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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 September 30, 2026
or

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

For the transition period from _____ to _____.

Commission File 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 November 10, 2026, 46,186,049 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)

	September 30, 2026	March 31, 2026
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 10,892	$ 30,789
Marketable securities	9,142	14,614
Prepaid expenses and other current assets	2,260	1,540
Total current assets	22,294	46,943
Property and equipment, net	325	427
Right-of-use asset - operating lease	513	801
Other assets	289	393
Total assets	$ 23,421	$ 48,564
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,084	$ 1,535
Accrued expenses	6,639	8,755
Note payable	—	96
Deferred revenue	96	1,710
Operating lease obligation - current portion	610	699
Total current liabilities	8,429	12,795
Operating lease obligation - non-current portion	—	249
Total liabilities	8,429	13,044
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at September 30, 2026 and March 31, 2026; no shares outstanding at September 30, 2026 and March 31, 2026	—	—
Common stock, $0.001 par value; 325,000,000 shares authorized at September 30, 2026 and March 31, 2026; 45,595,380 and 39,624,839 shares issued at September 30, 2026 and March 31, 2026, respectively	46	40
Additional paid-in capital	520,012	516,767
Treasury stock, at cost, 4,522 shares of common stock held at September 30, 2026 and March 31, 2026	(3,968)	(3,968)
Accumulated other comprehensive loss	(11)	(2)
Accumulated deficit	(501,087)	(477,317)
Total stockholders' equity	14,992	35,520
Total liabilities and stockholders' equity	$ 23,421	$ 48,564

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 September 30,		Six Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Revenues:				
Sublicense and other revenue	$ 138	$ 258	$ 1,614	$ 502
Total revenues	138	258	1,614	502
Operating expenses:				
Research and development	6,554	15,915	17,459	27,693
General and administrative	4,521	4,396	8,439	8,667
Total operating expenses	11,075	20,311	25,898	36,360
Loss from operations	(10,937)	(20,053)	(24,284)	(35,858)
Other income, net:				
Interest income, net	198	630	515	1,342
Other income	(1)	6	(1)	4
Loss before income taxes	(10,740)	(19,417)	(23,770)	(34,512)
Income taxes	—	—	—	—
Net loss	$ (10,740)	$ (19,417)	$ (23,770)	$ (34,512)
Unrealized gain (loss) on marketable securities	(4)	13	(9)	14
Comprehensive loss	$ (10,744)	$ (19,404)	$ (23,779)	$ (34,498)
Basic and diluted net loss per common share	$ (0.24)	$ (0.54)	$ (0.54)	$ (1.02)
Weighted average common shares outstanding, basic and diluted	44,440,372	35,749,160	43,714,263	33,850,346

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 (Loss)	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

	Common Stock		Additional Paid-in Capital	Treasury Stock	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount					
Balance at March 31, 2026	39,624,839	$ 40	$ 516,767	$ (3,968)	$ (2)	$ (477,317)	$ 35,520
Stock-based compensation expense	—	—	991	—	—	—	991
Sale of common stock pursuant to 2019 Employee Stock Purchase Plan	387,798	—	74	—	—	—	74
Unrealized loss on marketable securities available-for-sale, net	—	—	—	—	(5)	—	(5)
Issuance of common stock under Open Market Sale Agreement, net of issuance costs	1,580,176	1	927	—	—	—	928
Issuance of common stock upon exercise of Pre-Funded Warrants	2,788,620	3	—	—	—	—	3
Net loss	—	—	—	—	—	(13,030)	(13,030)
Balance at June 30, 2026	44,381,433	$ 44	$ 518,759	$ (3,968)	$ (7)	$ (490,347)	$ 24,481
Stock-based compensation expense	—	—	907	—	—	—	907
Issuance of common stock under Open Market Sale Agreement, net of issuance costs	1,213,947	2	346	—	—	—	348
Unrealized loss on marketable securities available-for-sale, net	—	—	—	—	(4)	—	(4)
Net loss	—	—	—	—	—	(10,740)	(10,740)
Balance at September 30, 2026	45,595,380	$ 46	$ 520,012	$ (3,968)	$ (11)	$ (501,087)	$ 14,992

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Six Months Ended September 30,	
	2026	**2025**
Cash flows from operating activities:		
Net loss	$ (23,770)	$ (34,512)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	102	93
Stock-based compensation	1,898	2,012
Amortization of operating lease right-of-use asset	288	261
Non-cash interest expense	—	2
Accretion on marketable securities	(249)	(270)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(758)	(165)
Other assets	101	(37)
Operating lease liability	(338)	(302)
Deferred revenue, net of deferred contract acquisition costs	(1,576)	(464)
Accounts payable and accrued expenses	(2,568)	777
Net cash used in operating activities	(26,870)	(32,605)
Cash flows from investing activities:		
Purchases of laboratory and other equipment	—	(125)
Sales and maturities of marketable securities	12,275	10,000
Purchases of marketable securities	(6,562)	(10,757)
Net cash provided by (used in) investing activities	5,713	(882)
Cash flows from financing activities:		
Proceeds from exercise of warrants	3	—
Proceeds from sale of common stock under Open Market Sale Agreement, net of offering costs	1,279	28,325
Proceeds from sale of common stock under 2019 Employee Stock Purchase Plan	74	161
Issuance of note payable for insurance policy	—	1,020
Repayment of note payable	(96)	(364)
Net cash provided by financing activities	1,260	29,142
Net change in cash and cash equivalents	(19,897)	(4,345)
Cash and cash equivalents at beginning of period	30,789	67,131
Cash and cash equivalents at end of period	$ 10,892	$ 62,786
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ —	$ 19
Non-cash investing and financing activities:		
Purchases of equipment included in accounts payable and accrued liabilities	$ —	$ 8

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 or the Company*), 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. The Company's 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 the Company's targeted patient population. Pherines 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 the Company's 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 as of March 31, 2026, has been derived from the Company's 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, 2026 (*Annual Report*), filed with the SEC on June 15, 2026.

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 the Company's neuroscience product candidates and to expand its infrastructure and operations in a manner the Company believes will be necessary to commercialize its product candidates, if approved, on its own or with one or more collaborators, the Company will require substantial additional capital. Until the Company can generate a sufficient amount of revenue from the commercialization of its product candidates, the Company 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 the Company's product candidates, the Company is unable to estimate the exact amount and timing of its capital requirements. The Company does not expect to generate any meaningful revenue unless and until the Company obtains regulatory approval of and commercializes any of the Company's product candidates, and the Company does not know when, or if, that will occur.

The Company has incurred significant losses and negative cash flows from operations since inception. As of September 30, 2026, the Company had an accumulated deficit of $501.1 million, and cash used in operations for the six months ended September 30, 2026 was $26.9 million. The Company expects that its operating losses and negative cash flows will continue for the foreseeable future as the Company continues to develop and, if approved, commercialize its product candidates.

In accordance with Accounting Standards Codification (*ASC*) 205-40, Going Concern, the Company evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to

continue as a going concern within one year from the date these condensed consolidated financial statements in this Quarterly Report on Form 10-Q (*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 alleviate substantial doubt about the Company's 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 the Company's control nor have these plans been approved by the Board as of the date of these condensed consolidated financial statements.

As of September 30, 2026, the Company had cash, cash equivalents, and marketable securities of $20.0 million. As of November 13, 2026, the issuance date of the condensed consolidated financial statements as of and for the three and six months ended September 30, 2026 in this Report, 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 exists about its ability to continue as a going concern.

When necessary and/or advantageous, the Company will seek additional capital to fund the Company's planned operations through (i) sales of its equity and/or debt securities in one or more public offerings and/or private placements, including, but not limited to sales of its securities under its 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 its product candidates. However, no assurance can be provided that any such sales of the Company's securities, awards, agreements or collaborations will occur in the future. While the Company may make additional sales of its equity and/or debt securities, the Company does not have an obligation to do so.

The Company's future working capital requirements will depend on many factors, including, without limitation, potential impacts related to adjustments in the size of the Company's staff or other actual and/or planned adjustments to its operations, the scope and nature of opportunities related to the Company's success or failure in nonclinical and clinical trials, including the development and commercialization of the Company's current product candidates, and the availability of, and its ability to enter into financing transactions and research, development and commercialization collaborations on terms acceptable to the Company. In the future, to further advance the nonclinical and clinical development of the Company's product candidates, as well as support the Company's operating activities, the Company plans 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 its operating costs, including, but not limited to, the Company's clinical and nonclinical programs.

There can be no assurance that future financings will be available to the Company in sufficient amounts, in a timely manner, or on terms acceptable to the Company, 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 August 4, 2026, the Company received a notification from the Listing Qualifications Staff of The Nasdaq Stock Market LLC granting the Company an additional 180 calendar day compliance period, until February 1, 2027, to regain compliance with the requirement that the Company's common stock maintain a minimum closing bid price of $1.00 per share for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2).

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, and determination of right-of-use assets under lease transactions and related lease obligations. Although these estimates are based on the Company's

knowledge of current events, historical experiences, actions the Company may undertake in the future and on various other assumptions the Company believes are reasonable, actual results may materially differ from these estimates and assumptions.

Fair Value Measurements

The Company measures 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.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company manages its operations as a single reportable segment for the purposes of assessing performance and making operating decisions.

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. The Company's 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. The Company's 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, 2026, and 2025 to the recently issued accounting standards, for the six months ended September 30, 2026.

Issued Accounting Pronouncements Not Yet Adopted

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. For the Company, ASU 2024-03 will be effective for the fiscal year beginning April 1, 2027, the Company's fiscal year ending March 31, 2028, and for interim periods beginning with the quarter ending June 30, 2028. ASU 2024-03 may be adopted

on a prospective or retrospective basis. The Company does not believe the adoption of ASU 2024-03 will have a material impact on the Company's consolidated financial statements, but it will increase the amount of expense information the Company provides.

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. For public business entities, ASU 2025-11 is effective for interim reporting periods within annual reporting periods beginning after December 15, 2027, with early adoption permitted. ASU 2025-11 may be adopted on a prospective or retrospective basis. For the Company, ASU 2025-11 will be effective for the fiscal year beginning April 1, 2028, the Company's fiscal year ending March 31, 2029, and for interim periods beginning with the quarter ending June 30, 2028. The Company is currently evaluating the impact of this guidance on its financial statements.

In December 2025, the FASB issued ASU 2025-12, Codification Improvements, which includes 33 amendments to the Accounting Standards Codification intended to clarify existing guidance, correct technical errors, and address minor inconsistencies across a broad range of topics. ASU 2025-12 is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods within those annual reporting periods, with early adoption permitted. For the Company, ASU 2025-12 will be effective for the fiscal year beginning April 1, 2027, beginning with the quarter ending June 30, 2027. Other than the amendments related to earnings per share, ASU 2025-12 may be adopted on a prospective or retrospective basis, and the transition method may be elected on an issue-by-issue basis. The Company has evaluated the amendments in ASU 2025-12 and does not expect adoption to have a material impact on its consolidated financial statements or disclosures.

3. Fair Value Measurements

The following tables show the Company's cash, cash equivalents and marketable securities measured at fair value as of September 30, 2026 and March 31, 2026 (in thousands):

	September 30, 2026			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets:				
Cash and cash equivalents:				
Cash and money market funds	$ 10,892	$ —	$ —	$ 10,892
Marketable securities:				
U.S. treasury securities	—	9,142	—	9,142
Total	$ 10,892	$ 9,142	$ —	$ 20,034

	March 31, 2026			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets:				
Cash and cash equivalents:				
Cash and money market funds	$ 30,789	$ —	$ —	$ 30,789
Marketable securities:				
U.S. treasury securities	—	14,614	—	14,614
Total	$ 30,789	$ 14,614	$ —	$ 45,403

The carrying amounts of the Company's prepaid expenses and other current assets, accounts payable, accrued expenses, and the note payable approximate fair value due to their short maturities. The Company has no financial liabilities measured at fair value on a recurring basis as of September 30, 2026 or March 31, 2026. There were no transfers between Levels 1, 2 or 3 for any of the periods presented.

The Company did not record any impairment charges related to the Company's marketable debt securities during the three and six months ended September 30, 2026 or 2025.

The following tables summarize the Company's marketable securities as of September 30, 2026 and March 31, 2026 (in thousands):

		September 30, 2026			
	Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. treasury notes	Less than 1	$ 9,153	$ —	$ (11)	$ 9,142
Total		$ 9,153	$ —	$ (11)	$ 9,142

		March 31, 2026			
	Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. treasury notes	Less than 1	$ 14,616	$ 2	$ (4)	$ 14,614
Total		$ 14,616	$ 2	$ (4)	$ 14,614

4. Note Payable

In May 2025, the Company executed a 6.54% promissory note in the principal amount of $1.0 million in connection with certain insurance policy premiums. The note was payable in monthly installments of approximately $0.1 million, including principal and interest, through April 2026. As of March 31, 2026, $0.1 million was outstanding under the note. The Company made the final payment in April 2026, and no amounts were outstanding as of September 30, 2026.

5. Capital Stock

Common Stock

October 2023 Public Offering

On October 2, 2023, the Company completed an underwritten public offering (the *October 2023 Public Offering*), whereby the Company offered and sold, for gross proceeds of approximately $100 million, a total of 15,010,810 shares of the Company's 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 the Company 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) were immediately exercisable upon issuance at the option of the holder. Holders of the remaining T2 Warrants may elect to exercise them for Pre-Funded Warrants. The Company may not effect the exercise of any outstanding 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 5635(b) or any successor rule) upon at least 61 days' prior notice from the holder to the Company subject to the terms of the respective Warrant agreement.

