) | 5.27 - 6.08 | 5.07 - 6.14 |
| Expected stock price volatility | 155.06% - 164.30% | 164.30% - 176.22% |
| Dividend yield | — | — |

Stock-based compensation expense recognized for all equity awards has been included in the consolidated statements of operations and comprehensive loss as follows (in thousands):

| | Three Months Ended December 31, | | Nine Months Ended December 31, | |
|---|---|---|---|---|
| | 2025 | 2024 | 2025 | 2024 |
| Research and development expense | $ 466 | $ 427 | $ 1,327 | $ 1,533 |
| General and administrative expense | 630 | 653 | 1,781 | 1,819 |
| Total stock-based compensation expense | $ 1,096 | $ 1,080 | $ 3,108 | $ 3,352 |

The weighted-average grant date fair value of options granted during the nine months ended December 31, 2025 and 2024 was $2.20 and $3.49 per share, respectively. The intrinsic value of options exercised during the nine months ended December 31, 2025 was immaterial. No options were exercised during the nine months ended December 31, 2024. As of December 31, 2025, total compensation cost not yet recognized related to unvested stock options was $6.9 million, which is expected to be recognized over a weighted-average period of 2.1 years.

From time to time, the Company grants to its employees, upon approval by the Board or an authorized committee thereof, options to purchase shares of common stock as an inducement to employment in accordance with Nasdaq Listing Rule 5635(c)(4). To date, all options to purchase shares of common stock granted as inducement awards were granted outside of an existing equity incentive plan. These options are subject to terms substantially the same as the 2019 Omnibus Equity Incentive Plan. During the nine months ended December 31, 2025, the Company granted an aggregate of 300,000 options to purchase shares of common stock as an inducement to employment for newly hired executive officers.

**7. Net Loss per Common Share**

Basic net loss per common share is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding for the period, without consideration for common stock equivalents. The Pre-Funded Warrants associated with the October 2023 Public Offering (see Note 5 above) are considered outstanding shares in the basic earnings per share calculation given their nominal exercise price. Dilutive common stock equivalents for the periods presented include warrants for the purchase of common stock and common stock options outstanding under the Company's equity compensation plans. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

The following table summarizes the outstanding potentially dilutive securities that have been excluded from the calculation of diluted net loss per share because their inclusion would be anti-dilutive:

| | As of December 31, | |
|---|---|---|
| | **2025** | **2024** |
| Outstanding options under the Company's Amended and Restated 2016 (formerly 2008) Stock Incentive Plan and Amended and Restated 2019 Omnibus Equity Incentive Plan, as amended | 4,856,038 | 3,121,892 |
| Outstanding warrants to purchase common stock | 20,559,108 | 20,571,460 |
| Total | 25,415,146 | 23,693,352 |

**8. Sublicensing and Collaborative Agreements**

The following table presents changes in contract assets and liabilities during the nine months ended December 31, 2025. Contract acquisition costs are included as a component of other assets on our condensed consolidated balance sheets.

| | **Balance at March 31, 2025** | **Additions** | **Deductions** | **Balance at December 31, 2025** |
|---|---|---|---|---|
| Contract assets: | | | | |
| Deferred contract acquisition costs | $ 130 | $ — | $ (56) | $ 74 |
| Contract liabilities: | | | | |
| Deferred revenue | $ 2,979 | $ — | $ (804) | $ 2,175 |

***AffaMed Agreement***

In June 2020, we entered into a license and collaboration agreement (the *AffaMed Agreement*) with EverInsight Therapeutics Inc., a company incorporated under the laws of the British Virgin Islands, now AffaMed Therapeutics, Inc. (*AffaMed*), pursuant to which we granted AffaMed an exclusive license to develop and commercialize fasedienol for social anxiety disorder (*SAD*) and potentially other anxiety-related disorders in Greater China, South Korea and Southeast Asia (which includes Indonesia, Malaysia, Philippines, Thailand and Vietnam) (collectively, *the Territory*). We retain exclusive development and commercialization rights for fasedienol in the U.S. and throughout the rest of the world outside the Territory.

We are responsible for pursuing clinical development and regulatory submissions of fasedienol for acute treatment of anxiety in adults with SAD, and potentially other anxiety-related indications, in the United States on a "best efforts" basis, with no guarantee of success. If conducted, AffaMed may participate in a Phase 3 global clinical trial of fasedienol and would assume all direct costs and expenses of conducting such clinical trial in the Territory and a portion of the indirect costs of a global trial in which they participate. We will transfer all development data (nonclinical and clinical data) and our regulatory documentation related to fasedienol throughout the term as it is developed or generated or otherwise comes into our control. We will grant to AffaMed a Right of Reference to our regulatory documentation and our development data, but retain exclusive development and commercialization rights for fasedienol in the U.S. and throughout the rest of the world outside the Territory.

Under the terms of the AffaMed Agreement, AffaMed paid to us a non-refundable upfront license payment of $5.0 million in August 2020. Additionally, upon successful development and commercialization of fasedienol in the Territory, we are eligible to receive milestone payments of up to $172.0 million. Further, we are eligible to receive royalty payments on a country-by-country basis on net sales for the later of ten years or the expiration of market or regulatory exclusivity in the

jurisdiction, except that payments will be reduced on a country-by-country basis in the event there is no market exclusivity in the period. Royalty payments may also be reduced if there is a generic competitive product in the Territory in the period.

We have determined that we have one combined performance obligation for the license to develop and commercialize fasedienol in the Territory and related development and regulatory services. In addition, AffaMed has an option that, if exercised by AffaMed, could create manufacturing obligations for us during development upon exercise. This option for manufacturing services was evaluated and determined not to include a material right.

Development and commercialization milestones were not considered probable at inception and therefore were excluded from the initial transaction price. The royalties were excluded from the initial transaction price because they relate to a license of intellectual property and are subject to a royalty constraint.

We recognize revenue as the combined performance obligation is satisfied over time using an input method. Significant management judgment is required to determine the level of effort attributable to the performance obligation included in the AffaMed Agreement and the period over which we expect to complete our performance obligation. The performance period or measure of progress was estimated at the inception of the AffaMed Agreement and is re-evaluated in subsequent reporting periods. This re-evaluation may shorten or lengthen the period over which we recognize revenue.

As of December 31, 2025 and March 31, 2025, we had short-term deferred revenue of $0.7 million and $1.3 million, respectively, and long-term deferred revenue of $0.2 million and $0.4 million, respectively, related to the AffaMed Agreement. During the three and nine months ended December 31, 2025, we recognized revenue of $0.3 million and $0.8 million, respectively, as compared to $0.2 million and $0.5 million during the three and nine months ended December 31, 2024, respectively, under the AffaMed Agreement, which was included in the deferred revenue balance at the beginning of each period. The remaining deferred revenue under the AffaMed Agreement will be recognized over the expected remaining contractual term.

***Fuji Pharma Agreement***

On September 1, 2023, we entered into an Exclusive Negotiation Agreement (the *Negotiation Agreement*) with Fuji Pharma Co., Ltd. (*Fuji Pharma*), a Tokyo Stock Exchange-listed, Japan-based pharmaceutical company with a significant research, development, and commercial focus on pharmacological therapies for women’s health conditions. Pursuant to the terms and conditions of the Negotiation Agreement, we agreed, for a limited period of time, to negotiate exclusively with Fuji Pharma for a potential exclusive license agreement to develop and commercialize refisolone (formerly PH80) in Japan. Refisolone, our clinical-stage pherine product candidate focused on women's health conditions, primarily the treatment of vasomotor symptoms (hot flashes) associated with menopause (the *Potential Definitive Agreement*). The Negotiation Agreement provides for an exclusive negotiation period beginning on the date of formal written notice being received by Fuji Pharma that we have selected a contract development and manufacturing organization to conduct preclinical toxicology studies for refisolone (the *Payment Event*), and terminating on the later to occur of (i) fourteen (14) months from the date of the Payment Event or (ii) ninety (90) days from the date that the U.S. Food and Drug Administration (*FDA*) accepts our refisolone Investigational New Drug (*IND*) application for clinical development of refisolone in the U.S. for the treatment of vasomotor symptoms (hot flashes) due to menopause (the *Exclusive Negotiation Period*).

As consideration for the Exclusive Negotiation Period, Fuji Pharma agreed to make a payment to us of $1.5 million (*Purchase Price*), payable upon occurrence of the Payment Event. The Payment Event occurred in October 2023, and we received payment of the Purchase Price in full in November 2023. The Purchase Price is non-refundable, except upon a material breach of the Negotiation Agreement by the Company; however, should the Company and Fuji Pharma enter into the Potential Definitive Agreement, the Purchase Price will be credited against any upfront fee due in connection with the execution of such Potential Definitive Agreement. Neither the Company nor Fuji Pharma is obligated to enter into the Potential Definitive Agreement, and if the Company and Fuji Pharma have not entered into the Potential Definitive Agreement on or before the end of the Exclusive Negotiation Period, either the Company or Fuji Pharma may terminate any further negotiations.

As of December 31, 2025, the entire amount remaining unrecognized under the Negotiation Agreement of $1.3 million was classified as short term, as a component of deferred revenue, current portion, on the condensed consolidated balance sheets. During the three and nine months ended December 31, 2025 and 2024, we recognized no revenue under the Negotiation Agreement. The remaining deferred revenue under the Negotiation Agreement will be recognized upon termination of the Exclusive Negotiation Period, or accounted for as a creditable prepayment under ASC 606, should an exclusive license agreement be reached with Fuji Pharma prior to the date of termination.

**9. Related Party Transactions**

In August 2023, in connection with his retirement, we entered into a consulting agreement with our former Chief Financial Officer, Jerrold D. Dotson, to assist in transition matters related to the employment of our new Chief Financial Officer. Pursuant to the agreement, Mr. Dotson received an initial payment of $100,000 and $10,000 per month from September 2023 through August 2024. In August 2024, the agreement was amended to extend the expiration date to March 31, 2025, and subsequently amended to extend the expiration to March 31, 2026. During the three and nine months ended December 31, 2025 and 2024, we recorded expense under the consulting agreement of $30,000 and $90,000, respectively.

**10. Commitments and Contingencies**

From time to time, we may be party to litigation, arbitration or other legal proceedings in the course of our business. Currently, we are party to a civil action filed against the Company and our Board of Directors, certain of our executive officers, professional services and financial advisors, and industry analysts in the United States District Court for the Northern District of California (Case No. 4:25-cv-01510) on February 13, 2025, by two purported stockholders, filed *pro se* (i.e., acting on their own behalf rather than through an attorney), seeking compensatory and punitive damages, as well as fees and costs. In addition, on January 15, 2026, a putative class action complaint was filed against the Company and certain of our executive officers in the United States District Court for the Northern District of California (Case No. 3:26-cv-00427) by a purported stockholder seeking an unspecified amount of damages. The Company believes both actions are wholly without merit, and intends to vigorously defend itself in both cases.

The outcome of any such legal proceedings, regardless of the merits, is inherently uncertain. In addition, litigation and related matters are costly and may divert the attention of our management and other resources that would otherwise be engaged in other activities. If we were unable to prevail in any such legal proceedings, our business, results of operations, liquidity, and financial condition could be adversely affected.

**11. Subsequent Events**

On February 3, 2026, the Company received a letter from the Nasdaq Listing Qualifications Staff indicating that, based upon the closing bid price of shares of the Company's common stock for the 30 consecutive business day period between December 17, 2025 and February 2, 2026, the Company did not meet the minimum bid price of $1.00 per share required for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2). The letter also indicated that the Company will be provided with a compliance period of 180 calendar days, or until August 3, 2026 (the *Compliance Period*), in which to regain compliance pursuant to Nasdaq Listing Rule 5810(c)(3)(A).

The letter has no immediate impact on the listing of the Company's common stock, which will continue to be listed and traded on Nasdaq, subject to the Company's compliance with the other listing requirements of Nasdaq.

The Company intends to actively monitor the closing bid price of its shares of common stock during the Compliance Period and may, if appropriate, evaluate available options to resolve the deficiency and regain compliance with the minimum bid price requirement. While the Company is exercising diligent efforts to maintain the listing of its common stock on the Nasdaq Capital Market, there can be no assurance that the Company will be able to regain or maintain compliance with the minimum bid price requirement or any other Nasdaq listing standard.

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

### Cautionary Note Regarding Forward-Looking Statements

*Certain statements in this Quarterly Report on Form 10-Q (Quarterly Report or Report) may constitute "forward-looking statements" for purposes of the federal securities laws, including the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act), that involve substantial risks and uncertainties. Our forward-looking statements include, but are not limited to, statements regarding our or our management team's expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are also forward-looking statements. The words "anticipate," "believe," "can," "contemplate," "continue," "could," "estimate," "expect," "future," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "strategy," "target," "will," "would," or the negative of these terms or 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 in this Report may include, for example, statements about:*

- *the period over which we anticipate our available financial resources will enable us to fund our operating expense;*
- *our ability to obtain additional funding for our operations, including funding necessary to complete further development, approval and, if approved, commercialization of our product candidates;*
- *the format, objectives, strategy, likelihood of success, and cost of our preclinical studies and clinical trials and other product development activities, including the design of our preclinical studies and clinical trials;*
- *the timing of initiation of our preclinical studies and clinical trials;*
- *our ability to recruit, enroll and randomize suitable patients in our clinical trials;*
- *the timing of completion of our preclinical studies and clinical trials and related preparatory work;*
- *our ability to collect and interpret preclinical and clinical data;*
- *the timing and outcome of regulatory interactions, including whether preclinical studies and clinical trials meet the criteria to enable early-stage or late-stage clinical development or support registration of our product candidates;*
- *the potential attributes and benefits of our product candidates;*
- *our ability to obtain and, if obtained, maintain regulatory approval for our product candidates, and any related restrictions, limitations or warnings on the label of an approved product candidate;*
- *the potential for our business development efforts to optimize the potential value of our neuroscience pipeline;*
- *our ability to compete with other companies currently marketing or engaged in the development of treatments for the indications that we pursue or are pursuing for our product candidates;*
- *our ability to obtain and maintain intellectual property protection for our product candidates and the duration of such protection;*
- *our ability to contract with and rely on the performance of third-parties to assist in conducting our preclinical studies and clinical trials and manufacturing our product candidates;*
- *the size and growth potential of the markets for our product candidates, and our ability to serve those markets, either on our own or in partnership with others;*
- *the rate and degree of market acceptance of our product candidates, if approved;*
- *the pricing and reimbursement of our product candidates, if approved;*
- *regulatory changes, including regulatory personnel, and developments in the U.S. and foreign countries;*

- *the impact of laws, regulations, accounting standards, regulatory requirements, judicial decisions and guidance issued by authoritative bodies;*
- *our ability to attract and retain key scientific, medical, commercial and management personnel and the impact of any reductions in force (RIFs);*
- *our estimates regarding expenses, future revenue, and needs for additional financing;*
- *our future financial performance;*
- *our ability to recognize the anticipated benefits of our License and Collaboration Agreement with AffaMed Therapeutics, Inc. (including our ability to receive future payments thereunder) and any other future financing or business development transactions;*
- *the effect of adverse market or macroeconomic conditions, including, among others, tariffs, inflation, interest rates and economic uncertainty, market volatility resulting from global political or economic developments, reduced staffing at the Company or at the FDA or other government regulatory agencies, war, international hostilities and terrorism, any future public health epidemics or outbreaks of infectious disease and other factors on any of the foregoing or other aspects of our business operations, including but not limited to our preclinical studies, clinical trials and other product development activities, healthcare systems and the global economy as a whole; and*
- *other risks and uncertainties, including those listed under Part I, Item 1A of this Quarterly Report titled "Risk Factors."*

*The forward-looking statements contained in this Quarterly Report are based on current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions or important factors that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," set forth in this Quarterly Report. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. There may be additional risks that we consider immaterial, or which are unknown. It is not possible to predict or identify all such risks. We do not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.*

*You should read this Quarterly Report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.*

*This Quarterly Report contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed as exhibits to this Quarterly Report. Unless the context otherwise requires, reference in this Quarterly Report to the terms "Vistagen," "the Company," "we," "us," "our," and similar designations refer to Vistagen Therapeutics, Inc., a Nevada corporation, and where appropriate, our consolidated subsidiaries.*

*This Quarterly Report may contain references to trademarks, trade names and service marks belonging to other entities. Solely for convenience, trademarks, trade names and service marks referred to in this Quarterly Report may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that the applicable licensor will not assert, to the fullest extent under applicable law, its rights to these trademarks and trade names. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.*

*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 or disorders, 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, market research, projections, or similar methodologies is inherently subject to uncertainties, and actual circumstances, events 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 the industry, market and competitive position data from our internal estimates and research, or from independent market research,*

*industry and general publications and surveys, governmental agencies and publicly available information in addition to research, surveys and studies conducted by third parties that have not been independently verified which may, in the future, prove not to have been accurate.*

**Business Overview**

We are a late clinical-stage biopharmaceutical company leveraging a deep understanding of nose-to-brain neurocircuitry to develop and potentially commercialize a new class of intranasal product candidates called pherines. Our broad and diverse neuroscience pipeline currently consists of five clinical-stage pherine product candidates, each with a novel proposed mechanism of action (*MOA*) and at least one positive clinical study involving our targeted patient population. Pherines rapidly, specifically and selectively bind to peripheral receptors in human nasal chemosensory neurons, and are designed to rapidly activate nose-to-brain neurocircuits believed to regulate brain areas without requiring systemic absorption or uptake into the brain to achieve desired therapeutic benefits.

Our most advanced intranasal pherine product candidate is fasedienol, which is being investigated in our U.S. registration-directed PALISADE Program for the acute treatment of social anxiety disorder (*SAD*). There are four Phase 3 trials of fasedienol for the acute treatment of SAD in our PALISADE Program – PALISADE-1, PALISADE-2, PALISADE-3 and PALISADE-4. We have concluded PALISADE-1, PALISADE-2 and the randomized portion of PALISADE-3. PALISADE-2 achieved its primary endpoint; neither PALISADE-1 nor PALISADE-3 achieved its primary endpoint. PALISADE-4, and a small exploratory Phase 2B trial designed to assess efficacy, safety and tolerability of a repeat dose of fasedienol in adults with SAD in a public speaking challenge in a clinical setting (the *Repeat Dose Study*), are ongoing. Topline data for PALISADE-4 and the Repeat Dose Study are expected in the first half of calendar year 2026.

We have also reported positive results from an exploratory Phase 2A clinical trial for each of our next most advanced pherine product candidates, itruvone for treatment of major depressive disorder, and refisolone (formerly PH80) for both vasomotor symptoms (hot flashes) due to menopause and premenstrual dysphoric disorder, as well as a pilot Phase 2A study of PH15 for improvement of psychomotor impairment due to mental fatigue and an exploratory Phase 2A study of PH284 for treatment of cancer cachexia.

We are passionate about developing transformative treatment options with potential to meet clear and growing unmet patient needs and delivering long-term value to our stockholders.

**Our Neuroscience Product Candidates**

**Fasedienol**

***Overview of Social Anxiety Disorder***

SAD is a highly prevalent, serious, and life-threatening psychiatric mental health disorder affecting over 30 million adults in the U.S. With onset typically early in life, usually during adolescence, SAD persists for many years thereafter, with a reported mean duration of about 20 years. Individuals with SAD experience extreme anxiety, distress, fear, and impairment due to their fear of being watched, embarrassed, judged, humiliated, negatively evaluated, and scrutinized. The profound acute anxiety associated with SAD often results in avoidance of everyday interactions and opportunities in academic, social and vocational settings, which can lead to impaired personal relationships, unsatisfactory work performance, and substance abuse, significantly impacting various aspects of daily life. Individuals with SAD face an increased risk of serious and life-threatening co-morbid depression, substance abuse, suicidal ideation and suicide.

***Fasedienol for the Acute Treatment of Social Anxiety Disorder***

Fasedienol, our lead clinical-stage product candidate, is a synthetic neurocircuitry-focused intranasal pherine in an ongoing U.S. registration-directed Phase 3 clinical development program for the acute treatment of anxiety in adults with SAD. Fasedienol's proposed MOA is fundamentally differentiated from all FDA-approved anti-anxiety medications. When administered intranasally in microgram-level doses, neurocircuitry-focused fasedienol modulates the nasal-limbic amygdala fear and anxiety neurocircuits involved in the pathophysiology of SAD. Fasedienol is pharmacologically active without requiring apparent systemic absorption or direct binding on neurons in the brain to achieve its rapid-onset anxiolytic effects. Fasedienol has no observed binding on certain cellular receptors in the brain that are associated with known drug abuse liability potential (for example, dopamine and opiate receptors) when activated by certain other pharmaceutical compounds for neuropsychiatric and neurological disorders. Unlike benzodiazepines, fasedienol has no observed potentiation of GABA-A. Because of its innovative non-systemic neurocircuitry-focused proposed MOA, we believe fasedienol has the potential to achieve rapid-onset anxiolytic effects for individuals with SAD on an acute, as-needed basis, with a significantly reduced risk of unwanted side effects and safety concerns, such as potential drug-drug

interactions, abuse, misuse, and addiction, associated with certain current oral and other systemically absorbed neuropsychiatric pharmaceuticals that act directly on neurons in the brain and are sometimes prescribed off-label for the acute treatment of SAD.

***Fasedienol's U.S. Registration-directed PALISADE Program***

Fasedienol is under development, and has received fast track designation, for the acute treatment of SAD, and is designed to reduce the wave of anxiety usually experienced by SAD patients before engaging in (and during) a feared and anxiety-provoking social or performance situation. While there are approved treatments for SAD, none are approved for the acute treatment of SAD on an as-needed basis in connection with an anxiety-producing social or performance-based event. We have designed fasedienol nasal spray with the goal of creating a product candidate with a rapid-onset non-systemic proposed MOA and pharmacological effect, a key and substantial difference between fasedienol and all other available therapies approved by the FDA for the treatment of SAD.

Our PALISADE Program includes the PALISADE-1, PALISADE-2, PALISADE-3, and PALISADE-4 Phase 3 studies. These clinical trials are randomized, double-blind, placebo-controlled, U.S. multi-center Phase 3 clinical trials designed to evaluate the efficacy, safety, and tolerability of a single dose of fasedienol to relieve anxiety symptoms in adult patients with SAD during a five-minute, simulated, anxiety-provoking public speaking challenge conducted in a clinical setting, as measured by the least squares (*LS*) mean change from baseline on the patient-rated Subjective Units of Distress Scale (*SUDS*) score for fasedienol compared with placebo as the primary efficacy endpoint. Neither PALISADE-1, completed in 2022, nor PALISADE-3, the randomized portion of which was completed in December 2025, achieved its primary endpoint in the randomized phase of each study, as measured by the LS mean change from baseline on the SUDS score for fasedienol compared with placebo. After receipt of negative top-line results from PALISADE-1 during the COVID-19 pandemic, we terminated PALISADE-2 prior to completion (after enrolling 141 patients out of a planned 208) and analyzed the data from the 141 enrolled subjects. In August 2023, we announced that PALISADE-2 achieved its primary efficacy endpoint as measured by the LS mean change from baseline on the SUDS score for fasedienol compared with placebo. Safety data for fasedienol have been consistently favorable across all clinical trials completed to date.

Based on the positive data from PALISADE-2, we initiated PALISADE-3 and PALISADE-4 using the same randomized trial designs and primary efficacy endpoint utilized in PALISADE-2, and added an open-label extension to each of the studies. As noted above, PALISADE-3, the randomized portion of which was completed in December 2025, did not achieved its primary endpoint. Topline data from the randomized portion of PALISADE-4 are expected in the first half of calendar 2026.

We have aligned with the FDA that a clinic-based public speaking challenge and the SUDS are the appropriate study design and primary efficacy endpoint, respectively, to measure anxiety immediately related to the specific stressor, and is an appropriate and efficient path for our U.S. registration-directed PALISADE Program, which is focused on fasedienol's potential to become the first FDA-approved acute treatment of anxiety for adults with SAD. Based on FDA feedback, in addition to the Repeat Dose Study, we plan to generate evidence to support the clinical meaningfulness of the duration and magnitude of effect of fasedienol, which, pending the results of PALISADE-4 and further feedback from the FDA, we intend to include in a potential NDA submission together with data from our pivotal program, Repeat Dose Study, open-label long-term safety studies, a human factors study, and other clinical and preclinical studies.

We believe PALISADE-4, if successful, together with the positive results from PALISADE-2 and evidence we plan to generate to support the clinical meaningfulness of the duration and magnitude of effect of fasedienol, may establish substantial evidence of the effectiveness of fasedienol in support of a potential NDA submission to the FDA for the acute treatment of SAD, although we have not discussed this plan with the FDA subsequent to receipt of top-line results from the randomized portion of PALISADE-3. As we move closer toward potential completion of Phase 3 development, we plan to seek further feedback from the FDA regarding the proposed submission package for a potential NDA.

We believe fasedienol has the potential to be the first FDA-approved acute treatment of SAD and may provide significant advantages relative to the suboptimal standard of care for the highly prevalent disorder.

**Itruvone**

***Overview of Major Depressive Disorder***

Depression is a serious medical condition and a global public health concern that can arise at any time during a person's life. According to the World Health Organization (*WHO*), depression affects over 300 million people worldwide. The U.S. National Institute of Mental Health (*NIMH*) reports that approximately 21 million adults in the U.S., or approximately 8.4% of all adults in the U.S., experienced at least one major depressive episode in 2020. While many individuals will

experience a depressive episode at some point during their lifetime, major depressive disorder (*MDD*) is different. MDD is the chronic, pervasive feeling of utter unhappiness and suffering, which impairs daily functioning. Symptoms of MDD can include a lack of pleasure in activities, changes in appetite resulting in weight fluctuations, insomnia or excessive sleeping, psychomotor agitation, loss of energy or increased fatigue, feelings of worthlessness or inappropriate guilt, difficulty thinking, concentrating or making decisions, and thoughts of death or suicide and attempts at suicide. MDD is the psychiatric diagnosis most commonly associated with suicide.

For many people, depression cannot be controlled for any length of time without treatment. However, approximately two out of every three people who are treated for depression do not experience adequate therapeutic benefits from their initial treatment with a standard antidepressant. Even after multiple treatment attempts, about one-third of treated individuals are unable to find a sufficiently effective therapy. Inadequate response to current treatments is among the key reasons MDD is one of the leading public health concerns in the U.S., creating a significant unmet medical need for new agents with fundamentally differentiated MOAs and differentiated safety.

***Itruvone for the Treatment of Major Depressive Disorder***

Itruvone is our investigational pherine product candidate under development as a stand-alone treatment of MDD. The FDA has granted fast track designation for development of itruvone for MDD. Unlike other antidepressants which rely on single or double-receptor occupancy in the brain, itruvone's proposed MOA involves modulation of the nasal-limbic amygdala anhedonia and depressed mood neurocircuits. The scope of itruvone's neural circuit activation, and potential impact on the brain, appears, in studies completed to date, to be faster and safer than can be achieved with current therapies targeting binding to any specific brain receptor. We believe non-systemic itruvone has the potential to treat MDD without causing the side effects and safety concerns that may be associated with currently approved systemic antidepressant therapies, including, among others, drug-drug interactions, psychological side effects, sexual side effects, sedation, weight gain and suicidal ideation.

In a randomized, double-blind, placebo-controlled parallel design exploratory Phase 2A clinical trial of itruvone as a stand-alone treatment for MDD, itruvone reduced depressive symptoms in as soon as one week based on the 17-item Hamilton Depression Scale (*HAM-D-17*) scores compared to placebo. Itruvone was well-tolerated and did not cause psychological side effects (such as dissociation), sexual side effects, weight gain, or other safety concerns that may be associated with other approved pharmacological therapies for MDD. Positive data from our June 2023 Phase 1 trial of itruvone demonstrated that there were no reported treatment-related serious adverse events (*SAEs*) or discontinuations due to adverse events in the trial, consistent with previous clinical studies of itruvone. As a result, building on the positive results from the previous Phase 2A clinical development of itruvone in MDD, we are currently planning for potential U.S. Phase 2B clinical development of itruvone as a stand-alone treatment for MDD.

**Refisolone (formerly PH80)**

***Overview of Vasomotor Symptoms (Hot Flashes) due to Menopause***

Vasomotor symptoms (*VMS*), comprised of hot flashes and night sweats, are the most common symptoms of the menopausal transition, affecting 60% - 80% of menopausal women in the U.S., according to SWAN (Study of Women Across the Nation) and other published studies. VMS can be described as a sudden, intense feeling of warmth spreading through the upper body and face, flushed appearance with red, blotchy skin, rapid heartbeat, and perspiration on the upper body. Each episode typically lasts between one and five minutes and may be accompanied by sweating, chills, and anxiety. Although there is individual variability in the frequency and severity of symptoms, VMS negatively impacts physical, emotional, social, and occupational well-being, and can significantly diminish the overall quality of life and work productivity for those who experience symptoms. While there are FDA-approved therapies for the treatment of moderate to severe VMS due to menopause, many women are unable to use current therapies due to contraindications and safety concerns, such as cardiovascular disorders, dementia, breast cancer, and liver toxicity.

***Refisolone for the Treatment of Vasomotor Symptoms (Hot Flashes) due to Menopause***

Refisolone (formerly PH80) is our investigational pherine product candidate under development as a novel, non-hormonal, non-systemic, as-needed treatment of moderate to severe VMS (hot flashes) due to menopause, and potentially additional women’s health-focused indications. Refisolone’s proposed MOA is fundamentally differentiated from all currently approved treatments for VMS (hot flashes) due to menopause. Administration of low microgram doses of refisolone appears to rapidly activate peripheral nasal chemosensory neurons that modulate the nasal-limbic amygdala-hypothalamic depressed mood and thermoregulatory neurocircuits. Notably, in vitro studies showed that refisolone had no observed engagement with steroid receptors. An in vivo study in mice showed no observed estrogenic and/or androgenic activity and no changes in weight of the uterus or seminal vesicles after intranasal administration. Additionally, in an in vitro study

refisolone did not exert observable effects on receptor targets with known abuse potential, and a clinical study in human volunteers showed no detectable refisolone in blood plasma, indicating the non-systemic nature of refisolone's potential therapeutic benefit.

In a randomized, double-blind, placebo-controlled exploratory Phase 2A clinical study of refisolone that was designed to explore the efficacy, safety, and tolerability of intranasal administration of refisolone for the management of menopausal hot flashes in women, refisolone produced a significant reduction in the daily number of hot flashes compared to placebo at the end of the first week of treatment, and the improvement was maintained through each treatment week until the end of the four consecutive week treatment period. Refisolone was well-tolerated with no treatment-related SAEs reported, and the adverse event profiles were comparable between refisolone and placebo. No subject discontinued participation in the study as a result of adverse events.

We are currently preparing for our planned submission of our U.S. IND to facilitate further Phase 2 clinical development of refisolone in the U.S. as a potential treatment of moderate to severe VMS (hot flashes) due to menopause and potentially additional women's health indications.

***Overview of Premenstrual Dysphoric Disorder***

According to the U.S. National Institutes of Health (*NIH*), 5% to 8% of menarcheal (menstruating women) individuals have moderate-to-severe symptoms that can cause significant distress and functional impairment, suggestive of premenstrual dysphoric disorder (*PMDD*), a severe, sometimes disabling extension of premenstrual syndrome (*PMS*). Like PMS, PMDD can cause bloating, breast tenderness, fatigue, and changes in sleep and eating habits, but distinctively, it can also cause extreme mood shifts that can disrupt daily life and damage relationships. The cause of PMDD is not clearly understood, but it is thought that neurotransmitter systems may trigger PMDD. Treatment of PMDD is aimed at preventing or minimizing symptomology.

***Refisolone for Premenstrual Dysphoric Disorder***

In an exploratory, randomized, double-blind, placebo-controlled Phase 2A clinical study of refisolone for management of the symptoms of PMDD in subjects with a regular menstrual cycle and at least a one-year history of PMDD, refisolone demonstrated a statistically significant improvement versus placebo in management of the symptoms of PMDD, including negative mood and physical and behavioral symptoms, using the subject-rated Penn Daily Symptom Report (*DSR*). Refisolone was well-tolerated with no SAEs.

**PH15**

***Overview of Cognitive and Psychomotor Impairment due to Mental Fatigue***

Numerous conditions and disorders, such as shift work disorder, sleep apnea, and narcolepsy, can lead to debilitating sleep deprivation and mental fatigue. The prevalence of these conditions and disorders is high. For example, moderate to severe sleep apnea affects approximately 20% of adult men and 10% of postmenopausal women. Individuals affected by mental fatigue require improved treatment options with a differentiated safety profile, one without the potential for abuse liability or negative and treatment-limiting side effects and safety concerns that may lead to self-treatment and subsequent substance use disorders.

***PH15 for Improvement of Psychomotor Impairment due to Mental Fatigue***

PH15 is our investigational pherine product candidate under development as a treatment to improve psychomotor impairment caused by mental fatigue. PH15 is thought to target nasal receptors that modulate the nasal-entorhinal cortex area/hippocampus cognition neurocircuits, which are known to be associated with psychomotor activity and cognition, without requiring systemic absorption or direct action on neurons in the brain. PH15 has demonstrated favorable safety data in all clinical trials completed to date and we believe PH15's potential MOA is differentiated from the MOA of all currently approved treatments to improve psychomotor impairment caused by mental fatigue.

In a randomized, double-blind, placebo-controlled, crossover Phase 2A pilot study (n=10) designed to explore the efficacy, safety, and tolerability of intranasal administration of PH15 on psychomotor performance as measured by reaction time in sleep-deprived participants, PH15 demonstrated a statistically significant improvement in reaction time and the number of errors on both isochronous and stochastic stimuli reactions tests as compared to placebo and caffeine in the sleep-deprived study participants. PH15 was well-tolerated in this study, with no treatment-related SAEs reported. The adverse event profiles of PH15 and placebo were comparable.

We are currently evaluating the potential Phase 2 development path forward for PH15 and the manufacturing, nonclinical and Phase 1 clinical programs required to support submission of a U.S. IND to facilitate further potential Phase 2 development of PH15 in the U.S.

**PH284**

***Overview of Cancer Cachexia***

Cachexia, also known as wasting syndrome, is a complex metabolic syndrome that causes a gradual loss of muscle and body weight. Cachexia is associated with chronic diseases like cancer, AIDS, heart failure, chronic obstructive pulmonary disease, anorexia nervosa, multiple sclerosis, tuberculosis, and anemia. According to the National Cancer Institute (*NCI*), cachexia is estimated to occur in up to 80% of people with advanced cancer, depending on the type of cancer and how well they respond to cancer treatment. Cachexia is thought to directly cause up to 30% of cancer deaths, often because of heart or respiratory failure related to muscle loss. Maintaining nutritional support and alleviating cachexia has the potential to improve the underlying condition of cancer. Currently, there are no medical interventions or approved drugs proven to optimally alleviate cachexia.

***PH284 for Cancer Cachexia***

PH284 is our investigational pherine product candidate with a novel, rapid-onset, neurocircuitry-focused proposed MOA that, we believe, is differentiated from all current treatments for the loss of appetite associated with chronic disorders, such as cancer or heart disease. PH284 is thought to act by modulating the nasal-limbic amygdala-hypothalamic depressed mood and appetite control neurocircuits.

In a double-blind, placebo-controlled exploratory Phase 2A study designed to evaluate the efficacy, safety, and tolerability of intranasal administration of PH284 in female patients diagnosed with cachexia (induced by chronic loss of appetite) due to terminal cancer, PH284 induced a cumulative effect on mean Subjective Feeling of Hunger (*SFH*) scores, as compared to placebo. No unusual changes in body weight were observed in either the PH284 or placebo groups, though on average, there was a small gain in body weight for PH284 versus a small loss in placebo. PH284 demonstrated no serious treatment-related adverse events, and adverse events reported for the PH284 group were similar to those reported in the placebo-treated group. All the adverse events reported were attributed to the underlying medical condition (cancer) and were not deemed to be related to the administration of PH284 or placebo.

We are currently evaluating the potential path forward for PH284, including an assessment of the manufacturing, nonclinical and Phase 1 clinical programs required to support a U.S. IND application for potential further Phase 2 clinical development of PH284 for the treatment of cancer cachexia or other appetite-related disorders.

**AV-101**

***AV-101 for NMDAR-related Neurological Disorders***

AV-101 (4-Cl-KYN) is our novel, oral prodrug candidate that targets the NMDAR (N-methyl-D-aspartate receptor), an ionotropic glutamate receptor in the brain. Abnormal NMDAR function is associated with numerous neurological diseases and disorders. The active metabolite of AV-101, 7-chloro-kynurenic acid (7-Cl-KYNA), is a potent and selective full antagonist of the glycine binding site of the NMDAR that inhibits the function of the NMDAR. Unlike ketamine and many other NMDAR antagonists, 7-Cl-KYNA is not an ion channel blocker. In clinical and nonclinical testing completed to date, AV-101 has demonstrated favorable oral bioavailability and pharmacokinetic results. No binding of AV-101 or 7-Cl-KYNA to off-site targets was identified by an extensive receptor screening study. Moreover, in all clinical trials completed to date, AV-101 has been safe and well-tolerated with no psychological side effects or safety concerns and no treatment-related SAEs that are often observed with classic channel-blocking NMDAR antagonists such as ketamine and amantadine. Nonclinical results also indicate that chronic administration of 4-Cl-KYN induces hippocampal neurogenesis and increases endogenous levels of KYNA, which also is a functional NMDAR glycine site antagonist.

Based on observations and findings from preclinical, animal model, and human clinical studies, we believe AV-101 has the potential to become an oral treatment alternative for multiple neuroscience disorders, including levodopa-induced dyskinesia (*LID*) and neuropathic pain (*NP*) potentially among others. We are currently assessing whether there is a path forward for potential collaborative manufacturing, clinical development and commercialization of AV-101 for one or more neurological disorders involving the NMDAR.

The FDA has granted fast track designation for the investigation of AV-101 for the treatment of NP and for the adjunctive treatment of MDD.

**Subsidiaries**

Our wholly-owned subsidiaries consist of Pherin Pharmaceuticals, Inc, a Delaware corporation (*Pherin*), and Vistastem, Inc., a California corporation founded in 1998 (*Vistastem*).

**Financial Operations Overview and Results of Operations**

*Financial Overview*

Since inception, we have devoted substantial resources to advancing initiatives related to research, development, and contract manufacturing of our neuroscience pipeline, including initiatives related to manufacturing processes, analytical methods and production programs for drug substance and finished drug product, as well as for preclinical studies and clinical trials focused on development and potential commercialization of our product candidates, with substantial emphasis on our lead pherine product candidates, fasedienol, itruvone, and refisolone, for the acute treatment of SAD, and treatment of MDD and VMS due to menopause, respectively. At the end of our fiscal year ended March 31, 2024, we launched our PALISADE-3 Phase 3 clinical trial as part of our U.S. registration-directed PALISADE Phase 3 program evaluating fasedienol for the acute treatment of anxiety in adults with SAD, and in September 2024, we initiated our PALISADE-4 Phase 3 clinical trial for the same indication, and incurred costs to plan and prepare for the initiation of the Repeat Dose Study, which we initiated in January 2025. Both the PALISADE-4 Phase 3 trial and the Repeat Dose Study are also parts of our PALISADE Phase 3 program for fasedienol in SAD. In addition, we are continuing to conduct various nonclinical studies and contract manufacturing activities involving other clinical-stage pherine product candidates in our neuroscience pipeline. We also have ongoing initiatives for creating, protecting and patenting intellectual property (*IP*) related to our neuroscience product candidates and nasal spray delivery device technologies.

At December 31, 2025, we had an accumulated deficit of approximately $461.0 million. Our net loss for the year ended March 31, 2025 (*Fiscal 2025*) and the year ended March 31, 2024 (*Fiscal 2024*) was approximately $51.4 million and $29.4 million, respectively. We incurred a net loss of approximately $18.9 million and $53.4 million for the three and nine months ended December 31, 2025, respectively. We expect losses to continue for the foreseeable future as we engage in further research, clinical and nonclinical development, contract manufacturing and regulatory activities related to fasedienol, itruvone, refisolone and our other pherine product candidates. We have not yet achieved revenue-generating status from any of our product candidates or technologies in amounts sufficient to sustain our operations and fund our strategic business plans.

**Components of Results of Operations**

***Sublicense and Other Revenue***

Sublicense and other revenue consist of revenue recognized under our License and Collaboration Agreement with AffaMed Therapeutics, Inc. (*the Affamed Agreement*) and our Exclusive Negotiation Agreement (the *Negotiation Agreement*) with Fuji Pharma Co., Ltd. Revenue is recognized as identified performance obligations are satisfied.

***Operating Expense***

*Research and Development Expense*

To date, our research and development expense has consisted primarily of external and internal costs related to the development of our product candidates and development programs. Our research and development expense primarily includes:

- External costs, including:
  - expenses incurred in connection with planning, preparing for and conducting clinical trials, including investigator grants and site payments, and pass-through expenses and expenses incurred under agreements with our contract research organizations (*CROs*), central laboratories and other vendors and service providers engaged to conduct our trials;
  - expenses incurred in connection with the discovery and preclinical development of our product candidates, including under agreements with third parties, such as consultants and CROs;
  - costs associated with consultants for chemistry, manufacturing, and control (*CMC*) development, and other manufacturing-related services;

- ◦the cost of manufacturing compounds for use in our nonclinical studies and clinical trials, including under agreements with third parties, such as consultants and third-party contract development and manufacturing organizations (*CDMOs*); and
- ◦costs related to compliance with development regulatory requirements.

- Internal costs, including:
  - ◦employee-related expenses, including salaries, related benefits, travel and share-based compensation expenses for employees engaged in research and development functions;
  - ◦the costs of laboratory supplies and acquiring and developing preclinical study materials; and
  - ◦facilities, depreciation and other expenses, which include allocated expenses for rent and maintenance of facilities, and supplies.

We expense research and development costs in the periods in which they are incurred. External expenses are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers or our estimate of the level of service performed at each reporting date.

Research and development activities are central to our business model. There are numerous factors associated with the successful research and development of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. In addition, future regulatory factors beyond our control may impact our preclinical and clinical development programs and regulatory pathways. Product candidates in later stages of development generally have higher development costs than those in earlier stages of development.

Our future research and development expenses may vary significantly based on a wide variety of factors, such as:

- the number and scope, rate of progress, expense and results of our preclinical development activities and clinical trials;
- the number of trials required for regulatory approval;
- the number of sites included in each of our clinical trials;
- the length of time required to enroll and randomize eligible patients in our clinical trials;
- the number of patients that participate in our clinical trials;
- the ability to identify appropriate patients eligible for our clinical trials;
- the number of doses that patients receive during our clinical trials;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the clinical trials and follow-up;
- the phase of development of the product candidate;
- the efficacy and safety profile of the product candidate;
- the timing, receipt, and terms of any approvals from applicable regulatory authorities including the FDA and non-U.S. regulators;
- maintaining a continued acceptable safety profile of our product candidates following approval, if any;
- the cost and timing of manufacturing our product candidates and our reliance on third-party CDMOs;

•significant and changing government regulation and regulatory guidance;

•the impact of any business interruptions to our operations or to those of the third parties with whom we work, including consolidation of third-party CROs, CDMOs or preclinical and clinical research sites involved in our product development programs;

•adverse effects on the financial markets, the global economy, the supply chain and our expenses due to pandemics or other epidemic diseases, geopolitical instability, government shutdowns and RIFs, inflation, rising interest rates, government tariffs and other factors; and

•the extent to which we establish additional strategic collaborations or other arrangements.

A change in the outcome of any of these variables with respect to the research and development of any of our product candidates could significantly change the costs and timing associated with the research and development of that product candidate. The process of conducting the necessary preclinical and clinical research and development to obtain regulatory approval is costly and time-consuming. The actual probability of success for our product candidates or any future candidates may be affected by a variety of factors. We may never succeed in achieving regulatory approval for any of our product candidates or any future candidates.