The Company 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.

As of September 30, 2026, all Pre-Funded Warrants have been exercised by their respective holders, and all T1 Warrants expired according to the terms thereof. As such, no Pre-Funded Warrants or T1 Warrants are outstanding as of the date of this Report.

Open Market Sale Agreement

In May 2021, the Company 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 the Company was permitted, at the Company's option, to offer and sell, from time to time, shares of the Company's common stock having an aggregate offering price of up to $175 million. As of September 30, 2026, shares of common stock with an aggregate offering price of approximately $139.2 million remained available for offer and sale under the Sales Agreement.

During the three and six months ended September 30, 2026, the Company sold 1,213,947 and 2,794,123 shares of the Company's common stock in at-the-market transactions under the Sales Agreement, resulting in net cash proceeds of approximately $0.3 million and $1.3 million after sales agent commissions, respectively. During the three and six months ended September 30, 2025, the Company sold 9,608,772 and 9,798,839 shares under the Sales Agreement, resulting in net cash proceeds of approximately $27.9 million and $28.3 million after sales agent commissions, respectively. The Company pays 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

The following table summarizes warrant activity for the periods presented:

	2026		2025	
	Warrants	**Weighted Average Exercise Price**	**Warrants**	**Weighted Average Exercise Price**
Outstanding, March 31,	23,347,728	$ 6.420	23,360,080	$ 6.430
Exercised	(2,788,620)	0.001	—	—
Outstanding, June 30,	20,559,108	$ 7.300	23,360,080	$ 6.430
Expired	(9,294,022)	5.380	(12,352)	21.900
Outstanding September 30,	11,265,086	$ 8.877	23,347,728	$ 6.420

No outstanding warrant is subject to any down-round anti-dilution protection feature. All outstanding warrants may be exercised through a cashless exercise, via exchange of a portion of warrants to cover the exercise price. Warrants outstanding as of September 30, 2026 will expire on October 4, 2028.

In August, 2026, T1 Warrants to purchase 9,294,022 shares of common stock with an exercise price of $5.38 per share expired unexercised. Pursuant to their terms, the T1 Warrants expired 60 days after the later of the Company’s first public disclosure of the topline results of its PALISADE-3 and PALISADE-4 Phase 3 clinical trials, which occurred on June 30, 2026.

6. Stock-Based Compensation

A summary of the Company's stock option activity for the period ended September 30, 2026 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, 2026	4,457,368	$ 7.78	7.8	$ —
Granted	1,031,426	$ 0.53		
Exercised	—	$ —		
Forfeited	(264,369)	$ 10.44		
Expired	—	$ —		
Outstanding at September 30, 2026	5,224,425	$ 6.22	7.8	$ —
Exercisable at September 30, 2026	2,792,339	$ 10.05	6.8	$ —
Vested and expected to vest as of September 30, 2026	5,224,425	$ 6.22	7.8	$ —

Stock-Based Compensation Expense

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

	Six Months Ended September 30,	
	2026	2025
Risk-free interest rate	4.01% - 4.44%	3.64% - 4.19%
Expected term (years)	5.63 - 6.08	5.27 - 6.08
Expected stock price volatility	161.55% - 168.97%	155.06% - 164.30%
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 September 30,		Six Months Ended September 30,	
	2026	2025	2026	2025
Research and development expense	$ 379	$ 475	$ 814	$ 861
General and administrative expense	528	621	1,084	1,151
Total stock-based compensation expense	$ 907	$ 1,096	$ 1,898	$ 2,012

The weighted-average grant date fair value of options granted during the six months ended September 30, 2026 and 2025 was $0.51 and $1.98 per share, respectively. During the three and six months ended September 30, 2025, options to purchase 211 shares were exercised for immaterial aggregate intrinsic value. As of September 30, 2026, total compensation cost not yet recognized related to unvested stock options was $3.9 million, which is expected to be recognized over a weighted-average period of 1.7 years.

As an inducement to accepting new employment with the Company, upon approval by the Board or an authorized committee thereof, the Company has granted options to purchase shares of common stock 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 those granted from the Company's Amended and Restated 2019 Omnibus Equity Incentive Plan, as amended. During the six months ended September 30, 2026, the Company granted an option to purchase an aggregate of 150,000 shares of common stock as an inducement to employment for newly hired executive officer.

7. Net Loss per Common Share

Basic net loss per common share is calculated by dividing net loss by the weighted average number of shares of common stock outstanding for the period. Because of their nominal exercise price, the Pre-Funded Warrants were also included in the weighted average number of shares outstanding prior to their exercise in June 2026. Diluted net loss per common share is the same as basic net loss per common share for all periods presented because the effect of potentially dilutive securities, consisting of outstanding stock options and warrants, would be anti-dilutive given the Company's net loss.

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 September 30,	
	2026	**2025**
Outstanding options to purchase common stock	5,224,425	4,875,866
Outstanding warrants to purchase common stock	11,265,086	20,559,108
Total	16,489,511	25,434,974

8. Sublicensing and Collaborative Agreements

The following table presents changes in contract assets and liabilities during the six months ended September 30, 2026. Contract acquisition costs are included as a component of other assets on the Company's condensed consolidated balance sheets.

	Balance at March 31, 2026	**Additions**	**Deductions**	**Balance at September 30, 2026**
Contract assets:				
Deferred contract acquisition costs	$ 56	$ —	$ (37)	$ 19
Contract liabilities:				
Deferred revenue	$ 1,710	$ —	$ (1,614)	$ 96

AffaMed Agreement

In June 2020, the Company 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 the Company 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*). The Company retains exclusive development and commercialization rights for fasedienol in the U.S. and throughout the rest of the world outside the Territory.

The Company is 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. The Company will transfer all development data (nonclinical and clinical data) and the Company's regulatory documentation related to fasedienol throughout the term as it is developed or generated or otherwise comes into its control. The Company will grant to AffaMed a Right of Reference to its regulatory documentation and its 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 the Company a non-refundable upfront license payment of $5.0 million in August 2020. Additionally, upon successful development and commercialization of fasedienol in the Territory, the Company is eligible to receive milestone payments of up to $172.0 million. Further, the Company is 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.

The Company has determined that it has 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 the Company 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.

The Company recognizes 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 the Company expects to complete its 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 the Company recognizes revenue.

As of September 30, 2026 and March 31, 2026, the Company had short-term deferred revenue of $0.1 million and $0.4 million, respectively, and no long-term deferred revenue related to the AffaMed Agreement. During the three and six months ended September 30, 2026, the Company recognized revenue under the AffaMed Agreement of $0.1 million and $0.3 million, respectively, as compared to $0.3 million and $0.5 million during the three and six months ended September 30, 2025, respectively, all of which was included in the deferred revenue balance at the beginning of each respective 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, the Company 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, the Company 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, the Company's 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 the Company has 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 the Company's 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 the Company of $1.5 million (*Purchase Price*), payable upon occurrence of the Payment Event. The Payment Event occurred in October 2023, and the Company 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 September 30, 2026 and March 31, 2026, the Company had no deferred revenue and $1.3 million short term deferred revenue on the condensed consolidated balance sheets. During the three and six months ended September 30, 2026, the Company recognized $0 and $1.3 million of revenue under the Negotiation Agreement, respectively. During the three and six months ended September 30, 2025, the Company recognized no revenue under the Negotiation Agreement. The Company's performance obligation under the Negotiation Agreement was fully satisfied upon termination of the Exclusive Negotiation Period, no transaction price remains allocated to unsatisfied performance obligations, and the Company expects no further revenue under the Negotiation Agreement.

9. Related Party Transactions

In August 2023, in connection with his retirement, the Company entered into a consulting agreement, as subsequently amended, with the Company's former Chief Financial Officer, Jerrold D. Dotson, to assist in transition matters related to the employment of the Company's new Chief Financial Officer. The agreement currently expires December 31, 2026. The Company recorded expense under the consulting agreement of $30,000 and $60,000 for the three and six months ended September 30, 2026 and 2025, respectively.

10. Commitments and Contingencies

From time to time, the Company may be party to litigation, arbitration or other legal proceedings in the course of its business, such as (i) the civil action filed against the Company and its Board of Directors, certain of its 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 seeking compensatory and punitive damages, as well as fees and costs, which case was dismissed by the Court, with prejudice on August 12, 2026, (ii) the stockholder derivative action filed by the same purported stockholders in the District of Nevada (Case No. 2:26-cv-01128) on April 10, 2026, (iii) the putative class action filed in the Northern District of California (Case No. 3:26-cv-00427) on January 15, 2026, and (iv) the stockholder derivative actions filed in the Northern District of California (Case Nos. 4:26-cv-02656 and 3:26-cv-04480) on March 26, 2026 and May 13, 2026, respectively. The Company believes all allegations in these legal proceedings are wholly without merit, and intends to vigorously defend itself.

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 the Company's management and other resources that would otherwise be engaged in other activities. If the Company were unable to prevail in any such legal proceedings, the Company's business, results of operations, liquidity, and financial condition could be adversely affected.

11. Segment Information

The Company operates as one operating segment, which includes all activities related to the discovery and development of its clinical and preclinical product candidates, for the purposes of assessing performance, making operating decisions, and allocating resources. The Company's chief operating decision maker (*CODM*) is its President and Chief Executive Officer.

The CODM regularly reviews total operating expenses, disaggregated into research and development expense and general and administrative expense, against budget and prior periods. The CODM also monitors cash, cash equivalents, and marketable securities and internal cash forecasts to assess the sufficiency of cash resources to support the Company's research and development activities. The categories of significant expenses regularly provided to the CODM are reflected in the condensed consolidated statements of operations and comprehensive loss. Other segment items included in net loss consist of interest income, net, and other income (expense).

There has been no change in the basis of segmentation or in the measurement of segment profit or loss from that disclosed in the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2026. Total assets for the reportable segment are reported on the condensed consolidated balance sheets.

12. Subsequent Events

On October 26, 2026, the Company implemented a Board-approved reduction in its workforce of approximately 31% (the *October 2026 RIF*), intended to reduce operating expenses and preserve capital while retaining the core clinical, regulatory, technical, and corporate capabilities necessary to support the continued development of the Company’s product candidates. The Company estimates that it will incur severance and termination costs of approximately $1.0 million in connection with the October 2026 RIF, consisting primarily of cash severance payments and continued health coverage for eligible affected employees which the Company expects to recognize in the quarter ending December 31, 2026. The Company may incur additional costs not currently contemplated as a result of, or in connection with, the October 2026 RIF.

Subsequent to September 30, 2026 and through November 10, 2026, the Company sold 595,191 shares of its common stock under the Sales Agreement for net proceeds of approximately $0.2 million, after sales agent commissions.

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, plans 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 expenses, and our ability to continue as a going concern;*
- *our ability to obtain additional funding for our operations, including funding necessary to advance or 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 and/or our ability to replicate past clinical trial results;*
- *the design, size, cost, timing and likelihood of success of any new Phase 3 clinical trial of fasedienol, including our proposed clinical trial using the Liebowitz Social Anxiety Scale (LSAS) as the primary efficacy endpoint;*
- *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 identify, negotiate and complete a potential financing, merger, sale, license or other strategic transaction on acceptable terms, or at all, and the potential effects of any such transaction, or of a dissolution and liquidation, on our stockholders;*
- *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 personnel and the impact of any reductions in force (RIFs) and related severance obligations;*
- *our estimates regarding expenses, future revenue, and needs for additional financing;*
- *our future financial performance;*
- *our ability to regain and maintain compliance with Nasdaq's continued listing requirements, including the minimum bid price requirement, and the effects of any reverse stock split;*
- *the market price and volatility of our common stock;*
- *the outcome of pending and any future litigation;*
- *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 U.S. Food and Drug Administration (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 II, 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. Forward-looking statements speak only as of the date of this Quarterly Report. 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 summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to in this Quarterly Report 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 focused on leveraging a deep understanding of nose-to-brain neurocircuitry to develop and commercialize a new class of rapid-onset neurocircuitry-focused intranasal product candidates called pherines. Our pherine product candidates are designed to achieve therapeutic benefits without requiring absorption into the blood or uptake into the brain, giving them the potential to be a safer alternative to other pharmacological options, if successfully developed and approved. Our most advanced intranasal pherine product candidates are fasedienol for the treatment of social anxiety disorder (*SAD*), itruvone for treatment of major depressive disorder, and refisolone for treatment of vasomotor symptoms (hot flashes) due to menopause.

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.

Recent Developments

Fasedienol Exploratory Phase 2 Repeat Dose Study

In August 2026, we announced topline results from the randomized portion of our repeat dose study of fasedienol, a three-arm, U.S. multicenter, randomized, double-blind, placebo-controlled exploratory Phase 2 clinical study (N=61), which included an open-label extension, designed to assess the efficacy, safety, and tolerability of two 3.2 µg doses of fasedienol administered ten minutes apart compared with a single 3.2 µg dose and placebo, for the acute treatment of anxiety induced by a public speaking challenge. The study was not designed to demonstrate statistically significant differences between the treatment groups.