*General and Administrative Expense*

General and administrative expenses consist of salaries, bonuses, related benefits and stock-based compensation expense for personnel in executive, legal, finance and administrative functions; professional fees for legal, consulting, accounting and audit services; and travel expenses, technology costs and other allocated expenses. We expense general and administrative expenses in the periods in which they are incurred.

**Results of Operations for the Three and Nine Months Ended December 31, 2025**

The following table summarizes the results of our operations for the three and nine months ended December 31, 2025 and 2024 (in thousands):

| | Three Months Ended December 31, | | Nine Months Ended December 31, | |
|---|---|---|---|---|
| | **2025** | **2024** | **2025** | **2024** |
| Revenues: | | | | |
| Sublicense and other revenue | $ 303 | $ 234 | $ 804 | $ 501 |
| Total revenues | 303 | 234 | 804 | 501 |
| Operating expenses: | | | | |
| Research and development | 14,223 | 11,305 | 41,914 | 29,168 |
| General and administrative | 5,626 | 4,049 | 14,299 | 12,811 |
| Total operating expenses | 19,849 | 15,354 | 56,213 | 41,979 |
| Loss from operations | (19,546) | (15,120) | (55,409) | (41,478) |
| Other income, net: | | | | |
| Interest income, net | 647 | 1,031 | 1,989 | 3,702 |
| Other income | — | — | 9 | — |
| Loss before income taxes | (18,899) | (14,089) | (53,411) | (37,776) |
| Income taxes | — | — | — | (7) |
| Net loss | $ (18,899) | $ (14,089) | $ (53,411) | $ (37,783) |

*Revenue*

We recognized $0.3 million and $0.8 million in sublicense and other revenue for the three and nine months ended December 31, 2025, as compared to $0.2 million and $0.5 million for the three and nine months ended December 31, 2024,

respectively. The increase in sublicense and other revenue is due to timing of revenue recognized under the AffaMed Agreement.

Absent the achievement of milestones under the AffaMed Agreement, or the execution of similar agreements in the future, if any, we expect sublicense and other revenue to stay materially consistent in future periods as we continue to recognize revenue under the AffaMed Agreement.

***Research and Development Expense***

The following table summarizes our research and development expense for the three and nine months ended December 31, 2025 and 2024 (in thousands):

| | Three Months Ended December 31, | | Nine Months Ended December 31, | |
|---|---|---|---|---|
| | **2025** | **2024** | **2025** | **2024** |
| Clinical and nonclinical studies and development expense by program | | | | |
| Fasedienol | $ 10,374 | $ 6,370 | $ 29,687 | $ 15,996 |
| All other | 44 | 1,627 | 1,029 | 2,492 |
| Total clinical and nonclinical studies and development expense | 10,418 | 7,997 | 30,716 | 18,488 |
| Salaries and benefits | 2,559 | 2,256 | 7,648 | 6,892 |
| Stock-based compensation | 466 | 427 | 1,327 | 1,533 |
| Consulting and professional services | 391 | 278 | 1,031 | 1,201 |
| Occupancy and all other costs | 389 | 347 | 1,192 | 1,054 |
| Total research and development expense | $ 14,223 | $ 11,305 | $ 41,914 | $ 29,168 |

Research and development expense was $14.2 million and $41.9 million for the three and nine months ended December 31, 2025, as compared to $11.3 million and $29.2 million for the three and nine months ended December 31, 2024, respectively.

The increase of $2.9 million in research and development expense for the three months ended December 31, 2025 as compared to the same period in Fiscal 2025 was primarily due to an increase in clinical development expense of $4.0 million related to our U.S. registration-directed PALISADE program for fasedienol for the acute treatment of SAD, and an increase of $0.3 million in connection with the increased headcount, partially offset by a decrease in expense related to our other product candidates.

The increase of $12.7 million in research and development expense for the nine months ended December 31, 2025 as compared to the same period in Fiscal 2025 was primarily due to an increase in clinical development expense of $13.7 million, related to our U.S. registration-directed PALISADE program for fasedienol for the acute treatment of SAD and an increase of $0.6 million in connection with increased headcount, partially offset by a decrease in expense related to our other product candidates.

During the quarter ended December 31, 2025, we began realizing a decrease in research and development expenses as a result of cash preservation measures implemented following the announcement of top-line results from our PALISADE-3 clinical trial. We expect research and development expenses to continue to decrease in future periods as a result of these cash preservation measures. However, should PALISADE-4 be successful, we expect that our research and development expense will increase over the next fiscal year as we continue to advance research and development of our pherine product candidates and maintain, expand, protect and enforce our intellectual property portfolio, and hire additional headcount. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the nonclinical and clinical development of any pherine product candidates we are developing or may develop. A change in the outcome of any number of variables could significantly alter the costs and timing associated with the development of any of our pherine product candidates.

***General and Administrative Expense***

General and administrative expense was $5.6 million and $14.3 million for the three and nine months ended December 31, 2025, as compared to $4.0 million and $12.8 million for the three and nine months ended December 31, 2024, respectively.

The increases in general and administrative expense for the three and nine months ended December 31, 2025, as compared to the same periods in 2024, are primarily due to an increase in consulting and professional fees.

During the quarter ended December 31, 2025, we began realizing a decrease in general and administrative expenses as a result of cash preservation measures implemented following the announcement of top-line results from our PALISADE-3 clinical trial. We expect general and administrative expenses to continue to decrease in future periods as a result of these cash preservation measures. However, should PALISADE-4 be successful and in the event our PALISADE program advances towards a submission of an NDA to the FDA, we expect that our general and administrative expenses will substantially increase. We also expect to continue to incur routine expenses associated with being a public company, including costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with Nasdaq Capital Market and SEC requirements, as well as director and officer insurance costs and investor and public relations costs.

***Other Income***

Interest income, net, decreased for the three and nine months ended December 31, 2025 as compared to the same period in Fiscal 2025 primarily due to a decrease in amounts invested in interest bearing securities.

**Liquidity and Capital Resources**

***Sources of Liquidity***

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from our operations. To date, as of December 31, 2025, we have financed our operations and technology acquisitions primarily through the issuance and sale of our equity securities for cash proceeds of approximately $372.5 million, as well as from an aggregate of approximately $22.7 million of government research grant awards (excluding the fair market value of government-sponsored and funded clinical trials), strategic collaboration payments, intellectual property licensing payments, and other revenues. Additionally, we have issued equity securities with an approximate value at issuance of $41.3 million for non-cash acquisitions of product licenses, consideration for our acquisition of Pherin Pharmaceuticals, Inc. in February 2023 (the *Pherin Acquisition*), and in settlements of certain liabilities, including liabilities for professional services rendered to us or as compensation for such services.

In addition, we received net proceeds of approximately $93.5 million from an underwritten public offering of our securities in October 2023 (*October 2023 Public Offering*), and $1.5 million in connection with the execution of the Negotiation Agreement with Fuji Pharma Co., Ltd. in September 2023.

In May 2021, we entered into an Open Market Sale Agreement (the *Sales Agreement*) with Jefferies LLC (*Jefferies*) as sales agent, with respect to an at-the-market offering program, under which we were permitted, at our option, to offer and sell, from time to time, shares of our common stock having an aggregate offering price of up to $75.0 million. In February 2024, the aggregate offering price available under the Sales Agreement was increased to up to $100 million, and in June 2025, the aggregate offering price available under the Sales Agreement was increased to up to $175 million. During the three and nine months ended December 31, 2025, we sold an aggregate of 604,405 and 10,403,244 shares under the Sales Agreement, for net proceeds of $2.3 million and $30.6 million, respectively. During the three and nine months ended December 31, 2024, we sold an aggregate of 428,322 shares under the Sales Agreement, for net proceeds of $1.1 million.

As of December 31, 2025, we had cash, cash equivalents, and marketable securities of approximately $61.8 million. As of February 12, 2026, the issuance date of the condensed consolidated financial statements in this Quarterly Report as of and for the three and nine months ended December 31, 2025, there is uncertainty about whether our combined cash, cash equivalents, and marketable securities will be sufficient to fund operations beyond twelve months from the issuance date of the condensed consolidated financial statements in this Report and therefore we concluded that substantial doubt existed about our ability to continue as a going concern.

When necessary and/or advantageous, we will seek additional capital to fund our planned operations through (i) sales of our equity and/or debt securities in one or more public offerings and/or private placements, including, but not limited to sales of our securities under the Sales Agreement, (ii) non-dilutive government grants and research awards and/or (iii) non-

dilutive strategic partnering collaborations to advance development and commercialization of one or more of our product candidates. However, no assurance can be provided that any such sales of our securities, awards, agreements or collaborations will occur in the future. While we may make additional sales of our equity and/or debt securities, we do not have an obligation to do so.

Our future working capital requirements will depend on many factors, including, without limitation, potential impacts related to adjustments in the size of our staff or other actual and/or planned adjustments to our operations, the scope and nature of opportunities related to our success or failure and the success or failure of certain other companies in nonclinical and clinical trials, including the development and commercialization of our current product candidates, and the availability of, and our ability to enter into financing transactions and research, development and commercialization collaborations on terms acceptable to us. In the future, to further advance the nonclinical and clinical development of our product candidates, as well as support our operating activities, we plan to seek additional financing, including both equity-based and/or debt-based capital and potentially from non-dilutive sources other than debt-based capital, and continue to carefully manage our operating costs, including, but not limited to, our clinical and nonclinical programs.
There can be no assurance that future financings will be available to us in sufficient amounts, in a timely manner, or on terms acceptable to us, if at all, or that any current or future development and commercialization collaborations will generate revenue from future potential milestone payments or otherwise. Further, on February 3, 2026, we received a letter from the Listing Qualifications Staff of The Nasdaq Stock Market, LLC (*Nasdaq*) indicating that, based upon the closing bid price of our common stock for the previous 30 consecutive business days, we are not currently in compliance with the requirement to maintain a minimum bid price of $1.00 per share for continued listing on the Nasdaq Capital Market. While the letter has no immediate effect on the listing of our common stock on the Nasdaq Capital Market, failure to meet applicable Nasdaq continued listing standards by August 3, 2026, the expiration of the 180-day period in which to regain compliance, unless extended, could potentially result in a delisting of our common stock. If we are unable to regain timely compliance with the Nasdaq continued listing standards and/or obtain additional financing on a timely basis when needed, our business, financial condition, and results of operations may be harmed, the price of our common stock may decline, we may be required to reduce, defer, or discontinue certain of our research and development activities, and we may not be able to continue as a going concern.

***Cash Flows***

The following table summarizes changes in cash and cash equivalents for the periods stated (in thousands):

| | Nine Months Ended December 31, | |
|---|---|---|
| | **2025** | **2024** |
| Net cash used in operating activities | $ (50,236) | $ (32,035) |
| Net cash used in investing activities | (778) | (13,675) |
| Net cash provided by financing activities | 31,254 | 1,259 |
| Net increase (decrease) in cash and cash equivalents | (19,760) | (44,451) |
| Cash and cash equivalents at beginning of period | 67,131 | 119,166 |
| Cash and cash equivalents at end of period | $ 47,371 | $ 74,715 |

*Operating Activities*

Net cash used in operating activities for the nine months ended December 31, 2025 was $50.2 million, consisting primarily of our net loss of $53.4 million, adjusted for $3.2 million of non-cash charges primarily related to stock-based compensation expense and amortization of our operating lease right-of-use asset, and $0.1 million in net changes in operating assets and liabilities.

Net cash used in operating activities for the nine months ended December 31, 2024 was $32.0 million, consisting primarily of our net loss of $37.8 million, adjusted for $3.6 million of non-cash charges primarily related to stock-based compensation expense and amortization of our operating lease right-of-use asset, and $2.2 million in net changes in operating assets and liabilities.

*Investing Activities*

Net cash used in investing activities for the nine months ended December 31, 2025 was $0.8 million, consisting of purchases of marketable securities and property and equipment, partially offset by the sale and maturity of marketable securities.

Net cash used in investing activities for the nine months ended December 31, 2024 was $13.7 million, consisting of purchases of marketable securities and property and equipment, partially offset by the sale and maturity of marketable securities.

*Financing Activities*

Net cash provided by financing activities during the nine months ended December 31, 2025 was $31.3 million, consisting primarily of net proceeds from the sale of common stock in at-the-market transactions under the Sales Agreement of $30.6 million, and proceeds from the issued note payable related to the insurance premium financing arrangement of $1.0 million, partially offset by repayments of the note payable.

Net cash provided by financing activities during the nine months ended December 31, 2024 was immaterial.

**Contractual Obligations**

There have been no other material changes in our contractual obligations and commitments during the three and nine months ended December 31, 2025, from those described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Commitments” in our Annual Report on Form 10-K for the year ended March 31, 2025, filed with the SEC on June 17, 2025 (the *Annual Report*).

**Critical Accounting Estimates**

There have been no material changes to our critical accounting estimates during the three and nine months ended December 31, 2025, as compared to the critical accounting policies and estimates disclosed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report.

## Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company, as defined by Rule 12b-2 under the Securities and Exchange Act of 1934, as amended (the *Exchange Act*), and in Item 10(f)(1) of Regulation S-K and are not required to provide the information under this item.

## Item 4. CONTROLS AND PROCEDURES

**Disclosure Controls and Procedures**

Our management, with the participation of our Chief Executive Officer (principal executive officer) and our Chief Financial Officer (principal financial and accounting officer), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2025. The term “disclosure controls and procedures” as defined in Rule 13a-15(e) of the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2025, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

**Internal Control over Financial Reporting**

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) from that described in our Annual Report that occurred during the quarter ended December 31, 2025, to which this Report relates, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II: OTHER INFORMATION

### Item 1. Legal Proceedings

*Cesario et al. v. Vistagen Therapeutics, Inc. et al.* On February 13, 2025, John Cesario and David Preka (the *Plaintiffs*) filed a civil action, *pro se* (i.e., acting on their own behalf rather than through an attorney), in the United States District Court for the Northern District of California (Case No. 4:25-cv-01510) (the *Complaint*) against the Company and its Board, certain of its executive officers, professional services and financial advisors, and industry analysts. The Plaintiffs filed an amended complaint on March 10, 2025 (the *First Amended Complaint*). On September 3, 2025, we filed a motion to dismiss the First Amended Complaint. On October 9, 2025, the Court granted Plaintiffs leave to amend the First Amended Complaint, and on November 3, 2025, the Plaintiffs filed a proposed second amended complaint (the *Second Amended Complaint*). On December 4, 2025, the Court granted Plaintiffs leave to file the Second Amended Complaint, and the Second Amended Complaint was filed with the Court on the same day. On December 24, 2025, we filed a motion to dismiss the Second Amended Complaint. A case management conference is currently scheduled for April 2, 2026. A hearing on the motion to dismiss the Second Amended Complaint is currently scheduled for April 21, 2026.

The Plaintiffs seek compensatory and punitive damages, as well as fees and costs. The operative complaint alleges violations of Section 10(b) of the Securities Exchange Act of 1934, as amended (the *Exchange Act*), and Rule 10b-5 promulgated thereunder, along with other causes of action. The Plaintiffs allege, among other things, that the Company, and certain of its executive officers, made misleading statements and material omissions in various public disclosures concerning clinical trials for certain of the Company's product candidates, which they allege caused plaintiffs to incur compensable losses. The Complaint also alleges that the Board, certain of the Company's professional and financial advisors, and industry analysts aided and abetted the alleged wrongful conduct. The Company believes all allegations asserted in the Complaint are wholly without merit, and intends to defend them vigorously.

*Eller v. Vistagen Therapeutics, Inc. et al*. On January 15, 2026, a putative class action complaint (the *Class Action Complaint*) was filed by alleged stockholder Dan Eller against the Company and certain of its executive officers (the *Defendants*) in the United States District Court for the Northern District of California (Case No. 3:26-cv-00427). The Class Action Complaint alleges that the Defendants made material misrepresentations and omissions concerning the PALISADE-3 Phase 3 clinical trial and asserts claims under Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder. Plaintiff seeks to represent a putative class of stockholders who purchased or otherwise acquired Company securities between April 1, 2024 and December 16, 2025, both dates inclusive. Plaintiff seeks unspecified damages.

The Company believes all allegations asserted in the Class Action Complaint are wholly without merit, and intends to defend them vigorously.

### Item 1A. Risk Factors

**Summary**

*Investing in our securities involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with the other information in this Report, including our Condensed Consolidated Financial Statements and the related notes included in this Report and in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our securities. The occurrence of one or more of the events or circumstances described in these risk factors, alone or in combination with other events or circumstances, may have a material adverse effect on our business, reputation, revenue, financial condition, results of operations and future prospects, in which event the market price of our common stock could decline, and you could lose part or all of your investment. Unless otherwise indicated, reference in this section and elsewhere in this Report to our business being adversely affected, negatively impacted or harmed will include an adverse effect on, or a negative impact or harm to, the business, reputation, financial condition, results of operations, revenue and our future prospects. The material and other risks and uncertainties summarized elsewhere in this Report and described below are not intended to be exhaustive and are not the only ones we face. Additional risks and uncertainties not presently known to us, or that we currently deem immaterial, may also impair our business operations. This Report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a number of factors, including the risks described below. See the section titled*

*"Cautionary Note Regarding Forward-Looking Statements."*

- we are a clinical-stage biopharmaceutical company with no approved products or revenues from product sales, and limited experience developing and commercializing new product candidates, which makes it difficult to assess our future viability;
- we have incurred significant net losses since inception, and we will continue to incur substantial operating losses for the foreseeable future;
- we require substantial additional financing to execute our business plan, including further nonclinical and clinical development, contract manufacturing and potential commercialization of our product candidates;
- raising additional capital in equity-based financing transactions will cause substantial dilution to our existing stockholders, may restrict our operations or require us to relinquish rights to our product candidates, and may require us to seek stockholder approval to authorize additional shares of our common stock;
- if we fail to regain compliance with the continued listing requirements of the Nasdaq Capital Market, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted;
- we depend heavily on the success of our product candidates, and we cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, any of our current or future product candidates;
- failures of ongoing or future nonclinical or clinical trials of our product candidates, or material delays in the completion and/or commencement of our ongoing or planned nonclinical or clinical trials, could result in increased costs to us and could delay, prevent or limit our ability to generate revenue and continue our business;
- we are focused on novel neuroscience drug development, a field that has seen very limited success. The ability to successfully develop product candidates in this field is extremely difficult and is subject to a number of unique challenges;
- if we are unable to retain or attract key management and scientific personnel, or effectively manage the impact of any potential RIFs, we may be unable to successfully produce, develop, and commercialize our product candidates;
- we rely on third party collaborators to assist in conducting our nonclinical studies and clinical trials and if they do not perform satisfactorily, we may not be able to obtain regulatory approval or commercialize our product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed;
- we operate in highly competitive and rapidly changing industries, which may result in others discovering, developing or commercializing competing products before or more successfully than we do;
- nonclinical and clinical drug development is a lengthy and expensive process, with an uncertain outcome. Our nonclinical and clinical programs have experienced delays and may experience additional delays or may never advance, which would adversely affect our ability to obtain regulatory approvals or commercialize our product candidates on a timely basis or at all, which could have an adverse effect on our business;
- we face significant competition, and if we are unable to compete effectively, we may not be able to achieve or maintain significant market penetration or improve our results of operations;
- if we are unable to adequately protect our proprietary technology and product candidates, or obtain and maintain issued patents that are sufficient to protect our product candidates, others could compete against us more directly, which would have a material adverse impact on our business, results of operations, financial condition and prospects;
- reduction in staffing, large staff turnover, changes to key personnel on applicable regulatory review teams and/or inadequate funding for the FDA or other government agencies, including those resulting from reduced staffing levels, could hinder those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business; and
- other risks and uncertainties, including those described below.

If we are unable to effectively manage the impact of these and other risks, our ability to operate and execute our strategic business plan would be substantially impaired. In turn, the value of our securities would be materially reduced.

**Risks Related to Our Business**

***The successful development of pharmaceutical products is highly uncertain.***

Successful development of pharmaceutical products is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- delays or difficulties in enrollment and completion of any of our clinical trials;
- clinical trial results may show the product candidates to be less effective than expected (for example, a clinical trial could fail to meet its primary or key secondary endpoint(s), as was the case in our PALISADE-1 and PALISADE-3 clinical trials) or have an unacceptable safety or tolerability profile;
- the FDA or other equivalent non-U.S. regulatory authorities may find the chemistry, manufacturing and controls, or (*CMC*) data insufficient to support the quality of our product candidates;
- preclinical study results may show the product candidate to be less effective than desired or to have harmful side effects;
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals, which, among other things, may be caused by patients who fail the trial screening process, slow enrollment in clinical trials, patients dropping out of trials, patients lost to follow-up, length of time to achieve trial endpoints, additional time requirements for data analysis, review of IND, NDA or similar foreign applications, preparation, discussions with the FDA or foreign regulatory authorities, a FDA or foreign regulatory authority request for additional preclinical or clinical data (such as long-term toxicology studies) or unexpected safety or manufacturing issues;
- post-marketing approval requirements; or
- the proprietary rights of others and their competing products and technologies that may prevent our product candidates from being commercialized.

The length of time necessary to complete clinical trials and submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one product candidate to the next and from one country or jurisdiction to the next and may be difficult to predict.

Even if we are successful in obtaining marketing approval, commercial success of any approved products will also depend in large part on the availability of coverage and adequate reimbursement from third-party payors, including government payors such as the Medicare and Medicaid programs and managed care organizations in the U.S. or country-specific governmental organizations in foreign countries, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. Third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other healthcare payors were not to provide coverage and adequate reimbursement for our products once approved, market acceptance and commercial success would be reduced.

In addition, if any of our product candidates receive marketing approval, we will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and registration, and will need to continue to comply (or ensure that our third-party providers comply) with current good manufacturing practices (*cGMPs*) and similar foreign requirements, and good clinical practices (*GCPs*) for any clinical trials that we conduct post-approval. In addition, there is always the risk that we, a regulatory authority or a third party might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any failure to comply or other issues with our product candidates post-approval could adversely affect our business, financial condition and results of operations.