The exploratory Phase 2 study met its safety objective, demonstrating that a second dose of fasedienol administered within ten minutes of the first dose produced safety and tolerability data comparable to single-dose administration, with no new safety findings and overall safety findings consistent with previous clinical studies. In addition, both active treatment arms in the primary endpoint analysis, the LS mean change in SUDS score from Visit 2 (baseline speech, V2) to Visit 3 (randomized speech, V3), showed numerical separation from placebo in LS mean SUDS change from V2 to V3, although the differences between treatment groups and placebo were not statistically significant (p=0.2).

In a prespecified analysis of patients with very severe social anxiety disorder as defined by a baseline score of ≥ 95 on the Liebowitz Social Anxiety Scale (*LSAS*), fasedienol showed nominally statistically significant responses for the single dose arm compared with placebo (p=0.05) and as pooled (p=0.04). These findings in the very severe group of patients defined by LSAS ≥95 are consistent with results previously observed in this very severe subpopulation in the randomized portion of our PALISADE-4 Phase 3 trial (p=0.036, post-hoc).

Fasedienol PALISADE-4 Open-Label Extension

In September 2026, we announced preliminary positive data from the open-label extension (*OLE*) portion of our PALISADE-4 Phase 3 clinical trial. Based on an analysis of subjects who elected to participate in the OLE portion of PALISADE-4 (n=322 subjects), as of the July 24, 2026, data cutoff date, administration of 3.2 µg of fasedienol, taken as needed up to six times per day in real-world, anxiety-provoking situations in daily life for up to 12 months, was well-tolerated, with no new drug-related safety findings or trends identified.

Preliminary exploratory efficacy data over the first four months of treatment in the OLE portion of PALISADE-4 demonstrated a clinically relevant improvement from repeated as-needed use of fasedienol over time on the LSAS, a clinician-administered scale which assesses both fear or anxiety and avoidance across 24 standardized anxiety-provoking social-interaction and performance situations, with the goal of capturing not only how distressing situations are, but also whether patients entered, tolerated, remained in, or avoided them. Continued improvements were observed through each month on both the fear or anxiety and avoidance subscales of the LSAS, suggesting that participants engaging in everyday life experienced less fear or anxiety and avoidance of anxiety-provoking situations over time.

The OLE portion of PALISADE-4 also explored the change from baseline on the Social Phobia Inventory (*SPIN*), a 17-item patient-reported scale (range 0-64) which measures fear, avoidance, and physiological components of social phobia over time. The preliminary analysis of the initial four-month data cut from the OLE portion of PALISADE-4 also demonstrated consistent improvement over time on the SPIN for subjects participating in the OLE.

Because the OLE portion of PALISADE-4 was open-label and uncontrolled, the LSAS and SPIN exploratory efficacy observations were not based on a comparison to placebo and should be interpreted with caution.

We believe the preliminary safety and exploratory efficacy results of the PALISADE-4 OLE are generally consistent with the safety and efficacy results previously reported in the fasedienol open-label Long-Term Safety Study completed in everyday life settings in conjunction with our PALISADE-1 and PALISADE-2 Phase 3 trials, the PALISADE-3 OLE and a randomized, double-blind, placebo-controlled multiple-dose Phase 2 crossover study of fasedienol, each conducted in an everyday life environment involving anxiety-provoking social and performance situations in daily life. In addition, we believe that results from all open-label and placebo-controlled clinical studies of fasedienol conducted to date in everyday life settings suggest that acute administration of fasedienol, as-needed at the patient's discretion, was accompanied by a persistent change in the overall severity of social anxiety disorder, including observed reductions in fear, anxiety, and avoidance, as measured by the LSAS over the course of fasedienol usage.

October 2026 Reduction in Force

On October 26, 2026, we implemented a Board-approved reduction in our workforce of approximately 31% (the *October 2026 RIF*) to reduce operating expenses and preserve capital, while retaining the core clinical, regulatory, technical, and corporate capabilities necessary to support the continued development of our product candidates. We estimate that we will incur severance and termination costs of approximately $1.0 million in connection with the October 2026 RIF, which we expect to recognize during the quarter ending December 31, 2026, and we expect the October 2026 RIF to reduce our annual salary and benefits costs by approximately $3.2 million. See Note 12 to our condensed consolidated financial statements included in this Report.

FDA Type C Meeting

We recently announced that the FDA provided productive feedback to us regarding a potential Phase 3 study of fasedienol in adults with SAD, including recommendations regarding use of the LSAS as the primary endpoint and interim assessments to assess whether acute effects of fasedienol could lead to longer-term overall functional improvement in patients over time, consistent with the unique proposed mechanism of action and hypothesized treatment model for fasedienol in SAD. We plan to incorporate interim assessments of fasedienol's effect using eDiaries and qualitative patient surveys in the future Phase 3 study design, and to submit a revised protocol to the FDA. Additionally, consistent with FDA feedback and recognition of fasedienol's reported safety profile, we plan to focus future Phase 3 development of fasedienol on the overall treatment of SAD (not only acute treatment of SAD) for the general SAD population.

Our Product Candidates

Fasedienol

Overview of Social Anxiety Disorder

Social anxiety disorder is a highly prevalent, serious, and sometimes 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 Treatment of Social Anxiety Disorder

Fasedienol, our most advanced neurocircuitry-focused pherine product candidate, is in U.S. Phase 3 clinical development in adults with social anxiety disorder. Fasedienol's proposed MOA and treatment model are fundamentally differentiated from all FDA-approved anti-anxiety medications. When administered intranasally in microgram-level doses, neurocircuitry-focused fasedienol is designed to modulate the nasal-limbic amygdala fear and anxiety neurocircuits involved in the pathophysiology of social anxiety disorder. Fasedienol is pharmacologically active without requiring apparent systemic absorption or uptake into the brain to achieve its rapid-onset anxiolytic effects. Fasedienol also has no observed binding on certain cellular receptors isolated from the brain that are associated with known drug abuse liability potential (for example, dopamine and opiate receptors) which are activated by certain other pharmaceutical compounds used for neuropsychiatric and neurological disorders. Unlike benzodiazepines, data showed that fasedienol has no observed potentiation of GABA-A receptors. Because of its innovative non-systemic neurocircuitry-focused proposed MOA, Vistagen believes fasedienol has the potential to achieve rapid-onset anxiolytic effects for individuals with social anxiety disorder 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 PALISADE Program

Fasedienol is in Phase 3 development in adults with social anxiety disorder. We believe there is a causal relationship between acute anxiety symptom relief and overall anxiety symptom relief. Fasedienol is designed to reduce the wave of anxiety usually experienced by individuals with social anxiety disorder before engaging in (and during) a feared and anxiety-provoking social or performance situation in everyday life. We have designed fasedienol nasal spray with the goal of creating a product candidate with a rapid-onset, non-systemic 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.

To date, our PALISADE Program includes four Phase 3 clinical trials, PALISADE-1, PALISADE-2, PALISADE-3, and PALISADE-4, and a small exploratory Phase 2 repeat dose study (the *Repeat Dose Study*). These clinical trials were randomized, double-blind, placebo-controlled, U.S. multi-center studies 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. The primary efficacy endpoint in each trial was the LS mean change from baseline on the patient-rated SUDS score for fasedienol compared with placebo. PALISADE-2 achieved its primary and secondary efficacy endpoints; PALISADE-1, PALISADE-3, and PALISADE-4 did not. The Repeat Dose Study, which was not designed to demonstrate statistically significant differences between the treatment groups, also did not achieve its primary and secondary endpoints.

After receipt of negative topline 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, as well as its secondary endpoints.

In PALISADE-4, in a post-hoc analysis of a subpopulation of patients with very severe social anxiety defined by a baseline score at screening of 95 or greater on the LSAS (n=123), fasedienol was nominally statistically significant as measured by the LS mean change from baseline on the SUDS score for fasedienol (-12.8+/-3.4 SE) compared with placebo (-3.7 +/-3.4 SE), with a difference in the LS mean of -9.1 (p=0.036) [(1)] .

Additionally, in the Repeat Dose Study, in the prespecified analysis of patients with very severe social anxiety disorder, fasedienol showed nominally statistically significant responses for the single dose arm compared with placebo (p=0.05) and as pooled (p=0.04), consistent with results previously observed in this subpopulation in the randomized portion of PALISADE-4.

(1) The post-hoc analysis for the very severe social anxiety disorder subpopulation (defined by LSAS ≥95) excludes data from one site (n=15) for irregularities documented and communicated before database lock that led to site disqualification from the trial. The post-hoc analysis also excluded data to account for public speaking challenge (*PSC*) ceiling and placebo effects: 1) subjects who had SUDS scores > 90 at visit 2 or visit 3 at baseline could not be provoked effectively by the PSC to have higher SUDS scores for the experiment to work effectively (SUDS scale is from 0-100 with above 90 being extreme anxiety) (n=5); and 2) subjects who had SUDS score improvement higher than 20 from baseline at visit 2 (the placebo run-in) either were placebo responders or could not be provoked effectively by the PSC (n=1).

Fasedienol Aggregate Safety Data

Safety data for fasedienol have been consistently favorable across all placebo-controlled clinical trials and open-label clinical studies completed to date.

We believe we have achieved the minimum fasedienol patient exposures as recommended under International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (*ICH*) E1, the international regulatory standard governing safety database exposure recommendations for drugs intended for long-term treatment (chronic or repeated intermittent use for longer than 6 months) of non-life-threatening conditions. As of May 31, 2026, we estimate that the fasedienol clinical development program now exceeds ICH E1 minimum recommendations with over 1,500 subjects receiving at least a single exposure to fasedienol, over 300 subjects with at least 6-months of exposure, and over 100 subjects with at least 12 months of exposure. The 6-month and 12-month exposure numbers represent our estimate of the number of subjects who have completed the 6-month and 12-month visits in the fasedienol open-label safety studies as of May 31, 2026. Given our belief that we have met the minimum ICH E1 recommendations, for business reasons, we closed the open-label extension portion of PALISADE-3 and PALISADE-4 in July, 2026 and the open-label portion of the Repeat Dose Study in August 2026.

Although we believe the minimum ICH E1 recommendations have been met, we have not yet aligned with the FDA on the specific patient exposure requirements to support a potential fasedienol New Drug Application (NDA) submission.

Refisolone

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, mental health 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 Moderate to Severe Vasomotor Symptoms (Hot Flashes) due to Menopause

Refisolone is our non-hormonal, non-systemic, as-needed pherine product candidate under development for the treatment of moderate to severe VMS (hot flashes) due to menopause, and potentially for the treatment of 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 hormonal 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. Furthermore, a clinical study in human volunteers showed no detectable refisolone in blood plasma after administration of 12.8 ug/day, 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 conducted in Mexico and 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 statistically significant reduction in the daily number of hot flashes compared to placebo at the end of the first week of treatment ($p<0.001$), 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 serious adverse events (*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.

In April 2026, we announced that we received a "Study May Proceed" letter from the FDA under our U.S. Investigational New Drug application (*IND*) application for refisolone. Our open IND enables us to pursue further Phase 2 clinical development of refisolone in the U.S. for the treatment of moderate to severe VMS (hot flashes) due to menopause, building on the successful exploratory Phase 2A clinical study described above.

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 conducted in Mexico 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.

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 intranasal pherine product candidate under development for the 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 conducted in Mexico, itruvone reduced depressive symptoms 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 U.S. 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 the previous clinical study of itruvone. We have an open IND for itruvone in the U.S. and plan to pursue Phase 2 clinical development of itruvone in the U.S. for the treatment of MDD, in an effort to build on the positive results from the previous exploratory Phase 2A clinical trial of itruvone in MDD described above.

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 intranasal pherine product candidate under development for the improvement of 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 conducted in Mexico 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 intranasal 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 in Mexico 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 in the U.S. 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 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 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 certain neuroscience disorders involving the NMDAR, including potentially levodopa-induced dyskinesia (*LID*) and neuropathic pain (*NP*). We do not anticipate further development and commercialization of AV-101 on our own. We are currently assessing whether there is a path forward for potential third-party collaborative manufacturing, 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. 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 September 30, 2026, we had an accumulated deficit of approximately $501.1 million. Our net loss for the year ended March 31, 2026 (*Fiscal 2026*) and the year ended March 31, 2025 (*Fiscal 2025*) was approximately $69.7 million and $51.4 million, respectively. We incurred a net loss of approximately $10.7 million and $23.8 million for the three and six months ended September 30, 2026, 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 consists 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;
- 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;
- 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 reductions in force, 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 Six Months Ended September 30, 2026

The following table summarizes the results of our operations for the three and six months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		Six Months Ended September 30,	
	2026	2025	2026	2025
Revenues:				
Sublicense and other revenue	$ 138	$ 258	$ 1,614	$ 502
Total revenues	138	258	1,614	502
Operating expenses:				
Research and development	6,554	15,915	17,459	27,693
General and administrative	4,521	4,396	8,439	8,667
Total operating expenses	11,075	20,311	25,898	36,360
Loss from operations	(10,937)	(20,053)	(24,284)	(35,858)
Other income, net:				
Interest income, net	198	630	515	1,342
Other income, net	(1)	6	(1)	4
Loss before income taxes	(10,740)	(19,417)	(23,770)	(34,512)
Income taxes	—	—	—	—
Net loss	$ (10,740)	$ (19,417)	$ (23,770)	$ (34,512)

Revenue

We recognized $0.1 million and $1.6 million in sublicense and other revenue for the three and six months ended September 30, 2026, respectively, as compared to $0.3 million and $0.5 million for the three and six months ended September 30, 2025, respectively. The decrease in revenue of $0.1 million for the three months ended September 30, 2026 as compared to the same period in the prior year was primarily related to the timing of revenue recognition under the AffaMed agreement. The increase in revenue in the amount for the six months ended September 30, 2026 was primarily attributable to the recognition of $1.3 million of revenue under the Negotiation Agreement with Fuji Pharma upon satisfaction of the related performance obligation following the expiration of the Exclusive Negotiation Period in June 2026. No deferred revenue remains under that agreement. We expect to recognize the remaining deferred revenue under the AffaMed Agreement of $0.1 million during the remainder of the fiscal year ending March 31, 2027.