***Our business is highly dependent on the success of our product candidates. If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize one or more of our product candidates, or if we experience delays in doing so, our business will be materially harmed.***

To date, as an organization, we have not completed the development of any of our product candidates. Our future success and ability to generate revenue from our product candidates is dependent on our ability to successfully develop, obtain regulatory approval for and commercialize one or more of our product candidates. All of our product candidates will require substantial additional investment for clinical development, regulatory review and approval in one or more jurisdictions. If any of our product candidates encounters safety or efficacy problems, development delays or regulatory issues or other problems, our development plans and business would be materially harmed.

Our nonclinical and clinical programs have experienced delays and may experience additional delays or may never advance, which would adversely affect our ability to obtain regulatory approvals or commercialize our product candidates on a timely basis or at all, which could have an adverse effect on our business. We may not have the financial resources to continue development of or commercialize our product candidates if we experience any issues that further delay or prevent regulatory approval of, or our ability to commercialize, our product candidates, including:

- negative or inconclusive results from our preclinical studies, clinical trials or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical studies, clinical trials or abandon a program;
- insufficiency of our financial and other resources to complete the necessary preclinical studies, clinical trials and regulatory submissions or necessary to fund pre-commercial and commercial activities to establish sales, marketing and distribution capabilities needed to successfully commercialize an approved product;
- poor effectiveness of our product candidates observed during clinical trials;
- better than expected performance of control arms, such as placebo groups, which could lead to negative or inconclusive results from our clinical trials;
- delays in enrolling and randomizing subjects in our clinical trials;
- high drop-out rates of subjects from our clinical trials;
- inadequate supply or quality of product candidates or other materials necessary for the conduct of our clinical trials;
- higher than anticipated clinical trial or manufacturing costs;
- product-related adverse events experienced by subjects in our clinical trials, including unexpected toxicity results, or by individuals using drugs or therapeutic biologics similar to our product candidates;
- delays in submitting an IND or comparable foreign applications or delays or failure in obtaining the necessary approvals or allowances from regulators to commence a clinical trial or a suspension or termination, or hold, of a clinical trial once commenced;
- our inability to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective;
- conditions imposed by the FDA or comparable foreign regulatory authorities regarding the scope or design of our clinical trials;
- unfavorable FDA or comparable regulatory authority inspection and review of our clinical trial sites;
- failure of our third-party contractors or investigators to comply with regulatory requirements or the clinical trial protocol or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policies and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our therapies in particular; or
- varying interpretations of data by the FDA and comparable foreign regulatory authorities.

***We are a clinical-stage biopharmaceutical company with no recurring revenues from product sales or approved products. We are not profitable and have incurred losses in each period since our inception. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, and commercialization of our product candidates.***

We are a clinical-stage biopharmaceutical company. We have no products approved for commercial sale and have generated no revenue from product sales to date. We will continue to incur significant research and development and other expenses related to our preclinical and clinical development and ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Our net losses totaled $51.4 million and $29.4 million for the years ended March 31, 2025 and 2024, respectively, and we incurred a net loss of $53.4 million during the nine months ended December 31, 2025. We expect to continue to incur significant losses for the foreseeable future.

We anticipate that our expenses will increase substantially in the event we:

- advance our product candidates through clinical development, including as we advance these candidates into and through later-stage clinical trials;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- hire additional clinical, quality control, medical, scientific and other technical personnel to support the clinical development of our product candidates;
- experience an increase in headcount as we expand our research and development organization and market development and pre-commercial planning activities;
- undertake any commercialization-related activities;
- advance preclinical-stage product candidates into clinical development; and
- maintain, protect and seek to expand our intellectual property portfolio.

Biopharmaceutical product development entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, secure market access and reimbursement, and become commercially viable, and therefore any investment in us is highly speculative. Accordingly, before making an investment in us, you should consider our prospects, factoring in the high costs, uncertainties, delays and difficulties frequently encountered by companies in clinical development, especially small clinical-stage biopharmaceutical companies such as ours. Any predictions you make about our future success or viability may not be as accurate as they would otherwise be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives.

Additionally, our expenses could increase beyond our expectations if we are required by the FDA or other regulatory authorities to perform preclinical studies or clinical trials in addition to those that we currently anticipate, or if there are any delays in establishing appropriate manufacturing arrangements for or in completing our clinical trials or the development of any of our product candidates.

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

Our ability to become and remain profitable depends on our ability to generate revenue or execute other business development arrangements. We do not expect to generate significant revenue, if any, unless and until we are able to obtain regulatory approval for, and successfully commercialize, one or more product candidates we are developing or may develop. Successful commercialization will require achievement of many key milestones, including demonstrating sufficient evidence of safety and efficacy in clinical trials, obtaining regulatory approval for these product candidates, manufacturing, marketing and selling those products for which we may obtain regulatory approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of revenues, the extent of any further losses or if or when we might achieve profitability. We may never succeed in these activities, and even if we do, we may never generate revenues that are significant enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

Our failure to become and remain profitable may depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. If we continue to incur losses as we have since our inception, investors may not receive any return on their investment and may lose their entire investment.

***We will need substantial additional financing to execute our business plan, and if we are unable to raise capital when needed, we could be forced to delay, reduce or terminate our research and development programs, pre-commercialization or commercialization efforts.***

Our operations have consumed substantial amounts of cash since inception. As in prior periods we expect to continue to spend substantial amounts of cash to continue the preclinical and clinical development of our product candidates. These expenditures will include costs associated with general and administrative costs, facilities costs, research and development, manufacturing, conducting nonclinical experiments and clinical trials, obtaining regulatory approvals and commercialization, should the FDA approve any of our product candidates for sale. We will need to raise substantial additional capital to complete certain of our currently planned preclinical and clinical development programs, including future late-stage clinical trials. If we are able to gain marketing approval for any product candidates that we develop, we will require significant amounts of additional capital in order to launch and commercialize such product candidates. As the outcome of our ongoing research and development activities, including the outcome of future anticipated preclinical studies and clinical trials, is highly uncertain, we cannot reasonably estimate the actual amounts of additional capital necessary to successfully complete the development and commercialization, alone or with one or more collaborators of any product candidate we develop. We do not expect to generate sustainable positive operating cash flows until, and unless, we obtain approval from the FDA and other regulatory authorities and successfully commercialize one or more of our product candidates alone or with one or more collaborators.

As a result of these and other factors, we will need to seek additional capital to fund our future operating plans and requirements, including capital necessary to develop, obtain regulatory approval for, and commercialize our product candidates, alone or with one or more collaborators, and may seek additional capital in the event there exists favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans and requirements.

Our future need for additional funding depends on many factors, including:

- the number and characteristics of future product candidates we pursue and their development requirements;
- the scope, progress, results and costs of researching, developing and commercializing our product candidates, alone or with one or more collaborators, and any other additional product candidates we may develop and pursue in the future;
- the timing of, and the costs involved in, obtaining marketing approvals for our product candidates and any other additional product candidates we may develop and pursue in the future;
- subject to receipt of regulatory approval, the costs of commercialization activities for our product candidates, to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to receipt of regulatory approval, revenue, if any, received from commercial sales of our product candidates or any other additional product candidates we may develop and pursue in the future;
- the cost of formulating and manufacturing our product candidates, and our reliance on third-party contract development and manufacturing organizations (*CDMOs*) to do so;
- the extent to which we establish and maintain strategic partnerships, licensing or other collaborative arrangements necessary for the development and commercialization of our product candidates, on favorable financial terms, if at all;
- subject to regulatory approval, market acceptance of our product candidates;
- the effect of competing technological and market developments;
- our headcount growth and associated costs if we expand our research and development, market development, pre-commercial and commercialization activities;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and
- the costs of operating as a public company.

As of December 31, 2025, the Company had cash, cash equivalents, and marketable securities of $61.8 million. As of February 12, 2026, the issuance date of the condensed consolidated financial statements as of and for the three and nine months ended December 31, 2025, there is uncertainty about whether the Company's combined cash, cash equivalents, and marketable securities will be sufficient to fund operations beyond twelve months from the issuance date of these condensed consolidated financial statements, and therefore the Company concluded that substantial doubt existed about the Company's ability to continue as a going concern.

The terms of any future financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. For example, the sale of additional equity securities and the conversion, exchange or exercise of certain of our outstanding securities will dilute all of our stockholders. The incurrence of debt could result in increased fixed payment obligations, and we could be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We may also seek funds through arrangements with collaborative partners in certain territories, including the U.S., or at an earlier stage than otherwise would be desirable or aligned with our business plan, and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

When necessary, including if we are unable to obtain additional funding on a timely basis and on acceptable terms, we may be required to significantly curtail, delay or terminate one or more of our research or product development programs or be unable to continue our current level of operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

***Due to the significant resources required for the development of our pipeline, and depending on our ability to access capital, we must prioritize the development of certain product candidates over others. Moreover, we may fail to expend our limited resources on product candidates or indications that may have been more profitable or for which there is a greater likelihood of success.***

Currently, our neuroscience pipeline consists of five clinical-stage product candidates. We seek to maintain a process of prioritization and optimal capital allocation to maintain an appropriate balance between the development of our most advanced product candidates and indications and ensuring the development of additional potential product candidates and indications, on our own or with strategic collaborators.

Due to the significant resources required for the development of our product candidates, we must decide which product candidates and indications to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates, therapeutic areas or indications may not lead to the development of viable commercial products and may divert resources away from better opportunities. If we make incorrect determinations regarding the viability or market potential of any of our product candidates or misread trends in the pharmaceutical industry, in particular for psychiatric and neurological disorders, our business, financial condition and results of operations could be materially and adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other disorders that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

***Raising additional capital may cause substantial dilution to our stockholders, restrict our operations or require us to relinquish significant rights to our technologies or product candidates.***

We expect our expenses to increase in connection with our planned operations. Unless and until we can generate a substantial amount of revenue from our product candidates, we expect to finance our future cash needs through public or private equity offerings, debt financings, royalty-based financing, collaborations, licensing arrangements or other sources, or any combination of the foregoing. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, the ownership interest of our stockholders may be substantially diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect the rights of our common stockholders. In addition, royalty-based financing or debt financing, if available, may result in our relinquishing significant rights to valuable future revenue streams or fixed payment obligations and may involve agreements that include restrictive

covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business. In addition, securing financing could require a substantial amount of time and attention from our management team and may divert a disproportionate amount of our attention away from day-to-day activities, which may adversely affect our management team's ability to oversee the development and commercialization of our product candidates, if approved.

If we raise additional capital through collaborations, strategic alliances or marketing, distribution or licensing arrangements, or royalty-based financings with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, 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 when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, obtain capital through arrangement with collaborators on terms unfavorable to us or pursue other strategies, all of which could adversely affect the holdings or the rights of our stockholders.

**Risks Related to Product Development, Regulatory Approval**

***The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.***

We are not permitted to commercialize, market, promote or sell any product candidate in the U.S. without obtaining regulatory approval from the FDA. Foreign regulatory authorities impose similar requirements. The time required to obtain approval by the FDA and comparable foreign authorities is inherently unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including substantial discretion of the regulatory authorities and such factors may vary among jurisdictions. For instance, jurisdictions outside of the U.S., such as China, the European Union (*EU*) or Japan, may have different requirements for regulatory approval, which may require us to conduct additional clinical, nonclinical or chemistry, manufacturing and control studies. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development. For example, certain early-stage clinical trials of our pherine product candidates were conducted outside of the U.S. Clinical Trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Although the FDA may accept data from clinical trials conducted outside the U.S., acceptance of these data is subject to conditions imposed by the FDA, and there can be no assurance that the FDA will accept data from trials conducted outside of the U.S. If the FDA does not accept the data from any trial that we conduct outside the U.S., it would likely result in the need for additional trials, which would be costly and time-consuming. Moreover, to date, we have not submitted a NDA to the FDA or similar drug approval submissions to comparable foreign regulatory authorities for any product candidate. We must complete additional preclinical studies and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we will be able to seek or obtain these approvals.

Nonclinical studies and clinical trials are expensive, difficult to design and implement, can take many years to complete and are inherently uncertain as to outcome. We cannot guarantee that any nonclinical studies or clinical trials will be conducted as planned or completed on schedule, if at all. The clinical development of our product candidates is susceptible to the risk of failure inherent at any stage of development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements and determination by the FDA or any comparable foreign regulatory authority that a product candidate may not continue development or is not approvable. It is possible that even if any of our product candidates have a beneficial effect, that effect will not be detected throughout the required phase of clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of such product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity of, or intolerability caused by, such product candidate, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not in fact the case. Serious adverse events or other adverse events, as well as tolerability issues, could hinder or prevent market acceptance of the product candidate at issue.

This lengthy approval process, as well as the unpredictability of nonclinical studies and clinical trial results, may result in our failing to obtain regulatory approval to market any product candidate we develop, which would substantially harm our business, results of operations and prospects. The FDA and other comparable foreign authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be granted for any product candidate

that we develop. Even if we believe the data collected from future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

***The FDA or comparable foreign regulatory authorities may disagree with our regulatory plan for the development and potential approval of our product candidates.***

In order to obtain FDA approval of our product candidates, we must, among other things, demonstrate substantial evidence of the effectiveness of such product candidates. FDA has generally considered this demonstration of substantial evidence of the effectiveness to require data gathered from at least two adequate and well-controlled clinical trials of the product candidate in the relevant patient population, or in some cases, one adequate and well-controlled trial plus other confirmatory evidence. Adequate and well-controlled clinical trials typically involve a large number of patients, have significant costs and take years to complete. The FDA or other regulatory authorities may disagree with us about whether a clinical trial is adequate and well-controlled or may request or provide feedback to suggest that we conduct additional nonclinical studies or clinical trials prior to granting any regulatory approval. In addition, there is no assurance that the doses, dosing strategy, endpoints and trial designs that we use for our clinical trials, including trials developed based on feedback from the FDA or other regulatory agencies or those that have been used for the approval of similar drugs, will be acceptable for future approvals. For example, while we have designed the PALISADE Phase 3 public speaking challenge studies in our U.S. registration-directed PALISADE program for fasedienol for the acute treatment of SAD using a public speaking challenge with SUDS as the primary endpoint based on FDA communications, the FDA has also communicated that additional studies or data are needed to support approval. For example, the Repeat Dose Study was designed to incorporate FDA feedback to evaluate the effect of repeat dosing of fasedienol, potential dosing interval for repeat dose, as well as potential dose response and duration of effect, but the FDA may ultimately determine that the study or its results are not adequate to support approval. Moreover, we plan to generate additional evidence recommended by the FDA to further characterize the clinical meaningfulness of the duration and magnitude of effect of fasedienol, but there can be no assurance that the design of our completed, ongoing and/or planned clinical trials or other activities to address FDA feedback on the development program will be satisfactory to the FDA or that the FDA will not require us to modify our trials or conduct additional clinical trials, generate additional information, or that completing these trials and other activities will result in regulatory approval, particularly given that the FDA has not granted regulatory approval to a drug on the basis of SUDS as a primary endpoint. Even if our ongoing and/or future clinical trials achieve their primary efficacy endpoint, there can be no assurance that the FDA will find them sufficient to support approval. Moreover, there are limited precedents for trial design, trial endpoints and regulatory pathway for the acute treatment of SAD and certain other therapeutic indications we are pursuing through the development of our product candidates, including fasedienol for the acute treatment of SAD, itruvone for the treatment of MDD and refisolone for the management of VMS (hot flashes) associated with menopause, which may make clinical development and regulatory approval for those product candidates more challenging.

Our clinical trial results may not support approval of our product candidates. In addition, our product candidates could fail to receive regulatory approval, or regulatory approval could be delayed, for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;
- the FDA or comparable foreign regulatory authorities may not file or accept our NDA or marketing application for substantive review;
- the FDA or other equivalent non-U.S. regulatory authorities may find the chemistry, manufacturing and controls, or data insufficient to support the quality of our product candidates;
- the FDA or comparable foreign regulatory authorities may disagree with the dosing regimen, design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications;

- the results of our clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from our preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a NDA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the U.S. or elsewhere;
- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

***We are dependent on third parties having accurately generated, collected, interpreted and reported data from certain preclinical studies and clinical trials that were previously conducted for our product candidates.***

We have acquired our pherine product candidates from Pherin, now our wholly-owned subsidiary, and Pherin undertook research and development of such product candidates prior to our acquisitions. We had no involvement with or control over the preclinical and clinical development of our pherine product candidates prior to acquiring or licensing them from Pherin. Therefore, we are dependent, in part, on Pherin's prior research and development efforts in accordance with the applicable protocols, legal and regulatory requirements, and scientific standards utilized by them; having accurately reported the results of all preclinical studies and clinical trials conducted with respect to such product candidates and having correctly collected and interpreted the data from these studies and trials. These risks also apply to any product candidates that we may acquire or in-license in the future, if any. If these activities were not compliant, accurate or correct, the clinical development, regulatory approval or commercialization of our pherine product candidates will be adversely affected.

***If our clinical trials fail to replicate results from earlier preclinical studies or clinical trials conducted by us or third parties, we may be unable to successfully develop, obtain regulatory approval for or commercialize our product candidates.***

The results observed from earlier preclinical studies or early-stage clinical trials of our product candidates, including positive results, may not necessarily be predictive of the results of ongoing or future clinical trials. Furthermore, our product candidates may not be able to demonstrate similar activity or adverse event profiles as other product candidates that we believe may have similar profiles. In addition, in our planned future clinical trials, we may utilize clinical trial designs or dosing regimens that have not been tested in prior clinical trials.

Moreover, there is a high failure rate for drugs candidate proceeding through clinical trials and there can be no assurance that any of our clinical trials will ultimately be successful. We, and many other companies in the pharmaceutical and biotechnology industries, have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier-stage development, such as the failure of our PALISADE-1 and PALISADE-3 Phase 3 clinical trials of fasedienol to meet its primary or secondary endpoints, and we cannot be certain that we will not face similar setbacks in the future. In addition to the risk of ongoing or planned clinical trials failing to meet primary endpoints, setbacks may also be caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Such failures or setback may have a material adverse effect on our ability to develop, obtain regulatory approval for or ultimately commercialize any of our product candidates.

***We may incur unexpected costs or experience material delays in completing, or ultimately be unable to complete, the contract manufacturing, nonclinical and clinical development and commercialization of our product candidates.***

To obtain the requisite regulatory approvals to commercialize any of our product candidates, we must demonstrate through extensive nonclinical studies and clinical trials that our product candidates are safe and effective in humans. We have experienced, and may further experience delays in completing our contract manufacturing, clinical trials or nonclinical studies and initiating or completing additional clinical trials or nonclinical studies, including as a result of regulators not

allowing or delay in allowing clinical trials to proceed under an IND or similar approval we need to initiate a clinical trial. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the product candidates we develop, including:

- regulators, institutional review boards (*IRBs*), or other reviewing bodies such as ethics committees may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- we may experience further challenges or delays in recruiting principal investigators or study sites to lead our clinical trials;
- the number of subjects or patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or materially slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, including CDMOs, CROs, clinical research sites or other third-parties acting on our behalf or in connection with our studies, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have to amend clinical trial protocols submitted to regulatory authorities or conduct additional studies to reflect changes in regulatory requirements or guidance, which may be required to resubmit to an IRB and regulatory authorities for re-examination;
- regulators or other reviewing bodies may find deficiencies with, fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for clinical and commercial supplies, or the supply or quality of any product candidate or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; and
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval.

Regulators or IRBs of the institutions in which clinical trials are being conducted may suspend, limit or terminate a clinical trial, or data monitoring committees may recommend that we suspend or terminate a clinical trial, due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Negative or inconclusive results from our clinical trials or preclinical studies could mandate repeated or additional clinical trials and, to the extent we choose to conduct clinical trials in other indications, could result in changes to or delays in clinical trials of our product candidates in such other indications. We do not know whether any clinical trials that we conduct will demonstrate efficacy and safety results adequate to obtain regulatory approval to market our product candidates for the indications that we are pursuing. If later-stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for and commercialize our product candidates will be adversely impacted.

Our failure to successfully initiate and complete required nonclinical studies and clinical trials and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates would significantly harm our business. Our product candidate development costs will also increase substantially if we experience delays in testing or regulatory approvals and we may be required to obtain additional funds to complete necessary nonclinical studies or clinical trials. We cannot assure you that our nonclinical studies or clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure or otherwise modify our trials after they have begun. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays of nonclinical studies or clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

***Our clinical development activities could be materially delayed or otherwise adversely affected by difficulties enrolling and randomizing patients in our clinical trials.***

We have experienced, and may continue to experience, difficulties in patient enrollment and randomization in our clinical trials for a variety of reasons, including the stringent entry eligibility criteria for our clinical trials. The timely completion of clinical trials requiring rigorous adherence to clinical trial protocols depends, among other things, on our ability to enroll and randomize a sufficient number of patients who qualify for and remain in the trial until its conclusion.

Patient enrollment and randomization is affected by many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size and nature of the patient population required for analysis of the trial's primary endpoints;
- the severity of the disease or condition under investigation;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit, train and retain clinical trial investigators and clinical research site staff with the appropriate competencies and experience through the duration of the trial;
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any drugs that may be approved for the indications that we are investigating;
- patient recruitment or referral practices of centralized recruiting firms, clinical trial sites and physicians;
- the ability to monitor patients adequately during and after treatment in the trial;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in our clinical trials will drop out of the trials before completion.

We may also experience challenges in recruiting principal investigators and patients to participate in ongoing and future clinical trials for our product candidates if we are unable to sufficiently demonstrate the potential of such product candidates to them. In addition, our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. Furthermore, if significant adverse events or other side effects are observed in any of our clinical trials that are related to or deemed to be caused by any of our product candidates, we may have difficulty recruiting patients to our trials and patients may drop out of our trials. Finally, business disruptions, including those relating to natural disasters (including as a result of climate change), geopolitical incidents, pandemics or macroeconomic conditions, may disrupt our clinical trials.

Our inability to enroll and randomize a sufficient number of patients for our clinical trials would result in significant delays or might require us to abandon one or more clinical trials or our development efforts altogether. Material delays in patient enrollment and randomization may result in increased costs, affect the timing or outcome of ongoing or planned clinical trials and the public disclosure of trial results, product candidate development and approval process and jeopardize our ability to raise additional capital and seek and obtain the regulatory approval required to commence product sales and generate revenue, which could prevent completion of these trials, adversely affect our ability to advance the development of our product candidates, cause the value of the Company to decline and limit our ability to obtain additional financing if needed.

***Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.***

As product candidates proceed through preclinical studies and clinical development trials towards potential approval and commercialization, it is common that various aspects of the development program, such as the vendors used to manufacture

drug product or manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA or comparable foreign regulatory authorities' notification or approval. This could delay or prevent completion of clinical development, require conducting bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay or prevent approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

***Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of our product candidates.***

Any product candidate we develop, and the activities associated with its development and commercialization, including its design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the U.S. and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates we are developing or may seek to develop in the future will ever obtain regulatory approval.

We have no experience in submitting and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs and regulatory consultants to augment our internal personnel and assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate’s safety and efficacy. Securing regulatory approval also requires the submission of extensive information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop 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 its obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the U.S. and abroad, is expensive, may take many years if additional clinical trials are required, 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 personnel and review processes for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval that we may ultimately obtain could be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of any product candidates we may develop, the commercial prospects for those product candidates may be harmed, and our ability to generate revenues will be materially impaired.

***Interim, topline and preliminary data from our nonclinical studies or clinical trials that we may announce or publish from time to time may change as more patient data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.***

From time to time, we may publish or publicly disclose interim, topline or preliminary data from our nonclinical studies or clinical trials. These publications or disclosures are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline, or preliminary results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated.

Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or topline data also

remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our reputation and business prospects. Further, disclosure of such data by us or by our competitors could result in volatility in the price of our common stock.

In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, if we publicly disclose certain information, you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, strategies, views, activities or otherwise regarding a particular product candidate or our business.

***If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the development and commercialization of our product candidates may be delayed, and our business and results of operations may be harmed.***

For planning purposes, we sometimes estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development activities or objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings, the timing of regulatory review or approvals, or initiation of commercialization activities or objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial of a product candidate, the initiation of other clinical programs, receipt of marketing approval or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions which, if not realized as expected, may cause the timing of achievement of the milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians, collaborators and trial participants;
- our ability to identify, enroll and randomize patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the FDA and other regulatory authorities and the timing thereof;
- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of materials used to manufacture our product candidates;
- the efforts of our collaborators with respect to the development and commercialization of our product candidates; and
- the securing of costs related to, and timing issues associated with, product manufacturing as well as sales and marketing activities.

If we fail to achieve announced milestones in the timeframes we expect, the development and commercialization of our product candidates may be delayed, and our business and results of operations may be harmed.

***We depend heavily on the success of one or more of our current product candidates and we cannot be certain that we will be able to obtain regulatory approval for or commercialize any of our product candidates.***

We are not permitted to market our product candidates in the U.S. until we receive approval of a NDA from the FDA, or in any foreign countries until we receive the requisite approval from such countries. Obtaining FDA approval of a NDA is a complex, lengthy, expensive and uncertain process. The FDA may refuse to permit the filing of our NDA, delay, limit or deny approval of a NDA for many reasons, including, among others:

- if we submit a NDA and it is reviewed by a FDA advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional nonclinical or clinical studies, limitations on approved labeling or distribution and use restrictions;

- a FDA advisory committee may recommend, or the FDA may require, a Risk Evaluation and Mitigation Strategies (*REMS*) safety program as a condition of approval or post-approval;

- a FDA advisory committee or the FDA or applicable regulatory agency may determine that there is insufficient evidence of overall effectiveness or safety in a NDA and require additional clinical studies or other information;

- the FDA or the applicable foreign regulatory agency may determine that the manufacturing processes or facilities of third-party contract manufacturers with which we contract do not conform to applicable requirements, including cGMPs; or

- the FDA or applicable foreign regulatory agency may change its approval policies or adopt new regulations.

Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and commercialize any current or future drug product candidate we may develop. Any such setback in our pursuit of regulatory approval for any product candidate would have a material adverse effect on our business and prospects.

In addition, all of our pherine product candidates will be subject to regulation as combination products, which means that they are composed of both a drug product and device product. Although we do not contemplate doing so, if marketed individually, each component would be subject to different regulatory pathways and reviewed by different centers within the FDA. As drug-device combination candidates, each will require review and coordination by FDA's drug and device centers prior to approval, which may delay approval. In the U.S., a combination product with a drug primary mode of action generally would be reviewed and approved pursuant to the drug approval processes under the Federal Food, Drug and Cosmetic Act. In reviewing the NDA application for such a product, however, FDA reviewers in the drug center could consult with their counterparts in the device center to ensure that the device component of the combination product met applicable requirements regarding safety, effectiveness, durability and performance. Under FDA regulations, combination products are subject to cGMP requirements applicable to both drugs and devices, including the Quality Management System Regulation (*QMSR*) applicable to medical devices. Problems associated with the device component of the combination product candidate may delay or prevent approval.

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

Undesirable side effects caused by any of our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. We may also observe safety or tolerability issues with our product candidates in ongoing or future clinical trials. Many compounds that initially showed promise in clinical or earlier-stage testing are later found to cause undesirable or unexpected side effects that prevent further development of the compound. Results of future clinical trials of our product candidates could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics, despite a favorable tolerability profile observed in earlier-stage testing. Moreover, clinical trials of our product candidates are conducted in carefully defined sets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects.

If unacceptable side effects arise in the development of our product candidates, specifically those deemed to be caused by or directly related to any of our product candidates, we, the FDA or comparable foreign regulatory authorities, the IRBs, or independent ethics committees at the institutions in which our trials are conducted, could suspend, limit or terminate our clinical trials, or the independent safety monitoring committee could recommend that we suspend, limit or terminate our trials, or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-emergent side effects that are deemed to be drug-related could delay recruitment of clinical trial subjects or may cause subjects that enroll in our clinical trials to discontinue participation in our clinical trials. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We may need to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in harm to patients that are administered our product candidates. Any of these occurrences may adversely affect our business, financial condition and prospects significantly.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. For example, the

FDA could require us to adopt a REMS, to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. We may also be required to engage in similar actions, such as patient education, certification of health care professionals or specific monitoring, if we or others later identify undesirable side effects caused by any product. Other potentially significant negative consequences associated with adverse events include:

- we may be required to suspend marketing of a product, or we may decide to remove such product from the marketplace;
- regulatory authorities may withdraw or modify their approvals of our product;
- we may be required to conduct post-marketing studies;
- we may be required to change the way our product is administered;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or be sued and held liable for harm caused to subjects or patients;
- our product may become less competitive, and
- our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of our product candidates, if approved by the FDA or other regulatory authorities.

***If any of our product candidates are ultimately regulated as controlled substances, we, our CDMOs, as well as future distributors, prescribers, and dispensers will be required to comply with additional regulatory requirements which could delay the marketing of our product candidates, and increase the cost and burden of manufacturing, distributing, dispensing, and prescribing our product candidates.***

Before we can commercialize our product candidates in the U.S. or any market outside the U.S., the U.S. Drug Enforcement Administration (*DEA*) or its foreign counterpart may need to determine whether such product candidates will be considered to be a controlled substance, taking into account the recommendation of the FDA or its foreign counterpart, as the case may be. This may be a lengthy process that could delay our marketing of a product candidate and could potentially diminish any regulatory exclusivity periods for which we may be eligible, which would increase the cost associated with commercializing such products and, in turn, may have an adverse impact on our results of operations. Although we currently do not know whether the DEA or any foreign counterpart will consider any of our current or future product candidates to be controlled substances, we cannot yet give any assurance that such product candidates will not be regulated as controlled substances.

If any of our product candidates are regulated as controlled substances, depending on the DEA controlled substance schedule in which the product candidates are placed or that of its foreign counterpart, we, our CDMOs, and any future distributors, prescribers, and dispensers of the scheduled product candidates may be subject to significant regulatory requirements, such as registration, security, recordkeeping, reporting, storage, distribution, importation, exportation, inventory, quota and other requirements administered by the DEA or a foreign counterpart of the DEA as the case may be. Moreover, if any of our product candidates are regulated as controlled substances, we and our CDMOs would be subject to initial and periodic DEA inspection. If we or our CDMOs are not able to obtain or maintain any necessary DEA registrations or comparable foreign registrations, we may not be able to commercialize any product candidates that are deemed to be controlled substances or we may need to find alternative CDMOs, which would take time and cause us to incur additional costs, delaying or limiting our commercialization efforts.

Because of their restrictive nature, these laws and regulations could limit commercialization of our product candidates, should they be deemed to contain controlled substances. Failure to comply with the applicable controlled substance laws and regulations can also result in administrative, civil or criminal enforcement. The DEA or its foreign counterparts may seek civil penalties, refuse to renew necessary registrations, or initiate administrative proceedings to revoke those registrations. In some circumstances, violations could result in criminal proceedings or consent decrees. Individual states also independently regulate controlled substances.

***We have concentrated a significant portion of our research and development efforts on the treatment of neuropsychiatric and neurological disorders, a field that faces certain challenges in drug development.***

We have focused a significant portion of our research and development efforts on addressing neuropsychiatric and neurological disorders. Efforts by pharmaceutical companies in this field have faced certain challenges in drug development. In particular, many neuropsychiatric disorders such as SAD and MDD rely on subjective assessments by clinicians and subjective patient-reported outcomes as key efficacy endpoints. This makes them more difficult to evaluate than indications with more objective endpoints. Furthermore, these indications are often subject to a placebo effect, which may make it more challenging to isolate the beneficial effects of our neuropsychiatric product candidates. There can be no guarantee that we will successfully overcome these challenges with our neuropsychiatric product candidates or that we will not encounter other challenges in the development of our other product candidates.

***Even if any of our product candidates receives regulatory approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable.***

We have never commercialized a product, and even if any of our product candidates is approved by the appropriate regulatory authorities for marketing and sale, it may nonetheless fail to achieve sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Certain of the indications for our product candidates have well-established standards of care that physicians, patients and payors are familiar with and, in some cases, are available generically. Even if our product candidates are successful in registrational clinical trials, they may not be successful in displacing these current standards of care, if any, if we are unable to demonstrate superior efficacy, safety, ease of administration and/or cost-effectiveness. For example, physicians may be reluctant to take their patients off their current medications and switch their treatment regimen to our product candidates. Further, patients often acclimate to the treatment regimen that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch due to lack of coverage and adequate reimbursement. Even if we are able to demonstrate our product candidates' safety and efficacy to the FDA and other regulators, safety or efficacy concerns in the medical community may hinder market acceptance.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, including management time and financial resources, and may not be successful. For example, even if fasedienol ultimately receives regulatory approval, we may have difficulty in convincing the medical community that fasedienol has the potential to deliver promising therapeutic benefits above and beyond antidepressants. If any product candidate is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product;
- the potential advantages of the product compared to any competitive therapies;
- the prevalence and severity of any side effects;
- whether the product is designated under physician treatment guidelines as a first-, second- or third-line therapy;
- our ability, or the ability of any future collaborators, to offer the product for sale at competitive prices;
- the product's convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- limitations or warnings, including distribution or use restrictions contained in the product's approved labeling;
- the strength of sales, marketing and distribution support;
- changes in the standard of care for the targeted indications for the product; and
- availability and adequacy of coverage and reimbursement from government payors, managed care plans and other third-party payors.

Any failure by one or more of our product candidates that obtains regulatory approval to achieve market acceptance or commercial success would adversely affect our business prospects.

***If we fail to develop and commercialize other product candidates, we may be unable to grow our business and our ability to achieve our strategic objectives would be impaired.***

Although the development and commercialization of our most advanced pherine product candidate, fasedienol, is currently our primary focus, as part of our longer-term growth strategy, we plan to develop other of our clinical stage pherine product candidates. We intend to evaluate internal opportunities from our existing pherine pipeline, and also may choose to in-license or acquire other product candidates to treat patients suffering from other disorders with significant unmet medical needs and limited treatment options. These other potential product candidates will require additional, time-consuming development efforts prior to commercial sale, including manufacturing, preclinical studies, clinical trials and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives.

In addition, we intend to devote substantial capital and resources for basic research to discover and identify additional pherine product candidates. These research programs require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential pherine product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete;
- product candidates that we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

In the future, we may also seek to in-license or acquire product candidates or the underlying technology. The process of proposing, negotiating and implementing a license or acquisition is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

In addition, should we seek to acquire additional product candidates, future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of management's time and attention to develop acquired products or technologies;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- higher than expected acquisition and integration costs;

- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;
- increased amortization expenses;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to motivate key employees of any acquired businesses.

If we are unsuccessful in identifying and developing additional product candidates, either through internal development or licensing or acquisition from third parties, our potential for growth and achieving our strategic objectives may be impaired.

***The number of patients with the neuroscience disorders for which we are developing our product candidates has not been established with precision. If the actual number of patients with the disorders we elect to pursue with our product candidates is smaller than we anticipate, we may have difficulties in enrolling patients in our clinical trials, which may delay or prevent development of our product candidates. Even if such product candidates are successfully developed and approved, the markets for our products may be smaller than we expect and our revenue potential and ability to achieve profitability may be materially adversely affected.***

Our neuroscience pipeline includes product candidates for a variety of conditions and disorders. There is no precise method of establishing the actual number of patients with any of these conditions and disorders in any geography over any time period. With respect to many of the indications in which we have developed, are developing, or plan to develop our product candidates, we have estimates of the prevalence of the disease or disorder. Our estimates as to prevalence may not be accurate, and the actual prevalence or addressable patient population for some or all of those indications, or any other indication that we elect to pursue, may be significantly smaller than our estimates. In estimating the potential prevalence of indications we are pursuing, or may in the future pursue, including, among others, our estimates as to the prevalence of SAD, MDD and vasomotor symptoms (hot flashes) due to menopause, we apply assumptions to available information that may not prove to be accurate. In each case, there is a range of estimates in the published literature and in marketing studies, which include estimates within the range that are lower than our estimates. The actual number of patients with these and other disease indications may, however, be significantly lower than we believe. Even if our prevalence estimates are correct, our product candidates may be developed for only a subset of patients with the relevant disease or disorder or our products, if approved, may be indicated for or used by only a subset. In the event the number of patients with the diseases and disorders we are studying is significantly lower than we expect, we may have difficulties in enrolling patients in our clinical trials, which may delay or prevent development of our product candidates. If any of our product candidates are approved and our prevalence estimates with respect to any indication or our other market assumptions are not accurate, the markets for our product candidates for these indications may be smaller than we anticipate, which could limit our revenues and our ability to achieve profitability or to meet our expectations with respect to revenues or profits.

***Competitive products may reduce or eliminate the commercial opportunity for our product candidates, if approved. If our competitors develop technologies or product candidates more rapidly than we do, or their technologies or product candidates are more effective and/or safer than ours, our ability to develop and successfully commercialize our product candidates may be adversely affected.***

The clinical and commercial landscapes for the treatment of neuroscience disorders, including those we are pursuing, are highly competitive and subject to rapid and significant technological change. We face competition with respect to our indications for our product candidates and will face competition with respect to any other drug candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell drugs or are pursuing the development of drug candidates for the treatment of the indications that we are pursuing. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

We believe that a significant number of product candidates are currently under development for certain of the same indications we are currently pursuing, and some or all may become commercially available in the future for the treatment of conditions for which we are trying or may try to develop product candidates. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. See the section entitled "*Competition*" in our Annual Report on Form 10-K for the fiscal year ended March 31, 2025, as filed with the SEC on June 17, 2025, for examples of the competition that our product candidates face.

In most cases, we do not currently plan to run head-to-head clinical trials evaluating our product candidates against the current standards of care, which may make it more challenging for our product candidates to compete against the current standards of care due to the lack of head-to-head clinical trial data.

Our competitors may have significantly greater financial resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. Accordingly, our competitors may be more successful than we may be in obtaining regulatory approval for therapies and achieving widespread market acceptance. Our competitors' products may be more effective, or more effectively marketed and sold, than any product candidate we may commercialize and may render our therapies obsolete or non-competitive before we can recover development and commercialization expenses. If any of our product candidates are approved, it could compete with a range of therapeutic treatments that are in development. In addition, our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective or less costly than our product candidates, which could render our product candidates obsolete and noncompetitive.

If we obtain approval for any of our product candidates, we may face competition based on many different factors, including the efficacy, safety and tolerability of our products, the ease with which our products can be administered, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Existing and future competing products could present superior treatment alternatives, including being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

In addition, our competitors may obtain patent protection, regulatory exclusivities or FDA approval and commercialize products more rapidly than we do, which may impact future approvals or sales of any of our product candidates that receive regulatory approval. If the FDA approves the commercial sale of any product candidate, we will also be competing with respect to marketing capabilities and manufacturing efficiency. We expect competition among products will be based on product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capabilities, product price, reimbursement coverage by government and private third-party payors, regulatory exclusivities and patent position. Our profitability and financial position will suffer if our product candidates receive regulatory approval but cannot compete effectively in the marketplace.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites, as well as in acquiring technologies complementary to, or necessary for, our programs.

***If we are unable to develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our product candidates.***

We currently have no marketing, sales or distribution capabilities. We intend to establish a sales and marketing capabilities, either on our own or in collaboration with third parties, with technical expertise and supporting distribution capabilities to commercialize one or more of our product candidates that may receive regulatory approval in key territories. These efforts will require substantial additional resources, some or all of which may be incurred in advance of any approval of the product candidate. Any failure or delay in the development of our or third parties' internal sales, marketing and distribution capabilities would adversely impact the commercialization of our product candidates.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- lack of sufficient capital resources available to us in a timely manner, if at all, and on commercially reasonable terms;
- our inability to recruit and retain adequate numbers of effective sales and marketing leadership and sales personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;

- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and

- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

With respect to our existing and future product candidates, we may choose to collaborate with third parties that have direct sales forces and established distribution systems to serve as an alternative to building or to augment our own sales force and distribution systems. In that case, our future product revenue would be lower than if we directly marketed or sold our product candidates, if approved, on our own. 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 not successful in commercializing any approved products, our future product revenue will suffer and we may incur significant additional losses.

If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

***Product liability lawsuits against us or any of our future collaborators could divert our resources and attention, cause us to incur substantial liabilities and limit commercialization of our product candidates.***

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. Currently, we have no products that have been approved for commercial sale; however, the use of our product candidates by us and any collaborators in clinical trials, and the sale of these product candidates, if approved, in the future, may expose us to liability claims. We face an inherent risk of product liability lawsuits related to the use of our product candidates in patients and will face an even greater risk if product candidates are approved by regulatory authorities and introduced commercially. Product liability claims may be brought against us by participants enrolled in our clinical trials, patients, health care providers, pharmaceutical companies, our collaborators or others using, administering or selling any of our future approved products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for any of our future approved products;

- injury to our reputation;

- withdrawal of clinical trial participants;

- termination of clinical trial sites or entire trial programs;

- significant litigation costs;

- substantial monetary awards to, or costly settlements with, patients or other claimants;

- product recalls or a change in the indications for which they may be used;

- loss of revenue;

- diversion of management and scientific resources from our business operations; and

- the inability to commercialize our product candidates.

Although the clinical trial process is designed to identify and assess potential side effects, clinical development does not always fully characterize the safety and efficacy profile of a new medicine, and it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If our product candidates were to cause adverse side effects during clinical trials or after approval, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies.

Although we maintain product liability insurance coverage consistent with industry norms, including clinical trial liability, this insurance may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. We will need to increase our insurance coverage if we commercialize any product that receives regulatory approval. Insurance coverage is becoming increasingly expensive. If we are unable to maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of our product candidates, which could harm our business, financial condition, results of operations and prospects.

***Cyberattacks or other failures in our telecommunications or information technology systems, or those of our collaborators, CDMOs, CROs, third-party logistics providers, distributors or other contractors or consultants, could result in information theft, data corruption and significant disruption of our business operations.***

We, along with our collaborators, CDMOs, CROs, third-party logistics providers, distributors and other contractors and consultants, utilize information technology (*IT*) systems and networks to process, transmit and store electronic information, including confidential information such as proprietary business information and personal information of our employees and contractors, in connection with our business activities. As use of digital technologies has increased, our IT systems and those of our third-party service providers, strategic partners and other contractors or consultants are increasingly vulnerable to attack, damage and interruption from cyber incidents, including third parties gaining access to employee accounts using stolen or inferred credentials, computer malware (e.g., ransomware), viruses, malicious code, spamming, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors, natural disasters, terrorism, war, telecommunication and electrical failures or other threats. Deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our, our collaborators', CDMOs, CROs', third-party logistics providers', distributors' and other contractors' and consultants' systems and networks, and the confidentiality, availability and integrity of our data. We may not be successful in preventing or identifying cyberattacks and may experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or successfully mitigate their effects due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. Like other companies, we have on occasion experienced, and will continue to experience, threats to our data and systems, including malicious codes and viruses, phishing, business email compromise attacks or other cyberattacks. Similarly, our collaborators, CROs, third-party logistics providers, distributors and other contractors and consultants may not be successful in protecting our clinical and other data that is stored on their systems. Any cyberattack, data breach or destruction or loss of data could result in a violation of applicable U.S. and international privacy, data protection and other laws and subject us to litigation and governmental investigations and proceedings by federal, state and local regulatory entities in the U.S. and by international regulatory entities, resulting in exposure to material civil and/or criminal liability. Further, our general liability insurance and corporate risk program may not cover all potential claims to which we are exposed and may not be adequate to indemnify us for all liability that may be imposed, which could have a material adverse effect on our business and prospects. For example, the loss of clinical trial data from completed or ongoing clinical trials for any of our product candidates could result in delays in our development and regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyberattacks or other data security breaches and may incur significant additional expense to implement further data protection measures.