Accordingly, 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 in future periods to be substantially lower than the amount recognized in the current period.

Research and Development Expense

The following table summarizes our research and development expense for the three and six months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		Six Months Ended September 30,	
	2026	2025	2026	2025
Clinical and nonclinical studies and development expense by program				
Fasedienol	$ 3,017	$ 11,342	$ 9,820	$ 19,313
All other	120	749	315	985
Total clinical and nonclinical studies and development expense	3,137	12,091	10,135	20,298
Salaries and benefits	2,279	2,604	4,908	5,089
Stock-based compensation	379	475	814	861
Consulting and professional services	437	350	918	640
Occupancy and all other costs	322	395	684	805
Total research and development expense	$ 6,554	$ 15,915	$ 17,459	$ 27,693

Research and development expense was $6.6 million and $17.5 million for the three and six months ended September 30, 2026, respectively, as compared to $15.9 million and $27.7 million for the three and six months ended September 30, 2025, respectively.

The decrease of $9.3 million in research and development expense for the three months ended September 30, 2026 as compared to the same period in 2025 was primarily due to a decrease in clinical development expense of $9.0 million following the completion of the open-label extension portions of the Company's PALISADE-3 and PALISADE-4 Phase 3 studies and the randomized and open-label extension portions of its exploratory Phase 2 repeat dose study as well as reduced headcount-related expenses.

The decrease of $10.2 million in research and development expense for the six months ended September 30, 2026 as compared to the same period in 2025 was primarily due to a decrease in clinical development expense of $10.2 million related to the conclusion of the PALISADE Program, a decrease of $0.2 million in connection with decreased headcount and related expenses, and a decrease in occupancy and other costs of $0.1 million, partially offset by an increase in consulting and professional services of $0.3 million.

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 topline results from our PALISADE-3 clinical trial. Research and development expenses continued to decrease as a result of these cash preservation measures and the conclusion of our current Phase 3 PALISADE-4 trial and Repeat Dose Study and we expect them to decrease further as a result of the October 2026 RIF, partially offset by severance and termination costs of approximately $1.0 million expected to be recognized during the quarter ending December 31, 2026. We anticipate decreases in future research and development expenses although the extent will depend on our ability to secure funding for and initiate a further Phase 3 trial for fasedienol with the LSAS as the primary endpoint. 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 $4.5 million and $8.4 million for the three and six months ended September 30, 2026, as compared to $4.4 million and $8.7 million for the three and six months ended September 30, 2025.

The increase of $0.1 million in general and administrative expense for the three months ended September 30, 2026, as compared to the same period in 2025, was primarily due to an increase in consulting and professional fees of $0.6 million,

driven by higher legal fees, partially offset by a decrease in compensation and related costs of $0.4 million, primarily related to reduced headcount, and a decrease in stock-based compensation of $0.1 million.

The decrease of $0.2 million in general and administrative expense for the six months ended September 30, 2026, as compared to the same period in 2025, was primarily due to a decrease in compensation and related costs of $0.5 million, primarily related to reduced headcount, partially offset by bonus expense, a decrease in insurance, occupancy and other expenses of $0.2 million, and a decrease in stock-based compensation of $0.1 million. These decreases were partially offset by an increase in consulting and professional fees of $0.6 million.

We expect general and administrative expenses to remain at current levels as a result of our cash preservation measures after the results of PALISADE-3, and our March 2026 reduction in force. Future general and administrative expenses will be dependent on feedback from FDA regarding the potential registrational pathway for fasedienol for the acute treatment of SAD described above.

Other Income

Interest income, net, decreased for the three and six months ended September 30, 2026 as compared to the same period in 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. As of September 30, 2026, we had financed our operations and technology acquisitions primarily through the issuance and sale of our equity securities for cash proceeds of approximately $372.6 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 May 2021, we entered into an Open Market Sale Agreement, as amended, (the *Sales Agreement*) with Jefferies LLC (*Jefferies*) as sales agent, with respect to an at-the-market offering program, under which we are 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 $175 million. During the three and six months ended September 30, 2026, we sold 1,213,947 and 2,794,123 shares, respectively, under the Sales Agreement for net proceeds of $0.3 million and $1.3 million, respectively. During the three and six months ended September 30, 2025, we sold an aggregate of 9,608,772 and 9,798,839 shares under the Sales Agreement, for net proceeds of $27.9 million and $28.3 million, respectively.

As of September 30, 2026, we had cash, cash equivalents, and marketable securities of approximately $20.0 million. As of November 13, 2026, the issuance date of the condensed consolidated financial statements in this Quarterly Report as of and for the three and six months ended September 30, 2026, 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 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 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 August 4, 2026, the Company received a notification (the *Extension Notice*) from the Listing Qualifications Staff of The Nasdaq Stock Market LLC (Nasdaq) granting the Company an additional 180 calendar day compliance period, until February 1, 2027 (the *Extension Period*), to regain compliance with the requirement that the Company's common stock maintain a minimum closing bid price of $1.00 per share for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (the *Minimum Bid Price Requirement*).

The Extension Notice has no immediate effect on the listing of the Company's common stock, which continues to be listed and traded on the Nasdaq Capital Market, subject to the Company's compliance with the other listing requirements of Nasdaq. To regain compliance, the closing bid price of the Company's common stock must be at least $1.00 per share for a minimum of 10 consecutive business days during the Extension Period.

Cash Flows

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

	Six Months Ended September 30,	
	2026	**2025**
Net cash used in operating activities	$ (26,870)	$ (32,605)
Net cash provided by (used in) investing activities	5,713	(882)
Net cash provided by financing activities	1,260	29,142
Net increase (decrease) in cash and cash equivalents	(19,897)	(4,345)
Cash and cash equivalents at beginning of period	30,789	67,131
Cash and cash equivalents at end of period	$ 10,892	$ 62,786

Operating Activities

Net cash used in operating activities for the six months ended September 30, 2026 was $26.9 million, consisting primarily of our net loss of $23.8 million, adjusted for $2.0 million of non-cash charges primarily related to stock-based compensation expense and amortization of our operating lease right-of-use asset, and $5.1 million in net changes in operating assets and liabilities.

Net cash used in operating activities for the six months ended September 30, 2025 was $32.6 million, consisting primarily of our net loss of $34.5 million, adjusted for $2.1 million of non-cash charges primarily related to stock-based compensation expense and amortization of our operating lease right-of-use asset, and $0.2 million in net changes in operating assets and liabilities.

Investing Activities

Net cash provided by investing activities for the six months ended September 30, 2026 was $5.7 million, consisting of proceeds from sales and maturities of marketable securities of $12.3 million, partially offset by purchases of marketable securities of $6.6 million.

Net cash used in investing activities for the six months ended September 30, 2025 was $0.9 million, consisting of purchases of marketable securities of $10.8 million and purchases of laboratory and other equipment of $0.1 million, partially offset by proceeds from sales and maturities of marketable securities of $10.0 million.

Financing Activities

Net cash provided by financing activities during the six months ended September 30, 2026 was $1.3 million, consisting primarily of net proceeds of $1.3 million from the sale of shares of our common stock under the Sales Agreement and $0.1 million from the sale of shares under our 2019 Employee Stock Purchase Plan, partially offset by $0.1 million of repayments on the note payable related to our insurance premium financing.

Net cash provided by financing activities during the six months ended September 30, 2025 was $29.1 million, consisting primarily of net proceeds of $28.3 million from the sale of shares of our common stock under the Sales Agreement, $1.0 million from the issuance of a note payable to finance certain insurance premiums, and $0.2 million from the sale of shares under our 2019 Employee Stock Purchase Plan, partially offset by $0.4 million of repayments on the note payable.

Contractual Obligations

There have been no material changes in our contractual obligations and commitments during the three and six months ended September 30, 2026, 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, 2026, filed with the SEC on June 15, 2026 (the *Annual Report*).

Critical Accounting Estimates

There have been no material changes to our critical accounting estimates during the three and six months ended September 30, 2026, 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 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 September 30, 2026. 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 September 30, 2026, 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 September 30, 2026, 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. (*Northern District of California*). On February 13, 2025, John Cesario and David Preka (the *Cesario 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 *Complain*t) against the Company and its Board, certain of its executive officers, professional services and financial advisors, and industry analysts. The Cesario Plaintiffs seek compensatory and punitive damages, as well as fees and costs. The operative complaint (filed December 4, 2025), alleges violations of Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder, along with other causes of action. The Cesario 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. Following multiple rounds of motion to dismiss briefing, on August 12, 2026, the Court issued an order dismissing the action with prejudice. The Cesario Plaintiffs filed a motion for reconsideration of the dismissal order. That motion was denied, with prejudice, on September 28, 2026. On October 23, 2026, the Cesario Plaintiffs filed a Notice of Appeal, appealing the Court's dismissal order and its denial of their motion for reconsideration to the U.S. Court of Appeals for the Ninth Circuit. The Company believes the appeal is without merit and intends to defend the case vigorously.

Cesario et al. v. Vistagen Therapeutics, Inc. et al. (*District of Nevada*). On April 10, 2026, the Cesario Plaintiffs filed a stockholder derivative action, pro se, in the District of Nevada (Case No. 2:26-cv-01128) against the Company, and certain current and former Board members, executive officers, Company employees and an advisor (the *Cesario Derivative Complaint*). On May 5, 2026, the Cesario Plaintiffs filed an amended derivative complaint (the Amended Cesario Derivative Complaint). The Cesario Plaintiffs purport to be Company stockholders, and the allegations are primarily the same as those made in the Second Amended Complaint. On July 29, 2026, the Company filed a motion for a bond in accordance with Nevada Revised Statutes section 41.520, requesting that the Court require the Cesario Plaintiffs to post a $100,000 bond as security to cover the Company's reasonably probable defense costs, including attorney's fees, before being allowed to proceed with the action. On September 23, 2026, the Court issued an order (i) requiring the Cesario Plaintiffs, by October 23, 2026, to retain counsel and to file a brief showing cause, if any, why the action should not be dismissed for failure to file proofs of service, and (ii) denying the Company's motion for a bond as moot. The Court advised that failure to timely comply with its directives will result in dismissal of the action. The Cesario Plaintiffs failed to comply with the Court's September 23, 2026 order and, on November 3, 2026, the Company filed a notice of the Cesario Plaintiffs' non-opposition, requesting that the Court dismiss the action. On November 10, 2026, the Court issued a report and recommendation to dismiss the action without prejudice. Objections to the report and recommendation are due by November 24, 2026.

Securities Class Action Lawsuit and Derivative Actions in the Northern District of California. On January 15, 2026, a putative class action complaint (the *Class Action Complaint*) was filed by alleged stockholder Dan Eller against the Company, Shawn Singh, and Joshua Prince (the *Class Action Defendants*) in the United States District Court for the Northern District of California, captioned Eller v. Vistagen Therapeutics, Inc. et al. (Case No. 3:26-cv-00427) (the Class Action). The Class Action Complaint alleges that the Class Action Defendants disseminated false and misleading statements and/or concealed material adverse facts concerning the Company's PALISADE-3 Phase 3 clinical trial. The Class Action Complaint asserts claims under Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder. On April 16, 2026, the Court appointed Eric Weinberger as the lead plaintiff (*Lead Plaintiff*). Lead Plaintiff filed an amended complaint on June 16, 2026, purporting 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, and seeking unspecified damages. On August 18, 2026, the Class Action Defendants filed a motion to dismiss the Class Action Complaint. A hearing on the motion to dismiss is scheduled for November 19, 2026.

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

Two stockholder derivative actions were filed against the Company, as nominal defendant, and certain of the Company's current and former officers and directors, in the United States District Court for the Northern District of California, captioned Do v. Singh et al. (Case No. 4:26-cv-02656) (the *Do Derivative Complaint*), on March 26, 2026, and Strekal v. Singh et al. (Case No. 3:26-cv-04480), on May 13, 2026 (the *Strekal Derivative Complaint* and, together with the *Do Derivative Complaint*, the *Derivative Complaints*). The plaintiffs in both Derivative Complaints purport to be current Company stockholders, and the allegations are primarily the same as those made in the Class Action Complaint. Motions to relate the Derivative Actions to the Class Action were granted on July 13, 2026, and July 2, 2026, respectively, and a stipulation consolidating the Derivative Actions and staying the consolidated Derivative Actions pending resolution of any motion to dismiss filed in the Class Action, or the dismissal of the Class Action with prejudice, or the announcement of a

settlement of the Class Action, was filed with the Court on July 13, 2026. The Court issued an order granting the stipulation, consolidating the Derivative Actions, and staying the consolidated Derivative Action on the terms stated in the stipulation on July 30, 2026.