***We may seek to establish collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.***

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We may derive revenue from research and development fees, license fees, milestone payments and royalties under any collaborative arrangement into which we enter. However, our ability to generate revenue from such arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. In addition, our collaborators have the right to abandon research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms. As a result, we can expect to relinquish some or all of the control over the future success of a product candidate that we license to a third party in the territories included in the licenses.

Moreover, upfront payments received upon execution of collaborative agreements, such as the AffaMed Agreement, may be recorded as deferred revenue, in which case they would be recognized over the period of performance for the related performance obligations with the third-party collaborator pursuant to the applicable agreement. The period of performance

obligations may also be revised on a prospective basis. Assumptions related to revenue recognition for performance obligations provided over time are reviewed in each accounting period and changes are recorded in the current period. In certain circumstances, changes in assumptions related to the measure of progress for a performance obligation performed over time could result in negative revenue or the acceleration of revenue for an accounting period.

We face significant competition in seeking appropriate collaborators. Whether we reach additional definitive agreements for collaborations will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of nonclinical and clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the U.S., the potential markets for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate. The terms of any collaboration or other arrangements that we may establish may not be favorable to us.

We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we will need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

In addition, any current or future collaboration that we enter into may not be successful. The success of our current and future collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

***Our future growth may depend, in part, on our ability to penetrate markets outside of the U.S., where we would be subject to additional regulatory burdens and other risks and uncertainties.***

Our future profitability may depend, in part, on our ability to develop and commercialize our product candidates with third-party collaborators in markets outside of the U.S. If we develop and commercialize our product candidates in markets outside of the U.S., we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for our product candidates;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;

- language barriers for technical training;
- reduced protection of intellectual property rights, different standards of patentability and different availability of prior art in some foreign countries as compared with the U.S.;
- the existence of additional potentially relevant third-party intellectual property rights;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Sales of our product candidates outside of the U.S. could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

***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 the success of our business.***

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development, or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties, or other sanctions, which could have a material adverse effect on our operations.

**Risks Related to Managing Our Business and Operations**

***We depend heavily on our key senior managerial personnel, third-party consultants and others and our ability to compete in the biopharmaceutical industry depends upon our ability to retain such highly qualified personnel. The loss of their services or our inability to hire such personnel could materially harm our business.***

Our success depends, and will likely continue to depend, upon our ability to attract and retain the services of our executive officers, key senior managerial and other key senior personnel within our organization. Our executive officers and other senior employees may terminate their employment with us at any time. In addition, we may seek to reduce employee headcount in connection with cost preservation efforts. The loss of the services of executive officers and other key senior employees might impede the achievement of our operational and strategic objectives.

Moreover, our ability to compete in the biopharmaceutical industry depends upon our ability to attract and retain highly qualified managerial, scientific, medical, regulatory and technical personnel. In particular, we will need to retain and, in some cases, hire, qualified personnel with expertise in clinical development and operations, preclinical research and development, manufacturing, quality management, medical and regulatory affairs, finance and accounting and other areas in connection with the continued development and commercialization of our product candidates. We currently rely, and for the foreseeable future will continue to rely, on third-party consultants and advisors, including scientific and clinical advisors, to assist us in formulating certain of our research and development objectives and activities as well as the development of certain of our commercialization strategies.

Our industry has experienced a high rate of turnover of management personnel in recent years. Replacing executive officers or other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully and the culture fit to be a leader in our organization. Competition to hire from this

limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Further, inflationary pressure may increase our costs, including employee compensation costs or result in employee attrition to the extent our compensation does not keep up with inflation, particularly if our competitors' compensation does.

There can be no assurance that the services of third-party consultants and advisors will continue to be available to us on a timely basis when needed, that we will be able to manage our existing consultants and advisors or that we can find qualified replacements on economically reasonable terms, or at all. Our consultants and advisors may be employed by other entities and may have commitments under consulting or advisory contracts with those entities that may limit their availability to us. If we are unable to continue to attract and retain highly qualified consultants and advisors, our ability to develop and commercialize our product candidates will be limited.

***We may not be able to hire or retain a sufficient number of employees or employees with the required expertise to develop our product candidates or operate our business successfully.***

As of December 31, 2025, we had 59 full-time employees. Our focus on the development of our lead product candidates requires us to optimize cash utilization and to manage and operate our business in a highly efficient manner. We cannot assure you that we will be able to hire or retain adequate staffing levels to develop our product candidates or run our operations and/or to accomplish all of the objectives that we otherwise would seek to accomplish. If we are not able to retain adequate staffing levels or effectively expand our organization by hiring new qualified employees as needed, our clinical trials may be delayed or terminated, we may not be able to successfully execute the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our development and commercialization goals.

***Our employees, independent contractors, consultants, collaborators, CDMOs and CROs may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.***

We are exposed to the risk that our employees, independent contractors, consultants, collaborators, CDMOs and CROs may engage in fraudulent conduct or other illegal activity. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Misconduct by those parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities that violates:

- study and trial protocols or the FDA regulations or similar regulations of comparable non-U.S. regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities;
- manufacturing standards;
- federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable non-U.S. regulatory authorities; and
- laws that require the reporting of financial information or data accurately.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of product materials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact

on our business and results of operations, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, integrity oversight and reporting obligations, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could have a material adverse effect on our ability to operate our business and our results of operations.

***Unfavorable domestic or global economic or political conditions could adversely affect our business, financial condition or results of operations.***

Our results of operations could be adversely affected by either domestic or global political conditions, as well as general conditions in the domestic or global economy and in the U.S. and global financial and stock markets. Domestic and global financial and political crises cause extreme volatility and disruptions in the capital and credit markets. A severe or prolonged government shutdown and/or economic downturn, could result in a variety of risks to our business, including, weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining domestic or global economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

***We or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

Natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party CDMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plan we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expense as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business.

***Remote working arrangements could significantly increase our digital and cybersecurity risks.***

Most of our employees are geographically dispersed from our headquarters facility in South San Francisco and now routinely work remotely. With the continuing shift to remote working, and the use of virtual board and executive management meetings, cybersecurity risks are exponentially greater, including increased risk of phishing and other cybersecurity attacks as well as increased risk of unauthorized dissemination of sensitive personal information or proprietary or confidential information about us or our customers, employees, or business partners. Despite our cybersecurity measures, we may be more susceptible to security breaches and other security incidents because we have less capability to implement, monitor, and enforce our information security and data protection policies. Techniques or software used to gain unauthorized access, and/or disable, degrade, or harm our systems may be difficult to detect for prolonged periods of time, and we may be unable to anticipate these techniques or put in place protective or preventive measures. The damage or disruption of our systems, or the theft or compromise of our technology, data, or intellectual property, may negatively impact our business, financial condition and results of operations, reputation, stock price and long-term value, which could adversely affect our business.

***Current politics in the U.S. could diminish the value of the pharmaceutical industry, thereby diminishing the value of our securities.***

The current political environment in the U.S. is volatile, and recent or future regulatory changes, especially at the FDA, have resulted, and may continue to result, in uncertainty throughout the pharmaceutical industry and, have an adverse effect on our business and the value of our securities. This political and regulatory uncertainty may receive increasing publicity which, in turn, may cause the investing public to reduce the perceived value of pharmaceutical companies. Any decrease in the overall perception of the pharmaceutical industry may have an adverse impact on our share price and may limit our ability to raise capital needed to continue our drug development programs.

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

***We rely on third parties to assist in conducting our clinical trials. If they do not perform satisfactorily, we may not be able to obtain regulatory approval or commercialize our product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed.***

We have relied upon and plan to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to augment our internal personnel in the conduct of our clinical trials and expect to rely on these third parties to augment our efforts to conduct clinical trials of any product candidate that we develop. Our ability to complete clinical trials in a timely fashion depends on a number of key factors. These factors include protocol design, regulatory and IRB or ethics committee approval, patient enrollment rates and compliance with GCPs. In most cases, we use the services of third parties, including CROs, to carry out many of clinical trial-related activities and rely on such parties to accurately report their results. Our reliance on third parties for clinical development activities may impact or limit our control over the timing, conduct, expense and quality of our clinical trials. Moreover, the FDA and certain foreign regulatory authorities require us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The FDA and comparable foreign regulatory authorities enforce these GCPs through periodic inspections of clinical trial sponsors, principal investigators, clinical trial sites and IRBs. For certain commercial prescription drug products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the U.S. Similar requirements may exist in foreign jurisdictions.

We remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. Our failure, or the failure of our third-party contract manufacturers, to comply with applicable protocol, legal and regulatory requirements and scientific standards could result in, among other things, rejection of our clinical data, sanctions being imposed on us, including clinical holds, a refusal to file determination by the FDA, receipt of a complete response letter (*CRL*), fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect our ability to achieve regulatory approval of our product candidates. If we or our third-party clinical trial providers or third-party CROs do not successfully carry out these clinical activities, our clinical trials or the potential regulatory approval of a product candidate may be delayed or be unsuccessful. Additionally, if we or our third-party contractors fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our product candidates, which would delay the regulatory approval process. We cannot be certain that, upon inspection, the FDA or comparable foreign regulatory authorities will determine that any of our clinical trials comply with GCPs. We are also required to register certain clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, the third parties conducting clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such independent contractors, we cannot control whether or not they devote sufficient time, skill and resources to our ongoing development programs. Moreover, many CROs, including some of those that we have engaged to conduct our clinical trials, are experiencing enrollment challenges as a result of, among other things, high employee turnover driven by the post-COVID macroeconomic environment and the inexperience of new employees. Furthermore, at clinical trial sites, the availability of staff and trial participants has been limited due to a decrease in the number of clinical investigative sites across the globe. Accordingly, enrollment and randomization of subjects in some of our clinical trials may be slower than expected as a result of these changes in the post-COVID clinical trial landscape. These contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If these third parties, including clinical investigators, do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates. If that occurs, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. In such an event, our financial results and the commercial prospects for any product candidates that we seek to develop could be harmed, our costs could increase and our ability to generate revenues could be delayed, impaired or foreclosed.

We also rely on third party CDMOs and others to manufacture, store and distribute drug supplies for our clinical trials. Any performance failure on the part of these third-parties could delay clinical development or regulatory approval of our product candidates or commercialization of any resulting products, producing additional losses and depriving us of potential product revenue.

Any of the third-party organizations we utilize may terminate their engagements with us under certain circumstances. The replacement of an existing CRO, manufacturer or other third party may result in the delay of the affected trials or otherwise adversely affect our efforts to obtain regulatory approvals and commercialize our product candidates. Although we believe

we have diversified our risk by engaging a number of CROs and other third-party organizations and there are a number of other CROs we could engage to continue these activities, we may not be able to enter into alternative arrangements or do so on commercially reasonable terms or in a timely manner. In addition, while we believe there may be suitable replacements for one or more of these service providers, there is a natural transition period when a new service provider begins work. As a result, delays may occur, which could negatively impact our ability to meet our expected clinical development timelines and harm our business, financial condition and prospects.

***Our use of third party CDMOs to manufacture our product candidates may increase the risk that we will not have sufficient quantities of our product candidates, raw materials, active pharmaceutical ingredients (APIs) or drug products when needed or at an acceptable cost.***

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates, and we lack the resources and the capabilities to do so. Our current strategy is to outsource all manufacturing of our product candidates to third party CDMOs.

We currently rely on and engage third-party CDMOs to provide all of the API and the final filled and finished drug product formulation of all of our product candidates that are being used in our clinical trials and preclinical studies. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement. However, if necessary, we can provide no assurance that we will be able to find an alternative manufacturer on acceptable terms. We may not be able to timely secure needed supply arrangements on satisfactory terms, or at all. Our failure to secure these arrangements as needed could have a material adverse effect on our ability to complete the development of our product candidates or, to commercialize them, if approved. We may be unable to conclude agreements for commercial supply with third-party manufacturers or may be unable to do so on acceptable terms. There may be difficulties in scaling up to commercial quantities and formulation of our product candidates, and the costs of manufacturing could be prohibitive.

The third-party CDMOs we rely on from time to time may have limited or no experience manufacturing our API and final drug products. If our third-party CDMOs have difficulty or suffer delays in successfully manufacturing material that meets our specifications, it may limit supply of our product candidates and could delay our clinical trials.

Even if we are able to establish and maintain arrangements with third-party CDMOs, reliance on third-party CDMOs entails additional risks, including:

- the failure of the third-party CDMOs to comply with applicable regulatory requirements and reliance on third parties for manufacturing process development, regulatory compliance and quality assurance;
- manufacturing delays if our third-party CDMOs give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreement between us;
- limitations on supply availability resulting from capacity and scheduling constraints of third parties;
- the possible breach of manufacturing agreements by third parties because of factors beyond our control;
- the possible termination or non-renewal of the manufacturing agreements by the third party CDMO, at a time that is costly or inconvenient to us; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

If we do not maintain our key third-party CDMO relationships, we may fail to find replacement manufacturers or develop our own manufacturing capabilities, which could delay or impair our ability to obtain regulatory approval for our product candidates. If we do find replacement third-party CDMOs, we may not be able to enter into agreements with them on terms and conditions favorable to us and there could be a substantial delay before new facilities could be qualified and registered with the FDA and other foreign regulatory authorities.

Additionally, if any third-party CDMO with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we do not and may not ever have the capabilities or resources, or enter into an agreement with a different manufacturer. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to the original third-party contract manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change third-party CDMOs for any reason, we will be

required to verify that the new third-party CDMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. We may be unsuccessful in demonstrating the comparability of clinical supplies, which could require the conduct of additional clinical trials. The delays associated with the verification of a new third-party CDMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a third-party CDMO may possess technology related to the manufacture of our product candidate that such third party owns independently. This would increase our reliance on such third-party CDMO or require us to obtain a license from such third-party CDMO in order to have another third party manufacture our product candidates.

If any of our product candidates is approved by any regulatory agency, we intend to utilize arrangements with third-party CDMOs for the commercial production of those products. This process is difficult and time consuming and we may face competition for access to manufacturing facilities as there are a limited number of CDMOs operating under cGMPs that are capable of manufacturing our product candidates. Consequently, we may not be able to reach agreement with third-party contract manufacturers on satisfactory terms, which could delay our commercialization.

Some of our third-party CDMOs are located outside of the U.S. There is currently significant uncertainty about the future relationship between the U.S. and various other countries, including Canada, China, India, Mexico and the United Kingdom with respect to trade policies, treaties, government regulations and tariffs. Increased tariffs could potentially disrupt our existing supply chains and impose additional costs on our business. Additionally, it is possible further tariffs may be imposed that could affect imports of APIs used in our product candidates, or our business may be adversely impacted by retaliatory trade measures taken by Canada, China, India, Mexico and the United Kingdom or other countries, including restricted access to raw materials we may use in our product candidates. Given the unpredictable regulatory environment in the U.S. and uncertainty regarding how the U.S. or foreign governments will act with respect to tariffs, international trade agreements and policies, further governmental action related to tariffs, additional taxes, regulatory changes or other retaliatory trade measures in the future could occur with a corresponding detrimental impact on our business and financial condition.

Our failure, or the failure of our third-party CDMOs, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or voluntary recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect supplies of our product candidates. The facilities used by our CDMOs to manufacture our product candidates must be evaluated by the FDA or comparable foreign regulatory authorities in connection with any NDA or other application we may submit. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs and similar foreign requirements. If our third-party contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we may not be able to secure and/or maintain regulatory approval for our product candidates manufactured at these facilities. In addition, we have no control over the ability of our third-party contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA finds deficiencies or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Third-party contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Any failure to comply with cGMP and similar foreign requirements or other FDA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products, if approved.

The FDA and other foreign regulatory authorities require our third-party CDMOs to register manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with cGMPs and similar foreign requirements.

***Failure of any third-party CDMO to comply with cGMP requirements for applicable drug/device combination products could significantly affect supplies of our product candidates.***

We expect each of our current clinical-stage pherine product candidates, fasedienol, itruvone, refisolone, PH15, and PH284, will be considered drug-device combination products. Third-party CDMOs may not be able to comply with cGMP requirements applicable to drug/device combination products, including applicable provisions of the FDA's or a comparable foreign regulatory authority's drug cGMP regulations, device cGMP requirements embodied in the QMSR or similar regulatory requirements outside the U.S. Our failure, or the failure of our third-party contract manufacturers, to

comply with applicable regulations could result in material adverse effects, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect supplies of our product candidates.

***If any third-party CDMO of our product candidates is unable to increase the scale of its production of our product candidates or increase the product yield of its manufacturing, then our manufacturing costs may increase and commercialization may be delayed.***

In order to produce sufficient quantities to meet the demand for clinical trials and, if approved, subsequent commercialization of our product candidates, our third-party CDMOs will be required to increase their production and optimize their manufacturing processes while maintaining the quality of our product candidates. The transition to larger scale production could prove difficult. In addition, if our third-party CDMOs are not able to optimize their manufacturing processes to increase the product yield for our product candidates, or if they are unable to produce increased amounts of our product candidates while maintaining the same quality then we may not be able to meet the demands of clinical trials or market demands, which could decrease our ability to generate profits and have a material adverse impact on our business and results of operations.

***We may need to maintain licenses for APIs from third parties to develop and commercialize some of our product candidates, which could increase our development costs and delay our ability to commercialize those product candidates.***

Should we decide to use any APIs in any of our product candidates that are proprietary to one or more third parties, we would need to maintain licenses to those APIs from those third parties. If we are unable to gain or continue to access rights to these APIs prior to conducting preclinical toxicology studies intended to support clinical trials, we may need to develop alternate product candidates from these programs by either accessing or developing alternate APIs, resulting in increased development costs and delays in commercialization of these product candidates. If we are unable to gain or maintain continued access rights to the desired APIs on commercially reasonable terms or develop suitable alternate APIs, we may not be able to commercialize product candidates from these programs.

**Risks Related to Government Regulation**

***Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.***

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable foreign regulatory authorities must also approve the manufacturing and marketing of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the U.S., including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the U.S., a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the U.S. have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

***Even if we receive regulatory approval of any product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.***

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the U.S. and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with cGMP and similar foreign requirements and GCP requirements for any clinical trials that we conduct post-approval.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP and similar foreign regulations and applicable product tracking and tracing requirements. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and similar foreign requirements and adherence to commitments made in any NDA, other marketing application and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

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 product candidate. Certain endpoint data we hope to include in any approved product labeling also may not make it into such labeling, including exploratory or secondary endpoint data such as patient-reported outcome measures. The FDA may also require a REMS, program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

The FDA may impose consent decrees or 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 our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical trials to assess new safety risks or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA or comparable foreign regulatory authorities to approve pending applications or supplements to approved applications filed by us or suspension or withdrawal of approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

Additionally, sponsors of approved drugs and biologics must provide six months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed.

The FDA and certain foreign regulatory authorities strictly regulate marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The policies of the FDA and comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

***While we have in the past and may in the future seek designations for our product candidates with the FDA and comparable foreign regulatory authorities that are intended to confer benefits such as a faster development process, an accelerated regulatory pathway or regulatory exclusivity, there can be no assurance that we will successfully obtain such designations. In addition, even if one or more of our product candidates are granted such designations, we may not be able to realize the intended benefits of such designations.***

The FDA and comparable foreign regulatory authorities offer certain designations for product candidates. These programs are designed to encourage the research and development of product candidates that are intended to address serious

conditions. These designations may confer benefits such as additional interaction with regulatory authorities and eligibility for expedited review procedures. However, there can be no assurance that we will successfully obtain such designations for our product candidates. In addition, while such designations could expedite the development or approval process, they generally do not change the standards for approval. Even if we obtain such designations for our product candidates, there can be no assurance that we will realize their intended benefits. For example, we have in the past and may in the future seek fast track designation and/or Breakthrough Therapy designation for some of our product candidates. The FDA has broad discretion whether or not to grant these designations, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it.

The FDA has granted fast track designation for development of fasedienol for the acute treatment of SAD, for development of itruvone for the treatment of MDD, and for development of AV-101 for the adjunctive treatment of MDD and the treatment of neuropathic pain, and we may seek fast track designation for some of our other pherine product candidates. If a drug or biologic is intended for the treatment of a serious or life-threatening condition and the therapy demonstrates the potential to address unmet medical needs for this condition, the therapy sponsor may be eligible for Fast Track designation. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a NDA is submitted, the application may be eligible for priority review. A NDA submitted for a Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

The receipt of fast track designation for development of fasedienol for acute treatment of SAD, for itruvone for the treatment of MDD and AV-101 for the adjunctive treatment of MDD and for the treatment of neuropathic pain, and any future receipt of fast track designation for other product candidates, does not guarantee a faster development process, review or approval compared to conventional FDA procedures, and receiving a fast track designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For a product candidate that has been designated as a Breakthrough Therapy, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Product candidates receiving Breakthrough Therapy designation also receive the same benefits associated with fast track designation, described above. Designation as a Breakthrough Therapy is within the sole discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. For example, the FDA has declined to grant our requests for breakthrough therapy designation for fasedienol for the acute treatment of SAD. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to therapies considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification.

***Some of our programs have been partially supported by government grant awards. Although we do not currently rely on government funding nor do we have a present intent to seek further grant funding from governmental agencies, should that change, such funding may not be available to us in the future or subject us to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S. industry.***

Currently, we do not rely on grant funding from government agencies for our development programs, and we do not have a present intent to seek grant funding from government agencies. While not a current priority, we may apply for grant funding from governmental agencies in the future. However, funding by these governmental agencies may be significantly reduced or eliminated in the future for a number of reasons. For example, some programs are subject to a yearly appropriations process in Congress. In addition, we may not receive full funding under current or future grants because of budgeting constraints of the agency administering the program or unsatisfactory progress on the study being funded. Therefore, we cannot assure you that we will receive any future grant funding from any government agencies, or, that if received, we will receive the full amount of the particular grant award. Any such reductions could delay the development of our product candidates.

Moreover, any intellectual property rights generated through the use of U.S. government funding are subject to the Bayh-Dole Act of 1980 (*Bayh-Dole Act*). These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if the government determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations, which we refer to as march-in rights. The U.S. government also has the right to take title to these inventions if we fail, or the applicable licensor fails, to disclose the invention to the government, elect title, and file an application to register the intellectual property within specified time limits. In addition, the U.S. government may acquire title to these inventions in any country in which a patent application is not filed within specified time limits. Intellectual property generated under a government-funded program is also subject to certain reporting requirements, compliance with which may require us, or the applicable licensor, to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the U.S. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the U.S. or that under the circumstances domestic manufacture is not commercially feasible.

As a result of any future arrangement involving government funding, and if we make inventions as a result of such funding, intellectual property rights to such discoveries may be subject to the applicable provisions of the Bayh-Dole Act. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply. Any exercise by the government of certain of its rights could harm our competitive position, business, financial condition, results of operations and prospects.

***Our relationships with healthcare providers and physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

Healthcare providers, physicians and third-party payors in the U.S. and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct research and would sell, market and distribute our products. Federal and state healthcare laws and regulations that may affect our ability to operate include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for the purchase, lease, order, arrangement, or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. Violations are subject to civil fines and criminal penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties;

- the federal civil and criminal false claims laws and civil monetary penalty laws, such as the federal False Claims Act, which impose criminal and civil penalties and authorize civil whistleblower or qui tam actions, against individuals or entities for, among other things: knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false statement of record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The federal False Claims Act also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery;

- the federal Health Insurance Portability and Accountability Act of 1996 (*HIPAA*), which prohibits, among other things, a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal Physician Payments Sunshine Act, which requires applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Centers for Medicare & Medicaid Services, within the U.S. Department of Health and Human Services, information related to payments or other transfers of value made to physicians, certain non-physician practitioners including nurse practitioners, certified nurse anesthetists, anesthesiologist assistants, physician assistants, clinical nurse specialists, and certified nurse midwives as well as teaching hospitals and to disclose ownership and investment interests held by physicians and their immediate family members;

- federal government price reporting laws, which require manufacturers to calculate and report complex pricing metrics in an accurate and timely manner to government programs; and

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute and False Claims Act, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time and resource-consuming and can divert a company's attention from the business.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment, reputational harm and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, defending against any such actions can be costly and time consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

***Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates profitably.***

The success of our product candidates, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the U.S., no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Private health insurers and other third-party payors in the U.S. often follow the coverage and reimbursement policies of government payors, including the Medicare or Medicaid programs. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates, once approved. Patients are unlikely to use our product candidates, once approved, unless coverage is provided and reimbursement is adequate to cover a significant portion of their cost. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives.

Moreover, increasing efforts by governmental and other third-party payors in the U.S. and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. There has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions

on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

***Healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.***

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example, (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of products have been a focus in this effort. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical products, limiting coverage and the amount of reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the U.S. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. For instance, in August 2022, the Inflation Reduction Act of 2022 (the *IRA*) was signed into law. The IRA includes several provisions that will impact our business to varying degrees, including provisions that allow the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for drug prices that increase faster than inflation, create an out-of-pocket cap for Medicare Part D beneficiaries, impose new manufacturer financial liability on all drugs in Medicare Part D and delay the rebate rule that would require pass-through of pharmacy benefit manager rebates to beneficiaries. In particular, the IRA allows CMS to begin negotiating prices for certain high-cost Medicare-covered small molecule drugs after they have spent seven years on the market. On August 29, 2023, CMS announced the list of the first ten drugs that will be subject to price negotiations. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. All of our disclosed product candidates are small molecule drugs and certain of them are being developed in indications that may rely heavily on Medicare reimbursement, such as depression. Accordingly, these new price-negotiation provisions may have a negative impact on our future revenue and profits. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effect of IRA on our business and the healthcare industry in general is not yet fully known. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our revenue generated from the sale of any approved products. Even if we do receive a favorable coverage determination for our products by third-party payors, coverage policies and third-party payor reimbursement rates may change at any time.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in several Congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. Congress has indicated that it will continue to seek new legislative measures to control drug costs. The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any of our product candidates, if approved;
- the ability to set a price that we believe is fair for any of our product candidates, if approved;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

In addition, recent and/or future policy changes may create uncertainty for our business. In its June 2024 decision in *Loper Bright Enterprises v. Raimondo* (the *Loper Decision*), the U.S. Supreme Court overturned the longstanding *Chevron* doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper Decision could result in additional legal challenges to regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. Additionally, the Loper Decision may result in increased regulatory uncertainty, inconsistent judicial interpretations and other impacts to the

agency rulemaking process. We cannot predict which additional measures may be adopted or the impact of current and additional measures on the marketing, pricing and demand for our products, which could have a material adverse effect on our business, financial condition and results of operations.

We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals or clearances of our product candidates, if any, may be.

***Off-label use or misuse of our product candidates may harm our reputation in the marketplace or result in injuries that lead to costly product liability suits.***

If our product candidates are approved by the FDA or comparable foreign regulatory authorities, we may only promote or market our product candidates in a manner consistent with their FDA-approved labeling (or the label approved by foreign regulatory authorities). We will train our marketing and sales force against promoting our product candidates for uses outside of the approved indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our product candidates off-label, when in the physician's independent professional medical judgment, he or she deems it appropriate. Furthermore, the use of our product candidates for indications other than those approved by the FDA or comparable foreign regulatory authorities may not effectively treat such conditions. Any such off-label use of our product candidates could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use our product candidates for these uses for which they are not approved, which could lead to product liability suits that might require significant financial and management resources and that could harm our reputation.

***Reduction in staffing and/or inadequate funding for the FDA or other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.***

The ability of the FDA and comparable foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including staffing levels, government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the FDA and comparable foreign regulatory authorities, have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions and personnel turnover, as a result of leadership changes, staff reductions or otherwise, or changes to key personnel on relevant regulatory review teams at the FDA, other government agencies and comparable foreign regulatory authorities may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies and comparable foreign regulatory authorities, which would adversely affect our business. For example, in recent years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities.

In addition, the current U.S. Presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA and the USPTO, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect ability of these agencies to conduct routine activities. If funding shortages, policy changes or staffing limitations hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other such regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Significant reductions in, or disruptions to, staffing and resources available at the USPTO could also lead to delays in the examination or approval of patent applications, or to other challenges in securing and/or enforcing our intellectual property rights.

***We are subject to evolving global data protection laws and regulations, which may require us to incur substantial compliance costs, and any failure or perceived failure by us to comply with such laws and regulations may harm our business and operations.***

The global data protection landscape is rapidly evolving, and we may be or become subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, transfer, security and processing of personal data, such as information that we collect about participants and healthcare providers in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, which may create uncertainty in our business, affect our or our service providers' ability to operate in certain jurisdictions or to collect, store, transfer use and share personal data, result in liability or impose additional compliance or other costs on us. Any failure or perceived failure by us to comply with federal, state, or foreign laws or self-regulatory standards could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others.

In the U.S., HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations implemented thereunder, imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. We may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA. Certain states have also adopted comparable privacy and security laws and regulations, which govern the privacy, processing and protection of health-related and other personal information. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California Consumer Privacy Act of 2018 (*CCPA*) went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that has increased the likelihood of, and risks associated with data breach litigation. Further, the California Privacy Rights Act (*CPRA*) generally went into effect on January 1, 2023, and significantly amends the CCPA. It imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may also be required. Other states have enacted similar consumer privacy laws that grant rights to data subjects and place privacy and security obligations on entities handling personal data of consumers or households. While we are not currently subject to laws such as the CCPA, such state privacy laws and similar legislation proposed at the state and federal level could mark the beginning of a trend toward more stringent privacy legislation in the U.S., which could increase our potential liability and adversely affect our business.

In addition to our operations in the U.S., which may be subject to healthcare and other laws relating to the privacy and security of health information and other personal information, we may seek to conduct future clinical trials in the United Kingdom or the European Economic Area (the *EEA*) and may become subject to additional European data privacy laws, regulations and guidelines. We will be subject to the data protection laws of the EU and United Kingdom in relation to personal data we collect from these territories. These laws impose additional obligations and risk upon our business, including substantial expenses and changes to business operations that are required to comply with these laws. For example, the European Union General Data Protection Regulation (*EU GDPR*) went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the EEA or in the context of our activities within the EEA. Companies that must comply with the EU GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. In addition, some of the personal data we process in respect of clinical trial participants is special category or sensitive personal data under the EU GDPR, and subject to additional compliance obligations and to local law derogations. Since the beginning of 2021, after the end of the transition period following the withdrawal of the United Kingdom from the EU (*Brexit*), we may also be subject to the United Kingdom General Data Protection Regulation and Data Protection Act 2018 (collectively, the *UK GDPR*) which imposes separate but similar obligations to those under the EU GDPR and comparable penalties, including fines of up to £17.5 million or 4% of a noncompliant company's global annual revenue for the preceding financial year, whichever is greater. The subsequent separation of the data protection regimes of these territories mean we are required to comply with separate data protection laws in the EU and United Kingdom, which may lead to additional compliance costs and could increase our overall risk.

The EU and UK GDPR (collectively, the *GDPR*), which deals with the processing of personal data and on the free movement of such data, imposes a broad range of strict requirements, including requirements relating to having lawful bases for processing personal data and transferring such information outside the EEA/UK, including to the U.S., providing details to those individuals regarding the processing of their personal data, keeping personal data secure, having data processing agreements with third parties who process personal data, responding to individuals' requests to exercise their rights in respect of their personal data, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact

assessments and record-keeping. In addition to fines, a breach of the GDPR may result in regulatory investigations, reputational damage, orders to cease/ change our data processing activities, enforcement notices, assessment notices (for a compulsory audit) and/or civil claims (including class actions).

The GDPR imposes strict rules on the transfer of personal data out of the EEA/UK to countries not regarded by European Commission and the United Kingdom government as providing adequate protection, or the third countries, including the U.S. and the efficacy and longevity of current transfer mechanisms between the EEA and the U.S. remains uncertain. Case law from the Court of Justice of the European Union (*CJEU*) states that reliance on the standard contractual clauses - a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism - alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. On October 7, 2022, President Biden signed an Executive Order on 'Enhancing Safeguards for U.S. Intelligence Activities' which introduced new redress mechanisms and binding safeguards to address the concerns raised by the CJEU in relation to data transfers from the EEA to the U.S. and which formed the basis of the new EU-US Data Privacy Framework (*DPF*), as released on December 13, 2022. The European Commission adopted its Adequacy Decision in relation to the DPF on July 10, 2023, rendering the DPF effective as a EU GDPR transfer mechanism to U.S. entities self-certified under the DPF. The DPF also introduced a new redress mechanism for EU citizens which addresses a key concern in the previous CJEU judgments and may mean transfers under standard contractual clauses are less likely to be challenged in future. On October 12, 2023, the UK Extension to the DPF came into effect (as approved by the UK Government), as a UK GDPR data transfer mechanism to U.S. entities self-certified under the UK Extension to the DPF. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. In particular, we expect the DPF Adequacy Decision to be challenged and international transfers to the U.S. and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As a result, we may have to make certain operational changes and we will have to implement revised standard contractual clauses and other relevant documentation for existing data transfers within required time frames. This may lead to additional compliance costs and could increase our overall risk.

Should we conduct future clinical trials in the U.K. or EU, we cannot assure you that our efforts to comply with any obligations under European privacy laws will be sufficient. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our reputation and materially harm our business. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

***Additional laws and regulations governing international operations could negatively impact or restrict our operations.***

If we expand our operations outside of the U.S., we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The FCPA prohibits any U.S. individual or business from paying, offering, authorizing payment or offering anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the U.S., or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the U.S., it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing or selling certain products and product candidates outside of the U.S., which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

***We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations.***

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, CROs, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase in time. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

**Risks Related to Our Intellectual Property Rights**

***If we are unable to adequately protect our proprietary technology or obtain and maintain issued patents that are sufficient to protect our product candidates, others could compete against us, which would have a material adverse impact on our business, results of operations, financial condition and prospects.***

We strive to protect and enhance the proprietary technologies that we believe are important to our business, including seeking patents intended to cover our product candidates, their compositions and formulations, their methods of use and methods of manufacturing, delivery devices and any other inventions we consider important to the development of our business. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our success will depend significantly on our ability to obtain and maintain commercially meaningful patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, to defend and enforce our patents, to preserve the confidentiality of our trade secrets and to operate without infringing the valid and enforceable patents and proprietary rights of third parties. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen and maintain the proprietary position of our product candidates. We own patents and patent applications related to product candidates fasedienol, itruvone, refisolone, PH15, and AV-101 and nasal spray delivery devices, and have licensed patents and patent applications related to certain stem cell technologies.

Although we own and have licensed issued and patents and pending patent applications relating to our product candidates in the U.S. and selected countries in other markets, we cannot provide any assurances that our pending U.S. and corresponding foreign patent applications will mature into issued patents and, if they do, that any of our patents will include claims with a scope sufficient to protect our product candidates or otherwise provide any competitive advantage.

Moreover, other parties may have developed technologies that may be related or competitive to our product candidates and may have filed or may file patent applications and may have been granted or may be granted patents that overlap or conflict with our patent properties, for example, either by claiming the same methods or formulations or by claiming subject matter that could dominate our patent position. Such third-party patent positions may limit or even eliminate our ability to obtain or maintain patent protection and may limit or eliminate our ability to commercialize our product candidates.

The uncertainty about adequate protection includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law in ways affecting the scope or validity of issued patents. Moreover, relevant laws differ from country to country.

***The patent positions of biopharmaceutical companies, including our patent portfolio with respect to our product candidates, involve complex legal and factual questions, and, therefore, the issuance, scope, validity, and enforceability of any patent claims that we may be granted cannot be predicted with certainty.***

Our ability to obtain valid and enforceable patents depends, among other factors, on whether the differences between our technology and the prior art allow our inventions to be patentable over the relevant prior art. Such prior art includes, for example, scientific publications, investment blogs, granted patents, and published patent applications. Patent uncertainty cannot be eliminated because of the potential existence of other prior art, about which we are currently unaware, that may be relevant to our patent applications and patents and that may prevent a pending patent application from being granted or result in an issued patent being held invalid or unenforceable. Moreover, the relevant standards for granting and reviewing patents vary among the countries in which we pursue patents.

In addition, some patent-related uncertainty exists because of the challenge of finding and addressing all of the relevant and material prior art in the biotechnology and pharmaceutical fields. For example, there are numerous reports in the scientific literature of compounds that target similar cellular receptors as do certain of our product candidates or that were evaluated in early (often pre-clinical) studies that did not progress to regulatory approval. Another source of uncertainty pertains to patent properties that were in-licensed by us for which prior art submissions were under the control of the licensor. We rely on these licensors to satisfy the relevant disclosure obligations.

In the event any prior art is deemed to be invalidating prior art, it may cause certain of our issued patents to be invalid and/or unenforceable, which would cause us to lose at least part, and perhaps all, of the patent protection on relevant product candidates. Such a loss of patent protection would have a material adverse impact on our business.

***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 other foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other provisions during the patent process. There are situations in which noncompliance can result in the abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

***Even if patents are granted in the U.S. or other countries, third parties may challenge the validity, enforceability, or scope of such issued patents or any other issued patents we own or license, which may result in such patents being narrowed, invalidated, or held unenforceable.***

U.S. and foreign patents and patent applications may be subject to various types of infringement and validity proceedings, including interference proceedings, ex parte reexamination, inter partes review proceedings, supplemental examination, and challenges in district court. Patents may be subjected to opposition, post-grant review, invalidity actions, or comparable proceedings lodged in various foreign, both national and regional, patent offices or courts. These proceedings could result in loss of a patent or rejection of a patent application or loss or reduction in the scope of one or more of the claims of the patent or patent in such a way that they no longer cover our product candidates or competitive products of third parties.

Furthermore, though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability, and the patent may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Even if a patent is granted and is held to be valid and enforceable, competitors may be able to design around our patents, for example, by using pre-existing or newly developed technology or non-infringing formulations, devices, or methods of their use. Other parties may develop and obtain patent protection for more effective technologies, designs, or methods.

If we or one of our licensing partners initiated 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. In patent litigation in the U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness, and non-enablement. Grounds for unenforceability assertions include allegations that someone connected with the prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

Third parties may also raise similar claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection would have a material adverse impact on our business.

In addition, such patent-related proceedings may be costly. Thus, any patent properties that we may own or exclusively license ultimately may not provide commercially meaningful protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to develop, market, or otherwise commercialize our product candidates.

We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, vendors, or former or current employees. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the U.S., and we may encounter significant problems in protecting our proprietary rights in these countries. Moreover, public policy, both within and outside the U.S., has become increasingly unfavorable

toward intellectual property rights. We cannot be certain that we will secure and maintain adequate patent protection for new products and technologies in the United States and other important markets. If these developments were to occur, they could have a material adverse effect on our sales.

Our ability to enforce our patent rights also depends on our ability to detect infringement. It is difficult to detect infringers who do not advertise the components or manufacturing processes that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement by a competitor's or potential competitor's product. Any litigation to enforce or defend our patent rights, even if we were to prevail, could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. We may not prevail in any lawsuits we initiate, or in which we participate as a third party, and the damages or other remedies awarded if we prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any patents covering our product candidates are invalidated or found unenforceable, our financial position and results of operations could be materially and adversely impacted. In addition, if a court found that valid, enforceable patents held by third parties covered our product candidates, our financial position and results of operations could also be materially and adversely impacted.

Overall, the degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any granted patents related to our product candidates or any pending patent applications, if granted and challenged by others, will include or maintain claims having a scope sufficient to protect these product candidates or any other products or product candidates against generic or other competition, particularly considering that any patent rights to these compounds per se have expired;
- any of our pending patent applications will issue as patents at all;
- we will be able to successfully commercialize our product candidates, if approved, before our relevant patents expire;
- we were the first to make the inventions covered by each of our patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe our patents;
- others will not use pre-existing technology to effectively compete against us;
- any of our patents, if issued, will ultimately be found to be valid and enforceable, including on the basis of prior art relating to our patent applications and patents;
- any of our U.S. patents, if issued, will be eligible for listing in the FDA's "Approved Drug Products with Therapeutics Equivalents Evaluations" (commonly known as *the Orange Book*);
- patents that are listed in the Orange Book may be challenged by the Federal Trade Commission or other as being listed inappropriately and subsequently removed, thereby depriving the Company of significant patent enforcement protections;
- any patents currently held or issued to us in the future will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or product candidates that are separately patentable; or
- our commercial activities or products will not infringe the patents or proprietary rights of others.

We also may rely upon unpatented trade secrets, unpatented know-how, and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and our collaborators and consultants. It is possible that technology relevant to our business will be

independently developed by a person who is not a party to such an agreement. Furthermore, if the employees, collaborators, and consultants who are parties to these agreements breach or violate the terms of these agreements, we may not discover or have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors and we may thereby lose intellectual property protection.

***Third parties may initiate legal proceedings against us, alleging that we infringe their intellectual property rights, which may prevent or delay our product development efforts and stop us from commercializing candidate products or increase the costs of commercializing them if approved. Also, we may file counterclaims or initiate other legal proceedings against third parties to challenge the validity or scope of their intellectual property rights, the outcomes of which also would be uncertain and a failure to prevail in such proceedings could have a material adverse effect on the success of our business.***

We cannot assure that our business, product candidates, and proprietary methods do not or will not infringe the patents or other intellectual property rights of third parties. Third parties may initiate legal proceedings against us or our licensors or collaborators, alleging that we or our licensors or collaborators infringe their intellectual property rights. In addition, we or our licensors or collaborators may file counterclaims in such proceedings or initiate separate legal proceedings against third parties to challenge the validity or scope of their intellectual property rights, including in oppositions, interferences, reexaminations, inter partes reviews, or derivation proceedings before the U.S. or other jurisdictions.

Our success will depend in part on our ability to operate without infringing the intellectual property and proprietary rights of third parties. Success also will depend on our ability to prevail in litigation if we are sued for infringement or to resolve litigation matters with rights and at costs favorable to us.

The biopharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may allege that our product candidates or the use of our technologies infringe their patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. As we continue to develop and, if approved, commercialize our current product candidates and future product candidates, competitors may claim that our technology infringes their intellectual property rights as part of their business strategies designed to impede our successful commercialization. There may be third-party patents or patent applications with claims to materials, formulations, devices, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, third parties may have currently pending patent applications that later result in issued patents that our product candidates may infringe, or that such third parties assert are infringed by our technologies.

The foregoing types of proceedings can be expensive and time-consuming and many of our own or our licensors' or collaborators' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these kinds of legal actions than we or our licensors or collaborators can dedicate. Our defense of litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, the misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the U.S. or the European Union.

The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products, or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Even if we are successful in these proceedings, we may incur substantial costs, and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient financial resources to bring these actions to a successful conclusion.

An unfavorable outcome in the foregoing kinds of proceedings could require us or our licensors or collaborators to cease using the related technology or developing or commercializing one or more of our product candidates or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license on commercially reasonable terms or at all. Even if we or our licensors or collaborators obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaborators.

In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business.

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.

Patent litigation and other types of intellectual property litigation can involve complex factual and legal questions, and litigation outcomes are uncertain. Any claim relating to intellectual property infringement that is successfully asserted against us may require us to pay substantial damages, including treble damages and attorney's fees if we are found to have willfully infringed a third party's patents, for past use of the asserted intellectual property and royalties and other consideration going forward if we are forced to take a license. In addition, if any such claim is successfully asserted against us and we are unable to obtain such a license, we may be forced to stop or delay developing, manufacturing, selling or otherwise commercializing one or more of our product candidates.

Patent litigation and other types of intellectual property litigation is costly and time-consuming. We may not have sufficient resources to bring these actions to a successful conclusion. Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court, or redesign our products.

In addition, intellectual property litigation or claims could force us to do one or more of the following:

- cease developing, selling or otherwise commercializing our product candidates;
- pay substantial damages for past use of the asserted intellectual property;
- obtain a license from the holder of the asserted intellectual property, which license may not be available on commercially reasonable terms, if at all; and
- in the case of trademark claims, redesign, or rename, some or all of our product candidates to avoid infringing the intellectual property rights of third parties, which may not be possible and, even if possible, could be costly and time-consuming.