Additional lawsuits against the Company and certain of its officers or directors may be filed in the future. If additional similar complaints are filed, absent new or different allegations that are material, the Company will not necessarily announce such additional filings.

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."

- Our existing cash, cash equivalents and marketable securities are expected to fund our operations into 2027, and substantial doubt exists about our ability to continue as a going concern. As such, we require substantial additional financing to execute our long-term business plan, including further development and commercialization of our pherine product candidates, and to continue to operate as a going concern;
- 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;
- 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 currently depend heavily on the success of fasedienol and, to a lesser extent, our other pherine product candidates, and we cannot be certain that ongoing or future clinical trials will produce successful results or that we will be able to obtain regulatory approval for fasedienol or any of our current or future product candidates;
- failures of ongoing or future nonclinical or clinical trials of our product candidates to meet pre-specified endpoints, such as our PALISADE-1, PALISADE-3 and PALISADE-4 Phase 3 clinical trials, and our Repeat Dose Study, each of which failed to meet its primary efficacy endpoint, 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 will need to complete a significant financing or a strategic transaction that includes a significant financing in the near term, and if we are unable to do so on acceptable terms, or at all, we may be required to further curtail our operations, seek protection under applicable bankruptcy or insolvency laws, or dissolve and liquidate, and our stockholders could lose all or substantially all of their investment;

- any strategic transaction, merger or business combination we may pursue, including a reverse merger or other business combination involving a micro-cap public or private biotechnology company, involves substantial risks, including valuation uncertainty, significant dilution to our stockholders, substantial transaction costs, diversion of management's attention, and the risk that the transaction is not completed or does not enhance stockholder value;

- 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;

- the successful completion of nonclinical studies and/or clinical trials in any of our product candidate development programs may not be sufficient to cause the FDA to approve any NDA that we may submit, or cause any other agency to provide regulatory approval of any of our product candidates, and, even if approved, does not ensure acceptance of such product candidates by clinicians leading to a revenue stream to support our operations;

- if we are unable to retain key management and scientific personnel, or effectively manage the impact of our recent workforce reductions, 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;

- 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;

- 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)) 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 fasedienol and, to a lesser extent, our other product candidates. If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize fasedienol or one or more of our other 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, including fasedienol, our most advanced product candidate. Our future success and ability to generate revenue from fasedienol or any other of 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.

We are continuing to refine our fasedienol Phase 3 development from the acute treatment of SAD to the overall treatment of SAD, subject to obtaining sufficient capital and further feedback from the FDA, and we intend to conduct an event driven, repeated as-needed dosing Phase 3 clinical trial in everyday life settings with the LSAS as the primary efficacy endpoint. We do not currently have sufficient capital to complete such a trial. If we are unable to obtain the funding

necessary to conduct a LSAS-based Phase 3 study, we may be required to suspend or discontinue the development of fasedienol, which would materially harm our business and prospects, would likely cause the market price of our common stock to decline significantly, and would impair our ability to complete a financing or strategic transaction.

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 do not currently have the financial resources to complete the development of, obtain regulatory approval for or commercialize any of our product candidates, including to conduct and complete an LSAS-based Phase 3 clinical trial of fasedienol. Moreover, we may experience 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, 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;
- the unwillingness of the FDA or comparable foreign regulatory authorities to accept data from prior clinical trials that did not meet their primary endpoints, as support for the continued development or approval of our product candidates;
- 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 $69.7 million and $51.4 million for the years ended March 31, 2026 and 2025, respectively, and we incurred a net loss of $10.7 million and $23.8 million during the three and six months ended September 30, 2026, respectively. 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;
- 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 capital 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, personnel, 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 prepare 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 operations, 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 operations 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 September 30, 2026, the Company had cash, cash equivalents, and marketable securities of $20.0 million. As of November 13, 2026, the issuance date of the condensed consolidated financial statements as of and for the three and six months ended September 30, 2026, 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.

Based on our current operating plan, including the cash preservation measures we implemented in December 2025, and our March and October 2026 workforce reductions, we expect our existing cash, cash equivalents and marketable securities to fund our operations into 2027, but not for at least twelve months from the date of this Report. This estimate is based on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect, including as a result of costs associated with our interactions with the FDA, the design and initiation of any new clinical trial of fasedienol, the evaluation or pursuit of a strategic transaction, severance obligations, litigation or other unanticipated expenses. Our current capital resources will not be sufficient to fund the next Phase 3 clinical trial of fasedienol with LSAS as the primary efficacy endpoint or the further clinical development of our other pherine product candidates. Our ability to raise additional capital has been, and is expected to continue to be, materially adversely affected by the failure of PALISADE-3, PALISADE-4 and the Repeat Dose Study to meet their primary endpoints, the significant decline in the market price of our common stock, the substantial doubt about our ability to continue as a going concern and the potential delisting of our common stock from Nasdaq. Any equity financing at or near current market prices would likely result in substantial dilution to our existing stockholders, and the number of shares we are able to issue may be limited by the number of authorized but unissued shares available under our Charter and by Nasdaq rules requiring stockholder approval of certain issuances. If we are unable to raise sufficient capital or complete a strategic transaction before our existing capital resources are exhausted, we may be required to further reduce our workforce, delay, suspend or discontinue the development of fasedienol or our other product candidates, sell or license our assets on unfavorable terms, seek protection under applicable bankruptcy or insolvency laws, or wind down our operations and dissolve and liquidate, in which case our stockholders could lose all or substantially all of their investment.

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 intranasal pherine candidates and AV-101. 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 pharmaceutical product candidates, we must decide which of our product candidates and indications to pursue and advance, as well as the amount of resources to allocate to each, if any. 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, neurological and women's conditions and 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 conditions or 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.

We may not realize the expected benefits from our workforce reduction and we may incur additional costs implementing it or other difficulties.

In March 2026, we implemented a workforce reduction. The objective of this reduction was to provide for disciplined cash management while prioritizing efficient execution of ongoing placebo-controlled clinical trials and real-world open-label clinical studies in our PALISADE Program for fasedienol, including, but not limited to, PALISADE-4 and the Repeat Dose Study. In October 2026, we implemented a further workforce reduction to better align resources with current business needs, further reduce operating expenses, and focus talent on critical development, regulatory, and operational priorities. We may implement additional workforce reductions or other cost-reduction measures to preserve cash in the future, including in connection with the evaluation or pursuit of a strategic transaction, which would subject us to similar risks.

However, the reductions in workforce may yield unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond our intended workforce reductions, a reduction in morale among our remaining employees, and the risk that we may not achieve the anticipated benefits, all of which may have an adverse effect on our development activities, ability to progress our product candidate development, and results of operations or financial condition.

We may also incur other charges, costs, future cash expenditures or impairments not currently contemplated due to events that may occur as a result of, or in connection with, workforce reduction. In addition, we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees.

In addition, in August 2026, our Board of Directors adopted a Change in Control Executive Severance Plan (now the Executive Severance Plan), which was amended and restated effective October 7, 2026 to provide severance benefits to eligible employees, including each of our executive officers, upon a termination without cause regardless of whether a change in control occurs, in addition to severance benefits upon certain qualifying terminations in connection with a change in control. As a result, any additional workforce reduction, including any reduction implemented in connection with a strategic transaction or a wind down of our operations, may require us to make significant cash severance payments, which would reduce the cash available to fund our operations or for distribution to our stockholders, and could make our company less attractive to potential acquirers or other strategic counterparties.

We may also discover that the workforce reduction and cost cutting measures will make it difficult for us to pursue new opportunities and initiatives and require us to hire qualified replacement personnel, which may require us to incur additional and unanticipated costs and expenses. Our failure to successfully accomplish any of the above activities and goals may have a negative impact on our business, financial condition, results of operations and growth prospects.

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 potentially 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 potentially 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.

We may pursue one or more strategic transactions, and there can be no assurance that we will be able to identify or complete any such transaction on acceptable terms, or at all, or that any such transaction will enhance stockholder value.

We are evaluating, and may in the future evaluate, a range of potential strategic alternatives intended to maximize the value of our pipeline and our company. These may include, among other things, sale of our equity securities, a merger, reverse merger or other business combination, a sale of our company or of one or more of our product candidates or other assets, licensing, partnering or other collaboration arrangements, royalty or other structured financings, a further restructuring of our operations, or a wind down and dissolution of our company. We have not set a timetable for any such evaluation and have not made any decision to pursue any specific transaction or other strategic alternative. There can be no assurance that this process will result in any transaction or other strategic outcome, or that any transaction will be completed on attractive terms, or at all.

The process of identifying, evaluating, negotiating and completing a strategic transaction is time-consuming, costly and complex and may divert management's attention from the operation of our business. We expect to incur substantial expenses for financial advisors, legal counsel, accountants and other advisors in connection with any such process, whether or not a transaction is completed, which will reduce the cash available to fund our operations. The failure of three of the four Phase 3 single-dose, in-clinic, public speaking challenge clinical trials of fasedienol to meet their primary endpoints, our current market capitalization, our limited cash position and the uncertainty regarding the regulatory pathway for fasedienol may significantly reduce the interest of potential counterparties and our bargaining power in any negotiation, and potential counterparties may seek to take advantage of our financial condition. The value attributed to our product candidates and other assets in any transaction may be substantially less than the value that we or our stockholders believe they have, and may be less than the prices at which our common stock has historically traded.

The potential future announcement or pendency of a strategic process, or speculation regarding a potential transaction, may cause volatility in the market price of our common stock, may make it more difficult to retain key employees and to maintain relationships with clinical trial sites, CDMOs, CROs and other third parties, and may lead to stockholder litigation. The completion of any potential transaction will also depend on a number of factors that may be beyond our control, including, among other things, market conditions, industry trends, the interest of third parties in our company and our assets, the availability of financing to us or the counterparty on reasonable terms, the content and timing of FDA feedback regarding fasedienol and, where required, the approval of our stockholders, and we may not be able to satisfy the conditions to closing of any transaction. If we are unable to complete a strategic transaction, or if we complete a transaction that does not deliver the anticipated benefits, our business, financial condition and prospects would be materially adversely affected and the market price of our common stock could decline significantly.

If we determine that no strategic transaction is available or in the best interests of our stockholders, our Board of Directors may decide to pursue a dissolution and liquidation of our Company. In that event, the amount of cash available for distribution to our stockholders would depend heavily on the timing of that decision, because the amount of cash available will continue to decrease as we fund our operations and pay our obligations, including severance, contract termination and other wind-down costs. In addition, in connection with any dissolution and liquidation, we would be required under Nevada law to pay, or make reasonable provision for, our outstanding obligations and contingent liabilities, including in respect of pending litigation, before making any distribution to our stockholders. As a result, there can be no assurance as to the amount or timing of any distribution to our stockholders, if any, and our stockholders could lose all or substantially all of their investment.

Strategic transactions involving micro-cap, pre-revenue biotechnology companies, including reverse mergers, involve significant risks, and any such transaction could result in substantial dilution to our stockholders and may not produce the anticipated benefits.

The market for strategic transactions involving micro-cap, clinical-stage biotechnology companies that have experienced clinical setbacks is highly competitive. It is characterized by a large number of companies seeking to sell, merge with or into, or otherwise monetize their assets through transactions with a limited number of counterparties that have the resources and interest to complete such transactions. In many such transactions, including reverse mergers with private companies seeking access to the public markets, the stockholders of the public company retain only a minority, and in some cases a small minority, of the combined company, and the value attributed to the public company is based largely on its net cash rather than on the value of its product candidates. As a result, if we complete such a transaction, our current stockholders may experience substantial dilution and may receive little or no value for our product candidates, including fasedienol. Transactions of this type often include provisions that adjust the relative ownership of the parties based on each party's net cash at closing, which could further reduce our stockholders' ownership if our expenses exceed our expectations or if the closing is delayed. Some transactions provide for contingent value rights or other contingent consideration tied to the future development, licensing or sale of the public company's legacy product candidates, which may never result in any payment to our stockholders. In addition, any such transaction would subject us to numerous risks, including:

- the counterparty's business, product candidates and technologies may be subject to risks that we are unable to identify or evaluate adequately through due diligence, and the combined company may assume unknown or contingent liabilities;
- a business combination that results in a change of control may require the combined company to satisfy Nasdaq's initial listing requirements, which are more stringent than its continued listing requirements, and the combined company may be unable to satisfy those requirements on a timely basis, or at all;
- we may be required to obtain stockholder approval of the transaction or of related matters, such as the issuance of shares in excess of the limits under Nasdaq rules, an increase in our authorized shares or a reverse stock split, and we may be unable to obtain such approval on a timely basis, or at all;
- a merger agreement or other definitive transaction agreement would likely restrict the conduct of our business before closing, including our ability to raise capital, pursue alternative transactions or make changes to our clinical programs, and may require us to pay a termination fee or reimburse expenses in certain circumstances;
- the combined company may require substantial additional financing, which may not be available on acceptable terms, or at all;
- the transaction could trigger severance and other payment obligations under our Executive Severance Plan and other arrangements, which would reduce the cash available to us or the combined company; and
- transactions of this type are frequently the subject of stockholder litigation, which could delay or prevent completion of the transaction and result in substantial costs.

Following any such transaction, the market price of the combined company's common stock may decline, including as a result of sales by our existing stockholders or by the counterparty's former equity holders following the expiration of any lock-up arrangements, and the combined company may not achieve the benefits anticipated from the transaction. Any of these risks could materially adversely affect the value of your investment.

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 of a product candidate, 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 required nonclinical 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 any regulatory approval.

Nonclinical studies and clinical trials are expensive, difficult to design and implement, can take many years to complete. All nonclinical studies and clinical trials 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, or, if completed, be successful. 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 approval and acceptance of the product candidate at issue.

This lengthy regulatory approval process, as well as the unpredictability of nonclinical study 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 regulatory 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 completed or future clinical trials of our product candidates are promising, such data may not be sufficient to support regulatory approval by the FDA or any other regulatory authority.

In addition, even if we were to obtain regulatory approval of any of our product candidates, 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, 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. The 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 designed the 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 efficacy endpoint based on FDA communications, the FDA 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 do not support approval. Moreover, prior to the announcement of the PALISADE-4 results, we had planned 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 FDA, or that the FDA will not require us to modify our development plans or clinical trial designs, conduct additional clinical trials, or generate additional information prior to submitting any marketing application. There can also be no assurance that evidence generated from the PALISADE program or from any other clinical trial we may conduct will ultimately assist in supporting any application for regulatory approval. Even if our future clinical trials achieve their primary efficacy endpoint, including our planned LSAS-based Phase 3 clinical trial of fasedienol, there can be no assurance that the FDA will find the results sufficient to support submission of an application for regulatory approval. Moreover, there are limited precedents for trial design, trial endpoints and regulatory pathway for the treatment of SAD with a proposed treatment hypothesis such as ours, and there are limited precedents for certain other therapeutic indications we are pursuing through the development of our product candidates, including fasedienol for the treatment of SAD, itruvone for the treatment of MDD and refisolone for the management of VMS (hot flashes) due to 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, including with respect to the dosing regimen utilized in a particular trial or the statistical analysis plan used to analyze trial data;
- 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;
- 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 nonclinical 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 Pharmaceuticals, Inc. (*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, PALISADE-3 and PALISADE-4 Phase 3 clinical trials of fasedienol to meet their primary endpoints, notwithstanding the positive results of PALISADE-2 and our earlier Phase 2 clinical trial of fasedienol, 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 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 regulatory approval or commercialize the product candidates we develop, including:

- regulators, institutional review board (*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 CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- we may experience further challenges or delays in recruiting principal investigators or clinical trial 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 nonclinical studies and clinical trials, 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 clinically meaningful 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 in a clinical trial is affected by many factors, including:

- the patient eligibility criteria defined in the protocol for such clinical trial;
- the size and nature of the patient population required for analysis of the trial's primary efficacy endpoints;
- the severity of the disease or condition under investigation in such clinical trial;
- the proximity of patients to clinical 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 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 to participate in our clinical trials at 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 regulatory 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 trials towards potential regulatory 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 development costs, delay or prevent regulatory 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 regulatory approval process is expensive, time-consuming and uncertain and may prevent us from obtaining regulatory 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, such as the preliminary data we previously announced from the open-label extension of our PALISADE-3 and PALISADE-4 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 significantly 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 meetings, 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, outcomes of regulatory meetings, receipt of regulatory 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 and adversely affect our business, 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 the FDA and other 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 significantly 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 FDA approval of a NDA, 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 submission 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 Strategy (*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 comparable foreign regulatory authorities 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 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 regulatory 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 FDCA. In reviewing the NDA 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 Regulations (*QMSR*) applicable to medical devices. Problems associated with the device component of the combination product candidate may delay or prevent regulatory approval. Any such delay would have a material adverse effect on our business and prospects.

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 product candidates that initially showed promise in clinical trials or earlier-stage testing are later found to cause undesirable or unexpected side effects that prevent further development of the product candidate. 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 adverse events 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 adverse events 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 adverse event and 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 adverse events or 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 healthcare 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 healthcare 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.

If our product candidates are approved by the FDA or other regulatory authorities, 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 approved and regulated as controlled substances, we, third-party 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 a product candidate 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, third-party 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 third-party CDMOs would be subject to initial and periodic DEA inspection. If we or our third-party 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 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 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. For example, we believe that a higher than expected placebo response in the single-dose, in-clinic, public speaking challenge studies contributed to the failure of PALISADE-3 to achieve its primary endpoint, and in PALISADE-4 the mean improvement in the placebo group exceeded the mean improvement in the fasedienol group in the overall study population. Placebo response in any future clinical trial of fasedienol, including our proposed LSAS-based Phase 3 clinical trial may detect a statistically significant treatment effect. 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 FDA or other 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 or suboptimal treatment options. These other potential product candidates will require additional, time-consuming development efforts prior to regulatory approval and commercial sale, including manufacturing, preclinical studies, clinical trials and approval by the FDA and comparable 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 and advanced in preclinical and clinical development. Our research programs may initially show promise in identifying potential pherine product candidates, yet fail to yield product candidates for preclinical and 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 conditions and disorders for which we are developing our product candidates has not been established with precision. If the actual number of patients with the conditions and 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 condition 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 conditions or disorders 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 conditions 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 condition or disorder or our other market assumptions are not accurate, the markets for our product candidates for these conditions or disorders 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 product 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 products or are pursuing the development of product candidates for the treatment of the conditions or disorders 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 conditions or disorders we are currently pursuing, and some or all may become commercially available in the future for the treatment of conditions or disorders 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, 2026, as filed with the SEC on June 15, 2026, 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 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 regulatory approval of the product candidate. Any failure or delay in the development of our or a third party collaborator's 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, healthcare 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.

We use predictive artificial intelligence tools provided by a third party to inform the design of our clinical trials and the prioritization of our product candidates. These tools may not accurately predict clinical outcomes and may not be given weight by the FDA, and their use exposes us to additional risks.

We collaborate with a predictive artificial intelligence (*AI*) platform, GATC Health Corp. (*GATC*), to inform protocol development, including for our proposed LSAS-based Phase 3 clinical trial of fasedienol and potential Phase 2 clinical trials of itruvone and refisolone, as well as our pipeline prioritization and resource allocation. The use of AI-based predictive modeling in clinical development is relatively new, and its ability to predict clinical outcomes has not been established. AI models may produce inaccurate, incomplete or biased outputs due to limitations in the data on which they are trained, including data that may not be representative of the patient populations in our trials, or because of the design of

the models themselves. GATC's models and training data are proprietary, and we have limited ability to evaluate or independently validate them.

If we rely on AI-generated predictions in selecting trial design elements, we may make decisions that reduce the likelihood of a successful trial. Given our limited capital resources, we may be unable to recover from such decisions. A favorable AI-generated prediction does not mean that a clinical trial will succeed, and our clinical trials, including any future trial of fasedienol, may fail regardless of such predictions.

Moreover, the FDA has not established a final framework for evaluating AI-generated information used to support clinical development decisions. To the extent we cite AI-generated analyses in our interactions with the FDA, the FDA may request information about the model that neither we nor GATC can provide, or may give such analyses no weight.

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, CDMOs, 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 capital 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. Moreover, the failure of prior clinical trials of fasedienol to achieve their primary endpoints, the uncertainty regarding the regulatory pathway for fasedienol and our limited capital resources may significantly reduce the interest of potential collaborators in our product candidates, or may result in collaboration terms that are substantially less favorable to us than we would otherwise seek.

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 could 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 reduced employee headcount in March and October 2026 in connection with cost preservation efforts and an alignment of the size and structure of our workforce with our late clinical-stage priorities. We may also implement further workforce reductions. As a result, the loss of the services of those employees might impede the achievement of our operational and strategic objectives.

Our ability to retain key personnel has been, and may continue to be, adversely affected by the failure of prior clinical studies to achieve their primary endpoints, the decline in the market price of our common stock, which has substantially reduced the retentive value of outstanding equity awards, our limited cash runway, the substantial doubt about our ability to continue as a going concern and uncertainty regarding any strategic transaction. The loss of key personnel during our

evaluation of strategic alternatives or our interactions with the FDA regarding fasedienol could impair our ability to advance our product candidates or to complete a strategic transaction.

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 cultural 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 and/or retain a sufficient number of employees or employees with the required expertise to develop our product candidates or operate our business successfully.

In March 2026, our Board of Directors approved a reduction of approximately 20% in our workforce, intended to provide disciplined cash management while prioritizing efficient execution of the ongoing clinical studies in our PALISADE Program. As of September 30, 2026, we had 40 full-time employees. In October 2026, we implemented a Board-approved reduction in workforce by approximately 31% that is intended to, among other things, further reduce operating expenses and to align the size and structure of our workforce with our late clinical-stage priorities. 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 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.

Our employees may use artificial intelligence tools in ways that expose our confidential information, intellectual property, or clinical data to third parties, and the evolving regulatory and legal landscape around artificial intelligence could adversely affect our business.

Our employees may use commercially available artificial intelligence tools, including generative AI platforms, in connection with their work. If our personnel inadvertently submit confidential information, proprietary research data, clinical trial data, or trade secrets to external AI platforms, that information may be exposed to third parties or incorporated into publicly accessible AI outputs, potentially compromising our intellectual property, our patent position, or our obligations under confidentiality agreements. The legal and regulatory framework governing AI tools remains uncertain and rapidly evolving, including with respect to ownership of AI-generated outputs and potential infringement of third-party intellectual property rights. Any failure to manage these risks appropriately could have a material adverse effect on our business, financial condition, and results of operations.

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 leadership 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 clinical 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, 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 CDMO, 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 CDMO 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 third-party 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, refisolone, itruvone, 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. and, as a result, if the FDA considers the indications we pursue as exceeded the scope of our Fast Track designations, we may lose the benefits associated with the applicable designation. 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 ituvone 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 Therapy designation, 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, 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, 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 Civil Monetary Penalties Law, which prohibits, among other things, the submission of false or fraudulent claims, the employment or contracting of an excluded individual or entity, and offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of reimbursable items or services;

- 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 (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), 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, if 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 whether and to what extent coverage and reimbursement for our product candidates will be available from third-party payors.

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 or statutes 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. Among

other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); redesigns the Medicare Part D benefit (beginning in 2024); and replaces the Part D coverage gap discount program with a new manufacturer discount program (beginning in 2025). CMS has published the negotiated prices for the initial ten drugs, which became effective in 2026, and the subsequent 15 drugs, which will first be effective in 2027. CMS has also published the next set of 15 drugs that will be subject to negotiation. The IRA permits the Secretary of the Department of Health and Human Services (*HHS*) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented, although the Medicare drug price negotiation program is currently subject to legal challenges. The impact of the IRA on us and the pharmaceutical industry cannot yet be fully determined, but is likely to be significant. 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, the IRA price-negotiation provisions may have a negative impact on our future revenue and profits. 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.

The One Big Beautiful Bill Act, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect our sales of any product candidate that we commercialize.

The current administration is also pursuing a two-fold strategy to reduce drug costs in the U.S. The current administration's policies are likely to have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for our products, if approved. On the one hand, the current U.S. president threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers entered into confidential pricing agreements with the federal government. Subsequently, in April 2026, the current administration issued a proclamation imposing tariffs under Section 232 of the Trade Expansion Act on imports of brand pharmaceuticals, biologics and associated pharmaceutical ingredients, beginning July 31, 2026. Exempted from these tariffs, among others, are companies that have executed or are negotiating agreements with the federal government regarding most favored nation pricing and onshoring of production and research and development. On the other hand, the current administration is also pursuing traditional regulatory pathways to impose drug pricing policies and published two proposed regulations in December 2025, referred to as GLOBE and GUARD. If finalized, these regulations would implement mandatory payment models under which manufacturers of eligible drugs would be required to pay rebates to the federal government on a portion of the units of their drugs that are reimbursed by Medicare, with the rebate amount based on most favored nation pricing. While the impact of the GLOBE and GUARD proposed regulations, if finalized, cannot yet be determined, it is likely to be significant. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business. In addition, pharmaceutical pricing and marketing has long been the subject of considerable discussion in Congress and among policymakers, and it is possible that Congress could enact additional laws that negatively affect the pharmaceutical industry.

In addition, pharmaceutical pricing and marketing has long been the subject of considerable discussion in Congress and among policymakers, and it is possible that Congress could enact additional laws that negatively affect the pharmaceutical industry. 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.

Moreover, the individual states in the United States have become increasingly active in developing proposals, passing legislation and implementing regulations designed to control drug pricing, including price or patient reimbursement constraints, discounts, formulary flexibility, marketing cost disclosure, drug price increase reporting, and other transparency measures. Some states have enacted legislation creating so-called prescription drug affordability boards, with the goal of imposing price limits on certain drugs in these states. At least one state board is imposing an upper payment limit, although the implementation is subject to ongoing litigation. States are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution. Some measures are designed to encourage importation from other countries. These types of initiatives may result in additional reductions in Medicare, Medicaid, and other healthcare funding, and may otherwise affect the prices we may obtain for any approved product candidate or the frequency with which any approved product candidate is prescribed or used.