Any of these risks coming to fruition could have a material adverse effect on our business, results of operations, financial condition and prospects.

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

We enter into confidentiality and intellectual property assignment agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. For example, even if we have a consulting agreement in place with an academic advisor pursuant to which such academic advisor is required to assign any inventions developed in connection with providing services to us, such academic advisor may not have the right to assign such inventions to us, as it may conflict with his or her obligations to assign their intellectual property to his or her employing institution.

Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we 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, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

***We do not seek to protect our intellectual property rights in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.***

Filing, prosecuting, and defending patents on product candidates in all countries and jurisdictions throughout the world is prohibitively expensive, and our intellectual property rights in some countries outside the U.S. could be absent, unavailable or less extensive than those in the U.S., assuming that rights are obtained 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. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling

or importing products made using our inventions in and into the U.S. or other jurisdictions. The statutory deadlines for pursuing patent protection in individual foreign jurisdictions are based on the priority filing date of each of our patent applications and the time periods allowed for filing related applications in a given country. Thus, for each of the patent families that we believe provide coverage for our lead product candidates or technologies, we must decide where and when to pursue protection outside the U.S.

Competitors may use our technologies in jurisdictions where we do not pursue and obtain patent protection to develop their own products and, further, may export otherwise 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. In addition, we may not be able to obtain a trademark registration in the US or other countries that provides optimal brand name protection, and we may not be able to obtain the same trademark registration in the US and other countries. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the U.S. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biotechnology and pharmaceuticals. This could make it difficult for us to stop the infringement of our patents if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties under certain circumstances. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

An unfavorable outcome could require us or our licensors or collaborators to cease using the related technology or developing or commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license on commercially reasonable terms or at all. Even if we or our licensors or collaborators obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaborators. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business.

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.

Furthermore, proceedings to enforce our patent rights in foreign jurisdictions 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, could put 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 in relevant foreign jurisdictions may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

***Some intellectual property that we have licensed may have been discovered through government-funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements, and a preference for U.S. industry. Compliance with such regulations may limit our exclusive rights, subject us to an expenditure of resources with respect to reporting requirements and limit our ability to contract with non-U.S. manufacturers.***

Some of the intellectual property rights we have licensed or may license in the future may have been generated through the use of U.S. government funding and may therefore be subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act. These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose.

In addition, the U.S. government has the right to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The U.S. government also has the right to take title to these inventions if we fail, or the applicable licensor fails, to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. Also, the U.S. government may acquire title to these inventions in any country in which a patent application is not filed within specified time limits.

Intellectual property generated under a government-funded program is further subject to certain reporting requirements, compliance with which may require us, or the applicable licensor, to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the U.S.to the extent they are commercialized in the U.S. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the U.S. or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property.

Although not a current priority, in the event that we apply for additional U.S. government funding, and we discover compounds or drug candidates as a result of such funding, intellectual property rights to such discoveries may be subject to the applicable provisions of the Bayh-Dole Act.

***If we do not obtain additional protection under the Hatch-Waxman Amendments and similar foreign legislation by extending the patent terms or obtaining regulatory and data exclusivity for our product candidates, our business may be materially harmed.***

In the U.S., depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of the U.S. patents we own or license may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. For example, we may not be granted an extension if the active ingredient of fasedienol, itruvone, or AV-101 is used in another drug company's product candidate and that product candidate is the first to obtain FDA approval.

Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our ability to generate revenues could be materially adversely affected.

Similar kinds of patent term and regulatory and data protection periods are available outside of the U.S. We will pursue such opportunities to extend the exclusivity of our products, but we cannot predict the availability of such exclusivity pathways or that we will be successful in pursuing them.

***Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.***

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is, therefore, costly, time-consuming, and inherently uncertain. In addition, the U.S., in recent years, enacted and is currently implementing wide-ranging patent reform legislation: the Leahy-Smith America Invents Act, referred to as the America Invents Act. The America Invents 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. It is not yet clear what, if any, impact the America Invents Act will have on the operation of our business. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any patents that may issue from our patent applications, all of which could have a material adverse effect on our business and financial condition.

In addition, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. The full impact of these decisions is not yet known. Recent court decisions and related USPTO examination guidelines must be considered, particularly as they relate to changes in what types of inventions are eligible for patent protection. Foreign patent and intellectual property laws are also evolving and are not predictable as to their impact on the Company and other biopharmaceutical companies.

In addition to increasing uncertainty regarding our ability to obtain future patents, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on these and other 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 any patents that may issue in the future.

***We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.***

Certain of our current employees have been, and certain of our future employees may have been, previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We also engage advisors and consultants who are concurrently employed at universities or who perform services for other entities.

Although we are not aware of any claims currently pending or threatened against us, we may be subject to claims that we or our employees, advisors, or consultants have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or another third party. We have and may in the future also be subject to claims that an employee, advisor or consultant performed work for us that conflicts with that person's obligations to a third party, such as an employer, and thus, that the third party has an ownership interest in the intellectual property arising out of work performed for us. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail to defend such claims, in addition to paying monetary claims, we may lose valuable intellectual property rights or personnel. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our product candidates, which would materially adversely affect our commercial development efforts.

***Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.***

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology but that is not covered by the claims of patents, should such patents issue from our patent applications;
- we might not have been the first to make the inventions covered by a pending patent application that we own;
- we might not have been the first to file patent applications covering an invention;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- pending patent applications that we own or license may not lead to issued patents;
- patents, if issued, that we own or license may not provide us with any competitive advantages, or may be held invalid or unenforceable or be narrowed, as a result of legal challenges by our competitors;
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we may not be able to obtain and/or maintain necessary or useful licenses on reasonable terms or at all; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business and results of operations.

**Risks Related to our Securities**

***If we fail to regain compliance with the continued listing requirements of the Nasdaq Capital Market, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted. Moreover, there can be no assurance that we will be able to regain compliance with such Nasdaq continued listing standards in the future.***

On February 3, 2026, we were notified by the Nasdaq Stock Market, LLC (*Nasdaq*) that we were not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on the Nasdaq Capital Market. Nasdaq Listing Rule 5550(a)(2) requires listed securities to maintain a minimum bid price of $1.00 per share, and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum bid price requirement exists if the deficiency continues for a period of 30 consecutive business days. The notification provides that we have 180 calendar days, or until August 3, 2026, to regain compliance with Nasdaq Listing Rule 5550(a)(2). To regain compliance, the bid price of our common stock must have a closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days. An additional 180 days may be granted to regain compliance, so long as we meet the Nasdaq Capital Market continued listing requirements (except for the bid price requirement) and notify Nasdaq in writing of our intention to cure the deficiency during the second compliance period by implementing a reverse stock split, if necessary. If we do not qualify for the second compliance period or fail to regain compliance during the second 180-day period, then Nasdaq will notify us of its determination to delist our common stock, at which point we will have an opportunity to appeal the delisting determination to a hearings panel.

No assurance can be given that we will regain compliance with the Nasdaq continued listing standards. Failure to regain compliance with all Nasdaq continued listing standards could result in a delisting of our common stock, which could cause Nasdaq to delist our shares of common stock from trading on its exchange. If our shares of common stock were delisted from Nasdaq, we and our stockholders could face significant material adverse consequences including:

- a limited availability of market quotations for our securities;
- reduced liquidity for our securities;
- a determination that our common stock is a “penny stock” which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

***Market volatility may affect our stock price and the value of your investment.***

The market price for our common stock, similar to that of other biopharmaceutical companies, is likely to remain highly volatile. The market price of our common stock may fluctuate significantly for no apparent reason or in response to a number of factors, most of which we cannot control, including, among others:

- volatility resulting from uncertainty and general economic conditions;
- plans for, progress of or results from nonclinical and clinical development activities related to our product candidates;
- the failure of the FDA or other regulatory authority to review or approve our product candidates in a timely manner, or at all;
- announcements of new products, technologies, commercial relationships, acquisitions or other events by us or our competitors;
- the success or failure of other neuroscience therapies in development by other companies;
- regulatory or legal developments in the U.S. and other countries;
- announcements regarding our intellectual property portfolio;
- failure of our product candidates, if approved, to achieve commercial success;

- fluctuations in stock market prices and trading volumes of similar companies;
- general market conditions and overall fluctuations in U.S. debt and equity markets;
- variations in our quarterly operating results;
- changes in our financial guidance or securities analysts' estimates of our financial performance;
- changes in accounting principles;
- our ability to raise additional capital and the terms on which we can raise it;
- sales or purchases of large blocks of our common stock, including sales or purchases by our executive officers, directors and significant stockholders;
- establishment of short positions by holders or non-holders of our stock or warrants;
- additions or departures of key personnel;
- discussion of us or our stock price by the press and by anonymous or other online investor communities; and
- other risks and uncertainties described in these risk factors.

***There may be issuances of shares of preferred stock in the future***.

Our Restated Articles of Incorporation, as amended (*the Articles*), permit us to issue up to 10.0 million shares of preferred stock. As a result, our Board could authorize the issuance of preferred stock in the future and such preferred stock could grant holders preferred rights to our assets upon liquidation, the right to receive dividends before dividends would be declared to holders of our common stock, and the right to the redemption of such shares, possibly together with a premium, prior to the redemption of the common stock. In the event and to the extent that we do issue additional preferred stock in the future, the rights of holders of our common stock could be impaired thereby, including without limitation, with respect to liquidation.

***We incur significant costs to ensure compliance with corporate governance, federal securities law and accounting requirements.***

We are subject to the reporting requirements of the Exchange Act which requires that we file annual, quarterly and current reports with respect to our business and financial condition, and the rules and regulations implemented by the SEC, the Sarbanes-Oxley Act of 2002, as amended (the *Sarbanes-Oxley Act*), the Dodd-Frank Act, and the Public Company Accounting Oversight Board, each of which imposes additional reporting and other obligations on public companies. We have incurred and will continue to incur significant costs to comply with these public company reporting requirements, including accounting and related audit costs, legal costs to comply with corporate governance requirements and other costs of operating as a public company. These legal and financial compliance costs will continue to require us to divert significant resources that we could otherwise use to achieve our research and development and other strategic objectives.

The filing and internal control reporting requirements imposed by federal securities laws, rules and regulations on companies that are not "smaller reporting companies" under federal securities laws are rigorous and, once we are no longer a smaller reporting company, we may not be able to meet them, resulting in a possible decline in the price of our common stock and our inability to obtain future financing. Certain of these requirements may require us to carry out activities we have not done previously and complying with such requirements may divert management's attention from other business concerns, which could have a material adverse effect on our business, results of operations, financial condition and cash flows. Any failure to adequately comply with applicable federal securities laws, rules or regulations could subject us to fines or regulatory actions, which may materially adversely affect our business, results of operations and financial condition.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory

and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We will continue to invest resources to comply with evolving laws, regulations and standards, however this investment may result in increased general and administrative expense, and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us, and our business may be adversely affected.

***The amount of our future losses is uncertain and our quarterly and annual operating results may fluctuate significantly or fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.***

Our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry,
- our ability to successfully recruit, enroll and retain subjects who meet our eligibility criteria for participation in our clinical trials, and any delays caused by difficulties in such efforts;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future therapeutics that compete with our product candidates;
- our ability to obtain marketing approval for our product candidates and the timing and scope of any such approvals we may receive;
- the timing and cost of, and level of investment in, research and development and commercialization activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with contract manufacturers;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional product candidates;
- the level of demand for our product candidates should they receive approval, which may vary significantly;
- the changing and volatile U.S. and global economic and political environments, including the impact of inflation and rising interest rates, and domestic or international political instability; and
- future accounting pronouncements or changes in our accounting policies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our operating results or revenue fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

***Because of potential volatility in our trading price and trading volume, we may incur significant costs from litigation, including class action securities litigation.***

The stock market in general, and Nasdaq and biotechnology and pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Historically, securities class action litigation has often been brought against companies following periods of volatility in the market price of a company's securities. For example, purported stockholders of the Company have filed lawsuits in the United States District Court for the Northern District of California against the Company and certain of our executive officers, the members of our Board and certain other parties, claiming, under the U.S. federal securities laws and

certain California civil statutes, among other things, allegedly false or misleading statements, and alleged omissions of material facts, related to our public disclosures. We believe all claims are without merit and intend to vigorously defend all claims. These types of litigation could result in substantial costs and a diversion of management's attention and resources, which could harm our business, operating results, or financial condition. Additionally, the dramatic increase in the cost of directors' and officers' liability insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover significant defense costs, settlements, and damages awarded to plaintiffs.

***Our issuance of additional capital stock in connection with financings, acquisitions, investments, our stock incentive plans or otherwise may, and likely will significantly dilute all other stockholders.***

We expect to issue additional capital stock in the future that may, and likely will result in substantial dilution to all of our stockholders. We expect to grant equity awards to employees and directors under our stock incentive plans. We may also raise capital through equity financings in the future, as well as securities convertible into equity. As part of our business strategy, we may acquire or make investments in complementary companies, products, or technologies and issue equity and/or debt securities to pay for any such acquisition or investment. Any such issuances resulting in the issuance of additional equity securities will cause stockholders to experience significant dilution of their ownership interests and the per share value of our common stock to decline.

***Because we have no current plans to pay cash dividends on our common stock, you may not receive any return on investment unless you sell your common stock for a price greater than that which you paid for it.***

We have never declared or paid any cash dividends on our capital stock and have no current plans to pay cash dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions, and other factors that our board of directors may deem relevant. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

***Future offerings of debt or equity securities by us may adversely affect the market price of our common stock.***

In the future, we may attempt to obtain financing or to further increase our capital resources by issuing additional shares of our common stock or offering debt or other equity securities, including commercial paper, medium-term notes, senior or subordinated notes, debt securities convertible into equity or shares of preferred stock.

Issuing additional shares of our common stock or other equity securities or securities convertible into equity will dilute the economic and voting rights of our existing stockholders and may reduce the market price of our common stock or both. Upon liquidation, holders of such debt securities and preferred shares, if issued, and lenders with respect to other borrowings would receive a distribution of our available assets prior to the holders of our common stock. Debt securities convertible into equity could be subject to adjustments in the conversion ratio pursuant to which certain events may increase the number of equity securities issuable upon conversion. Preferred shares, if issued, could have a preference with respect to liquidating distributions or a preference with respect to dividend payments that could limit our ability to pay dividends to the holders of our common stock. Our decision to issue securities in any future offering will depend on market conditions and other factors beyond our control, which may adversely affect the amount, timing and nature of our future offerings.

**General Risk Factors**

***Adverse market or macroeconomic conditions or market volatility resulting from global economic and political developments, including those affecting the financial services industry, could adversely affect our business operations and our financial condition and results of operations.***

Adverse market or macroeconomic and political conditions or market volatility resulting from global economic developments, political activity and uncertainty, high inflation, rising interest rates or other factors, could materially and adversely affect our business operations. For instance, actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. These events could result in a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations.

In addition, any deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our partners, vendors or suppliers, which in turn, could have a material adverse effect on our current and/or projected

business operations and results of operations and financial condition. For example, a partner may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy, or a supplier may determine that it will no longer deal with us as a customer. In addition, a vendor or supplier could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on us, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. The bankruptcy or insolvency of any partner, vendor or supplier, or the failure of any partner to make payments when due, or any breach or default by a partner, vendor or supplier, or the loss of any significant supplier relationships, could cause us to suffer material losses and may have a material adverse impact on our business.

***Changes in tax law could adversely affect our business and financial condition.***

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application), including with respect to net operating losses and research and development tax credits, could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. For example, on July 4, 2025, the United States enacted tax legislation commonly referred to as the One Big Beautiful Bill Act (*OBBB Act*). In accordance with U.S. GAAP, the Company will account for the tax effects of changes in tax law in the period of enactment which is the quarter ended September 30, 2025. The Company is currently in the process of analyzing the tax impacts of the OBBB Act, but we do not expect a material impact on our financial statements. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock

***Our ability to use our net operating losses and research and development tax credits to offset future taxable income may be subject to certain limitations.***

As of March 31, 2025, we had U.S. federal net operating loss carryforwards totaling $229.2 million. Federal net operating loss carryforwards of approximately $82.1 million generated through our fiscal year ended March 31, 2018 will expire in our fiscal years ending March 31, 2025 through March 31, 2038. Federal net operating loss carryforwards of approximately $147.1 million generated in fiscal years ending after March 31, 2018 will carry forward indefinitely, but are subject to an 80% taxable income limitation. As of March 31, 2025, we had state net operating loss carryforwards totaling $66.6 million, which expire at various dates between 2029 and 2045. As of March 31, 2025, we also had U.S. federal and state research and development tax credit carryforwards of $7.6 million and $2.0 million, respectively. The federal tax credits will expire at various dates beginning with our fiscal year ending March 31, 2029, unless previously utilized. The state tax credits do not expire and will carry forward indefinitely until utilized. The net operating losses which are limited in life and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, in general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the *Code*) a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses (*NOLs*) or tax credits or credits, to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who own at least 5% of a corporation's stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a specified testing period. Our existing NOLs or credits may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change in the future, our ability to utilize NOLs or credits could be further limited by Sections 382 and 383 of the Code. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code. Our NOLs or credits may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or credits. If we determine that an ownership change has occurred and our ability to use our historical NOLs or credits is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. Section 382 and 383 of the Code would apply to all net operating loss and tax credit carryforwards, whether the carryforward period is indefinite or not.

Furthermore, our ability to utilize our historical NOLs or credits is conditioned upon us attaining profitability and generating U.S. federal and state taxable income. We are a clinical-stage biopharmaceutical company with a limited operating history. We have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; and therefore, we do not know whether or when we will generate the U.S. federal or state taxable income necessary to utilize our historical NOLs or credits that may be subject to limitation by Sections 382 and 383 of the Code.

***Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.***

Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

***If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.***

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing we conduct in connection with Section 404 of the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

If we identify any future material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports or applicable stock exchange listing requirements, investors may lose confidence in our financial reporting and our stock price may decline as a result. We also could become subject to investigations by Nasdaq, the SEC or other regulatory authorities.

***Reports published by analysts, including projections in those reports that differ from our actual results, could adversely affect the price and trading volume of our common stock.***

Independent securities research analysts may establish and publish their own periodic analysis of and projections relating to our operation and prospects. These analyses and projections may vary widely and may not accurately predict the results we actually achieve. Our share price may decline if our actual results do not match the analyses, opinions, and projections of these securities research analysts. Similarly, if one or more of the analysts who write reports on us downgrades our stock or publishes inaccurate or unfavorable research about our business, our share price could decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, our share price or trading volume could decline.

***The price of our common stock may be volatile.***

The price of our common stock may fluctuate due to a variety of factors, including:

- changes in the industries in which we and our customers operate;
- variations in our operating performance and the performance of our competitors in general;
- actual or anticipated fluctuations in our quarterly or annual operating results;
- publication of research reports by securities analysts about us, our competitors or our industry;
- the public's reaction to our press releases, other public announcements and filings with the SEC;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- additions and departures of key personnel;
- changes in laws and regulations affecting our business;

- commencement of, or involvement in, litigation involving us;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- the volume of shares of our common stock available for public sale; and
- general economic and political conditions such as recessions, rising or unchanged interest rates, inflation, fuel prices, foreign currency fluctuations, international tariffs, boycotts, curtailment of trade and other business restrictions, social, political and economic risks, natural disasters and acts of war or terrorism, such as the conflicts involving Ukraine and Russia, or Israel and its surrounding regions.

These market and industry factors may materially reduce the market price of shares of our common stock regardless of our operating performance.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

None.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

Not Applicable.

**Item 5. Other Information.**
None

**Item 6. Exhibits**

| Exhibit Number | Description |
|---|---|
| 10.1 | Indemnification Agreement by and between Vistagen Therapeutics, Inc. and Nick B. Tressler, dated December 1, 2025, incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 3, 2025 |
| 31.1* | Certification of the Principal Executive Officer required by Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 31.2* | Certification of the Principal Financial Officer required by Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 32* | Certification of the Principal Executive and Financial Officers required by Rule 13a-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 101.INS * | The instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document. |
| 101.SCH* | Inline XBRL Taxonomy Extension Schema |
| 101.CAL* | Inline XBRL Taxonomy Extension Calculation Linkbase |
| 101.DEF* | Inline XBRL Taxonomy Extension Definition Linkbase |
| 101.LAB* | Inline XBRL Taxonomy Extension Label Linkbase |
| 101.PRE* | Inline XBRL Taxonomy Extension Presentation Linkbase |
| 104* | Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101) |

* Filed 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.

VISTAGEN THERAPEUTICS, INC.

Dated: February 12, 2026

/s/ Shawn K. Singh, JD
Shawn K. Singh, JD
*President and Chief Executive Officer*
*(Principal Executive Officer)*

/s/ Nick B. Tressler
Nick B. Tressler
*Chief Financial Officer*
*(Principal Financial and Accounting Officer)*

**EXHIBIT 31.1**

**CERTIFICATION**

I, Shawn K. Singh, certify that;

1. I have reviewed this quarterly report on Form 10-Q of Vistagen Therapeutics, Inc.;

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 the 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-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(s) 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.

February 12, 2026

/s/ *Shawn K. Singh*

Shawn K. Singh

Principal Executive Officer

**EXHIBIT 31.2**

**CERTIFICATION**

I, Nick B. Tressler, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Vistagen Therapeutics, Inc.;

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 the 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-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(s) 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.

February 12, 2026

/s/ *Nick B. Tressler*

*Nick B. Tressler*

Principal Financial Officer

**EXHIBIT 32**

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,**
**AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Vistagen Therapeutics, Inc. (the "*Company*") for the quarter ended December 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "*Report*"), Shawn K. Singh, JD, the Company's Principal Executive Officer, and Nick B. Tressler, the Company's Principal Financial Officer, certifies, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to the best of their knowledge:

1. The Report fully complies with the requirement of Section 13(a) or Section 15 (d) of the Securities Exchange Act of 1934, and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

February 12, 2026

/s/ *Shawn K. Singh*
Shawn K. Singh
Principal Executive Officer

/s/ *Nick B. Tressler*
Nick B. Tressler
Principal Financial Officer