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, including those 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 certain issued patents, license others and have patent applications pending 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. For example, the U.S. Supreme Court recently decided *Hikma v. Amarin* (June 2026), which concerned alleged "induced" infringement by a generic manufacturer that obtained FDA approval to market a drug under a "skinny label" corresponding to an unpatented treatment method while a second indication remained under patent. The Court found that merely stating

that a product was a generic equivalent did not constitute active steps to encourage infringement of the patented treatment indication. Although this decision will not have any direct, immediate impact on the Company, it could be relevant in the future should the Company receive FDA approval to treat multiple indications using unpatented compounds or formulations. In addition, the coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform and is subject to change.

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 August 4, 2026, the Company received a notification (the *Extension Notice*) from the Listing Qualifications Staff of The Nasdaq Stock Market LLC (*Nasdaq*) granting the Company an additional 180 calendar day compliance period, until February 1, 2027 (the *Extension Period*), to regain compliance with the requirement that the Company's common stock maintain a minimum closing bid price of $1.00 per share for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (the *Minimum Bid Price Requirement*).

As previously disclosed, on February 3, 2026, the Company received a letter from Nasdaq indicating that, based upon the closing bid price of its common stock for the 30 consecutive business day period from December 17, 2025 through February 2, 2026, the Company did not satisfy the Minimum Bid Price Requirement, and that the Company would be afforded a compliance period of 180 calendar days, or until August 3, 2026, in which to regain compliance pursuant to Nasdaq Listing Rule 5810(c)(3)(A). The Company did not regain compliance within that period and advised Nasdaq of its intent to cure the deficiency during the Extension Period.

The Extension Notice has no immediate effect on the listing of the Company's common stock, which continues to be listed and traded on the Nasdaq Capital Market, subject to the Company's compliance with the other listing requirements of Nasdaq. To regain compliance, the closing bid price of the Company's common stock must be at least $1.00 per share for a minimum of 10 consecutive business days during the Extension Period.

If the Company does not regain compliance with the Minimum Bid Price Requirement during the Extension Period, Nasdaq will provide written notification that the Company's common stock is subject to delisting, at which time the Company may appeal the delisting determination to a Nasdaq Hearings Panel. There can be no assurance that the Company will regain compliance with the Minimum Bid Price Requirement or any other Nasdaq listing standard, or that any such appeal, if pursued, would be successful.

To regain compliance with the Minimum Bid Price Requirement, we may effect a reverse stock split of our common stock. There can be no assurance that a reverse stock split, if effected, would result in a sustained increase in the market price of our common stock sufficient to regain or maintain compliance, and reverse stock splits are frequently followed by declines in the market price and liquidity of the affected securities. In addition, under Nasdaq rules, if our common stock has a closing bid price of $0.10 or less for ten consecutive trading days during any compliance period, Nasdaq will issue a delisting determination without regard to any remaining compliance period, and if we effect a reverse stock split and our common stock subsequently fails to satisfy the Minimum Bid Price Requirement within one year, we will not be eligible for any compliance period. Further, because the Extension Period is our second consecutive compliance period, if we do not regain compliance by the end of the Extension Period, our common stock would be suspended from trading on the Nasdaq Capital Market, and would trade, if at all, on the over-the-counter market, during the pendency of any appeal to a Nasdaq Hearings Panel. A delisting or suspension of our common stock would also be likely to substantially impair our ability to raise capital and to complete a strategic transaction.

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 studies and clinical trials of 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;
- announcements regarding our interactions with the FDA;
- announcements regarding, or speculation about, any strategic transaction, including a merger, sale, licensing transaction or dissolution;
- the results of, and market perception of, post-hoc, subgroup or pooled analyses of our clinical trial data;

- 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.

For example, following our announcements of the topline results of PALISADE-3 in December 2025 and PALISADE-4 in June 2026, the market price of our common stock declined by approximately 80% and 70%, respectively, in a single trading day.

Actions of activist or other significant stockholders could cause us to incur substantial costs, divert the attention of our management and Board of Directors, and adversely affect our business and the market price of our common stock.

Stockholders may from time to time engage in proxy solicitations, advance stockholder proposals, seek representation on our Board of Directors or otherwise attempt to effect changes in, or acquire control of, our company, particularly in light of our recent clinical results, the decline in the market price of our common stock and our evaluation of strategic alternatives. Responding to such actions can be costly and time-consuming, can disrupt our operations and divert the attention of our Board of Directors and management, and can make it more difficult to attract and retain qualified personnel and to pursue a financing or strategic transaction. In addition, perceived uncertainty as to our future direction resulting from such actions, or purchases or sales of large blocks of our common stock by significant stockholders, could cause significant volatility in the market price of our common stock.

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

Our Restated Articles of Incorporation, as amended, 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 nonclinical studies and 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 regulatory 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 regulatory 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 the 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 and the District of Nevada 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 wholly without merit and intend to vigorously defend all claims. The significant declines in the market price of our common stock following our announcements of the PALISADE-3 and PALISADE-4 results may increase the risk of additional securities litigation, and any strategic transaction we may pursue could also become the subject of stockholder litigation. These types of litigation could result in substantial costs and a significant 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, potential settlements, and damages awarded to plaintiffs, if any.

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

We expect to issue additional capital stock in the future that 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 likely 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 U.S. 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, 2026, we had U.S. federal net operating loss carryforwards totaling $314.3 million. Federal net operating loss carryforwards of approximately $80.6 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 $233.7 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, 2026, we had state net operating loss carryforwards totaling $63.7 million, which expire at various dates between 2029 and 2045. As of March 31, 2026, we also had U.S. federal and state research and development tax credit carryforwards of $8.6 million and $2.2 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.

Trading Arrangements

During the period ended September 30, 2026, no director or officer (as defined in Exchange Act Rule 16a-1(f)) of the Company adopted or terminated a 'Rule 10b5-1 trading arrangement' or 'non-Rule 10b5-1 trading arrangement' as defined in Regulation S-K Item 408.

Item 6. Exhibits

Exhibit Number	Description
10.1*	Vistagen Therapeutics, Inc. Change in Control Executive Severance Plan, dated August 11, 2026.
10.2	Vistagen Therapeutics, Inc. Executive Severance Plan, dated October 7, 2026, incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 9, 2026.
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: November 13, 2026

/s/ Shawn K. Singh, JD

Shawn K. Singh, JD

President and Chief Executive Officer
(Principal Executive Officer)

Dated: November 13, 2026

/s/ Nick B. Tressler

Nick B. Tressler

Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 10.1

Vistagen

VISTAGEN THERAPEUTICS, INC.
CHANGE IN CONTROL EXECUTIVE SEVERANCE PLAN
AND SUMMARY PLAN DESCRIPTION

Effective Date: ***August 11, 2026***

1. Purpose. The Board of Directors of Vistagen Therapeutics, Inc. (the "*Board*"), a Nevada corporation ("*Vistagen*" or the "*Company*"), recognizes that a potential involuntary termination of employment of Vistagen's senior management in connection with a Change in Control of the Company, and the uncertainty a potential Change in Control may create, may cause key employees to depart or become distracted, to the detriment of the Company and its stockholders. Accordingly, the Company will provide Eligible Employees with rights to receive certain severance payments and other benefits upon a Qualifying Termination pursuant to this Change in Control Executive Severance Plan ("*Plan*"), as set forth below. This Plan is an "employee welfare benefit plan," as defined in Section 3(1) of ERISA. This Plan is governed by ERISA and, to the extent applicable, the laws of the State of Nevada. This document constitutes both the written instrument under which this Plan is maintained and the required summary plan description for this Plan.

2. Definitions. The following definitions are applicable for purposes of this Plan, including in Section 1 above and in addition to terms defined in Section 1 above:

    a. "***Accrued Obligations***" means, for an Eligible Employee, the Eligible Employee's (i) base salary otherwise payable through the Date of Termination, and (ii) unreimbursed business expenses reimbursable under Company policies then in effect.

    b. "***Administrator*****"** means the Board, whether or not acting through authority delegated to the Compensation Committee of the Board or another duly constituted committee of members of the Board, or any person or persons to whom the Administrator has delegated any authority or responsibility with respect to this Plan.

    c. "***Affiliate***" means with respect to a specified Person, a Person that directly, or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, the specified Person.

    d. "***Awards***" means each outstanding and unvested equity award held by an Eligible Employee granted pursuant to an Equity Plan, including, without limitation, each restricted stock, stock option, restricted stock unit or other equity award.

    e. "***Base Pay Severance Period***" means, for an Eligible Employee, the number of months equal to the Eligible Employee's Base Pay Severance Period set forth for such Eligible Employee's Tier on Appendix A.

    f. "***Bonus Severance Period***" means, for an Eligible Employee, the number of months equal to the Eligible Employee's Bonus Severance Period set forth for such Eligible Employee's Tier on Appendix A.

    g. "***Beneficial Owner***" means "***Beneficial Owner***" as defined in Rule 13d-3 and Rule 13d-5 under the Exchange Act; except that, in calculating the beneficial ownership of any particular Person, such Person shall be deemed to have beneficial ownership of all securities that such Person has the right to acquire by conversion or exercise of other securities, whether such right is currently exercisable or is exercisable only after the passage of time. The term "Beneficial Ownership" has a corresponding meaning.

h. "***Benefit Plans***" means all medical, dental and vision benefit plans of the Company, as may be in effect from time to time.

i. "***Benefits Continuation Period***" means, for an Eligible Employee, the number of months equal to the Eligible Employee's Benefits Continuation Period set forth for such Eligible Employee's Tier on Appendix A as of the date of his or her Qualifying Termination.

j. "***Board***" means the Board of Directors of the Company.

k. "***Cause***" means the occurrence of any of the following events, in each instance that has a material adverse impact on the Company or any successor or Affiliate thereof, as determined by the Company in its reasonable discretion: (i) an Eligible Employee's conviction of, or plea of "guilty" or "no contest" to, any non-vehicular felony or any crime involving fraud, dishonesty or moral turpitude under the laws of the United States or any state thereof; (ii) an Eligible Employee's commission of, or participation in, a fraud or act of dishonesty or other illegal act against the Company; (iii) an Eligible Employee's intentional, material violation of any contract or agreement between an Eligible Employee and the Company or any material Company policy or of any statutory duty owed to the Company; (iv) an Eligible Employee's intentional unauthorized use or disclosure of the Company's confidential information or trade secrets; (v) an Eligible Employee's gross misconduct; or (vi) the Eligible Employee's ongoing and repeated failure, refusal or neglect to perform her or his duties to the Company or to comply with the lawful instructions of the Company, which failure, refusal or neglect continues for thirty (30) days after the Eligible Employee receives written notice from the Company stating with specificity its nature; provided that this clause (vi) shall not permit the Company to terminate an Eligible Employee's employment for Cause solely because of (A) an Eligible Employee's failure to meet specified performance objectives or achieve a specific result or outcome, or (B) the Company's dissatisfaction with the quality of services provided by an Eligible Employee in the good faith performance of her or his duties to the Company.

l. "***Change in Control***" shall mean the occurrence of any of the following events: (i) the acquisition, directly or indirectly, by any Person or group (within the meaning of Section 13(d)(3) of the Exchange Act) of the Beneficial Ownership of fifty percent (50%) or more of the outstanding securities of the Company; (ii) a merger or consolidation in which the Company is not the surviving entity, except for a transaction the principal purpose of which is to change the state in which the Company is incorporated; (iii) the sale, transfer or other disposition of all or substantially all of the assets of the Company; or (iv) any reverse merger in which the Company is the surviving entity but in which securities possessing more than fifty percent of the total combined voting power of the Company's outstanding securities are transferred to a Person or Persons different from the Persons holding those securities immediately prior to such merger; provided, however, that in no event will a transaction undertaken for purposes of a bona fide financing the ongoing operations of the Company wherein the Company issues debt and/or equity securities to investors constitute a Change in Control for purposes of this Plan. If a Change in Control would give rise to a payment or settlement event with respect to any payment or benefit that constitutes "nonqualified deferred compensation," the transaction or event constituting the Change in Control must also constitute a "change in control event" (as defined in U.S. Treasury Regulation §1.409A-3(i)(5)) in order to give rise to the payment or settlement event for such payment or benefit, to the extent required by Code Section 409A.

m. "***COBRA***" means the continuation coverage requirements for "group health plans" under Title X of the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended, and as codified in Code Section 4980B and ERISA Sections 601 through 608, each as amended from time to time, including rules thereunder and successor provisions and rules thereto.

n. "***Code***" means the U.S. Internal Revenue Code of 1986, as amended from time to time, and all regulations, interpretations, and administrative guidance issued thereunder.

o. "***Code Section 409A***" means Section 409A of the Code.

p. "***Company***" means Vistagen Therapeutics, Inc., a Nevada corporation, including its Affiliates, collectively (and any successors or assigns thereto), and any successor that assumes the obligations of the Company under this Plan, by way of merger, acquisition, consolidation or other transaction.

q. "***Date of Termination***" means, for an Eligible Employee, the date of the Eligible Employee's Separation from Service.

r. "***Eligible Employee***" means, except as provided in Section 6(d) of the Plan, an employee of the Company who (i) holds an organizational title as an executive as indicated in Appendix A of this Plan who is not a party to an Individual Agreement, and (ii) is a full-time employee of the Company. An individual otherwise satisfying the requirements to be an Eligible Employee will continue to be considered an employee of the Company for purposes of this Plan if she or he is on Company-approved leave of absence immediately prior to the date of her or his Qualifying Termination, and her or his regular full-time status for purposes of determining his or her Severance Payments and Benefits under this Plan will be determined based on her or his employment status immediately prior to the commencement of such leave. For the avoidance of doubt, in no event will an independent contractor or consultant to the Company, or a part-time employee of the Company, be eligible for benefits under this Plan. Notwithstanding the foregoing, the Chief Executive Officer of the Company shall be considered an Eligible Employee for purposes of the benefits in Section 6(c) of the Plan notwithstanding that he is a party to an Individual Agreement.

s. "***Equity Plan***" means an equity incentive plan maintained by the Company.

t. "***ERISA***" means the Employee Retirement Income Security Act of 1974, as amended.

u. "***Good Reason***" means any of the following actions taken without Cause by the Company or a successor corporation or entity without an Eligible Employee's consent: (i) a material reduction of an Eligible Employee's base compensation, other than, prior to a Change in Control, a reduction that applies generally to all similarly-situated personnel; (ii) material reduction or material adverse change in an Eligible Employee's authority, duties or responsibilities; (iii) a relocation of the principal place at which an Eligible Employee is required to provide services to the Company or an Eligible Employee's principal place of employment that results in an increase in an Eligible Employee's one-way driving distance by more than 50 miles from his or her then-current principal place of business or residence, as applicable (for the avoidance of doubt, a remote employee's principal place of employment shall be deemed to be their home office); and (iv) any other action or inaction that constitutes a material breach by the Company or any successor or Affiliate of its obligations to an Eligible Employee under this Plan. In order to resign for Good Reason, an Eligible Employee must provide written notice of the event giving rise to Good Reason to the Company within 90 days after the condition arises, allow the Company 30 days to cure such condition, and if the Company fails to cure the condition within such 30-day period, then an Eligible Employee's resignation from all positions she or he then holds with the Company must be effective not later than 90 days after the end of the Company's 30-day cure period.

v. "***Individual Agreement***" means an Eligible Employee's employment agreement with the Company that provides for cash severance benefits.

w. "***Monthly Base Pay***" means the quotient of (i) the Eligible Employee's annual base salary as of the Date of Termination (disregarding any reduction thereto that serves as the basis for the Eligible Employee's resignation for Good Reason), divided by (ii) twelve (12). Monthly Base Pay does not include incentive compensation, bonuses, commissions, benefits, fringe benefits, expense reimbursements, or other compensation.

x. "***Person***" means an individual, corporation, partnership, limited liability company, association, trust, other entity, group or organization, including a governmental authority.

y. "***Qualifying Termination***" means (i) a termination of an Eligible Employee's employment with the Company within three (3) months preceding or eighteen (18) months following the date of a Change in Control and (ii) is either (A) initiated by the Company without Cause or (B) initiated by the Eligible Employee for Good Reason. Termination due to death or disability shall not be treated as a Qualifying Termination. No benefits are payable under this Plan if a Change in Control does not occur. Notwithstanding anything else to the contrary contained in this Plan, an Eligible Employee shall not experience a Qualifying Termination for purposes of this Plan to the extent his or her termination of employment occurs pursuant to a Board-approved wind down of the Company's operations (whether pursuant to a reduction in force or otherwise) or would otherwise, in the Board's good faith determination, cause the Company to become insolvent.

z. "***Release***" has the meaning specified in Section 6 of this Plan.

aa. "***Release Period***" has the meaning specified in Section 6 of this Plan.

ab. "***Separation from Service***" means a "separation from service" as defined in U.S. Treasury Regulation § 1.409A-1(h). "***Severance Payments and Benefits***" means all benefits provided or payments made by the Company to or for the benefit of an Eligible Employee under this Plan as the result of a Qualifying Termination. "***Tier***" means the tier of Severance Payments and Benefits an Eligible Employee is entitled to receive under this Plan pursuant to Section 6 of this Plan, depending on the Eligible Employee's rank and title on the date of the Qualifying Termination (disregarding any diminution in title that results in an Eligible Employee being in a lower Tier that serves as the basis for the Eligible Employee's resignation for Good Reason), as set forth on Appendix A of this Plan.

3. Eligibility. An Eligible Employee shall be eligible for Severance Payments and Benefits under this Plan, subject to the terms and conditions described herein, only if he or she experiences a Qualifying Termination and is an Eligible Employee on his or her Date of Termination.

4. Administration.

a. This Plan shall be interpreted, administered and operated by the Administrator, which shall have complete authority, subject to the express provisions of this Plan, to interpret this Plan, to prescribe, amend and rescind rules and regulations relating to this Plan, to determine eligibility for benefits under this Plan, and to make all other determinations necessary or advisable for the administration of this Plan. Such authority shall include the powers to resolve ambiguities, inconsistencies, and omissions, and to amend the Plan to correct any scrivener's error. The Administrator may delegate any of its duties hereunder to a subcommittee, or to such person or persons from time to time as it may designate. All decisions, interpretations and other actions of the Administrator shall be final, conclusive and binding on all parties who have an interest in this Plan.

b. Notwithstanding anything in this Plan to the contrary, upon or after a Change in Control, neither the Administrator nor any other person shall have discretionary authority in the administration of the Plan, and any court or tribunal that adjudicates any dispute, controversy, or claim in connection with benefits under this Plan will apply a de novo standard of review to any determinations made by the Administrator or the Company. Such de novo standard shall apply notwithstanding the grant of full discretion hereunder to the Administrator or any person or characterization of any decision by the Administrator or by such person as final, binding or conclusive on any party.

5. Termination of Employment for any Reason. Subject to the terms and conditions hereof, in the event of an Eligible Employee's termination of employment with the Company for any reason, including a Qualifying Termination:

a. The Company shall pay the Eligible Employee the Accrued Obligations, payable on the dates such amounts would have been payable under the Company's policies if the Eligible Employee's employment had not terminated or as otherwise required by applicable law.

b. Subject to Section 6(c), all outstanding Awards held by the Eligible Employee as of the Date of Termination shall be governed by the terms and conditions of the applicable Equity Plan(s) and Award agreements evidencing such Awards.

c. Subject to Section 6(b) below, the Eligible Employee's benefits and rights under the Company's benefit plans shall be determined in accordance with the applicable provisions of such plans, in each case as in effect and amended from time to time.

6. Qualifying Termination. In addition to the payments and benefits set forth in Section 5 of this Plan, if an Eligible Employee's termination of employment with the Company is a Qualifying Termination, the Eligible Employee shall also be entitled to receive the following payments and benefits, subject to the Release requirement in Section 6(e) below:

a. The Eligible Employee shall be entitled to payment of her or his Monthly Base Pay for the number of months in the Base Pay Severance Period applicable to her or his Tier as of the date of such Qualifying Termination as set forth on Appendix A hereto, which shall be payable in cash in a lump sum on the Company's first regularly scheduled payroll date following the later of (i) the effective date of the Eligible Employee's Release, or (ii) the date of a Change in Control occurring within three (3) months following the Eligible Employee's Qualifying Termination;

b. If the Eligible Employee and/or his or her eligible dependents who were covered under the Company's Benefit Plans as of the Date of Termination timely elect to continue coverage under the Company's Benefit Plans pursuant to COBRA, then the Company shall pay to the Eligible Employee a lump sum cash payment equal to (i) the total monthly COBRA premium for the elected level of Benefit Plan coverage (calculated by reference to the premium as of the Date of Termination), multiplied by (ii) the Eligible Employee's Benefits Continuation Period. The foregoing amount shall be payable in cash in a lump sum on the Company's first regularly scheduled payroll date following the later of (i) the effective date of the Eligible Employee's Release, or (ii) the date of a Change in Control occurring within three (3) months following the Eligible Employee's Qualifying Termination. The Eligible Employee shall be solely responsible for all matters relating to continuation of coverage pursuant to COBRA, including, without limitation, the election of such coverage and the timely payment of premiums;

c. The Eligible Employee's outstanding Awards granted under the Company's Equity Plans will vest in full and, if applicable, become exercisable in full upon the later of (i) the effective date of the Eligible Employee's Release, or (ii) the date of a Change in Control occurring within three (3) months following the Eligible Employee's Qualifying Termination (for the avoidance of doubt, if an Eligible Employee's Qualifying Termination occurs prior to a Change in Control, then any unvested portion of the Eligible Employee's outstanding Awards will remain outstanding for three (3) months following the Date of Termination (or, if earlier, until the occurrence of a Change in Control) so that any vesting acceleration benefits provided under this Section 6(c) can be provided if a Change in Control occurs within three (3) months following such termination (provided that in no event will an Award remain outstanding beyond the Award's maximum term or expiration date)). In such case, if no Change in Control occurs within three (3) months following an Eligible Employee's termination, any unvested portion of the Eligible Employee's Awards automatically will be forfeited without having vested. For purposes of the accelerated vesting in this Section 6(c), any Award subject to performance-based vesting conditions will vest with those conditions deemed achieved at target, unless the applicable Award agreement provides otherwise. Notwithstanding the foregoing, in the event the Award agreement or the Equity Plan pursuant to which an Eligible Employee's Awards were granted provides for more favorable treatment of Awards upon a Change in Control or a Qualifying Termination, nothing in this Plan is intended to limit an Eligible Employee's right to such more favorable treatment as provided in such Award agreement or Equity Plan; and

d. The Eligible Employee shall be entitled to payment of an amount equal to the product of (i) one-twelfth (1/12th) of the Eligible Employee's target annual discretionary cash incentive bonus for the year in which the Date of Termination occurs (or, if no target discretionary bonus has been

established for that year, the target annual cash discretionary incentive bonus for the immediately preceding year), disregarding any reduction that serves as the basis for a resignation for Good Reason, multiplied by (ii) the number of months in the Bonus Severance Period applicable to his or her Tier as set forth on Appendix A hereto, payable in cash in a lump sum on the Company's first regularly scheduled payroll date following the later of (i) the effective date of the Eligible Employee's Release, or (ii) the date of a Change in Control occurring within three (3) months following the Eligible Employee's Qualifying Termination; and

e. Notwithstanding anything in this Plan to the contrary, the Eligible Employee's right to the payments and benefits described in this Section 6 is conditioned on the Eligible Employee's execution and non-revocation of a general release of claims in favor of the Company and its Affiliates, in the form approved by the Company for purposes of the Plan (the "***Release***"), that becomes effective and irrevocable no later than the sixtieth (60^{th}) calendar day following the Date of Termination (such period, the "***Release Period***"). The Company shall deliver the Release to the Eligible Employee within 7 calendar days following the Date of Termination. If the Release does not become effective and irrevocable within the Release Period, the Eligible Employee shall forfeit all rights to the payments and benefits described in this Section 6.

7. Other Provisions Applicable to Severance Payments and Benefits; Non-Duplication of Payments or Benefits.

a. All references in this Plan to salary and annual incentive amounts mean those amounts before reduction pursuant to any plan or other arrangement for deferral of compensation.

b. Anything in this Plan to the contrary notwithstanding, a transfer of employment from the Company to an Affiliate or vice versa shall not be considered a Qualifying Termination for purposes of this Plan.

c. Except as expressly provided herein with respect to Section 6(c), if an Eligible Employee is eligible to receive severance payments or benefits in connection with a Qualifying Termination under an Individual Agreement, the Individual Agreement shall govern.

8. Restrictive Covenants.

a. Each Eligible Employee hereby expressly confirms her or his continuing obligations to the Company and its Affiliates pursuant to the confidentiality provisions of any code of conduct of the Company or its Affiliates, the Company's standard form of confidential information and inventions assignment agreement and/or other agreements regarding non-competition, non-solicitation, non-disparagement, confidentiality, assignment of inventions or other similar covenants between such Eligible Employee and the Company (the "***Restrictive Covenants***").

b. Each Eligible Employee is hereby provided with the following notice of immunity rights in compliance with the requirements of the U.S. Defend Trade Secrets Act: (i) an Eligible Employee shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of proprietary information that is made in confidence to a Federal, State, or local government official or to an attorney solely for the purpose of reporting or investigating a suspected violation of law, (ii) an Eligible Employee shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of proprietary information that is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal, and (iii) if an Eligible Employee files a lawsuit for retaliation by the Company for reporting a suspected violation of law, the Eligible Employee may disclose the proprietary information to her or his attorney and use the proprietary information in the court proceeding, if the Eligible Employee files any document containing the proprietary information under seal, and does not disclose the proprietary information, except pursuant to court order. In addition, nothing in this Plan or any Restrictive Covenant agreement shall prevent an Eligible Employee from (x) communicating directly with, cooperating with, or providing information to, or receiving financial awards from, any federal, state or local government agency, including without limitation the U.S. Securities and Exchange Commission, the U.S. Commodity Futures Trading Commission, the U.S. Department of Justice, the U.S. Equal Employment Opportunity Commission, or the U.S.

National Labor Relations Board, without notifying or seeking permission from the Company, (y) exercising any rights the Eligible Employee may have under Section 7 of the U.S. National Labor Relations Act, such as the right to engage in concerted activity, including collective action or discussion concerning wages or working conditions, or (z) discussing or disclosing information about unlawful acts in the workplace, such as harassment or discrimination based on a protected characteristic or any other conduct that the Eligible Employee has reason to believe is unlawful.

9. Special Rules for Compliance with Code Section 409A. This Section 9 serves to ensure compliance with applicable requirements of Code Section 409A. If the terms of this Section 9 conflict with other terms of this Plan, the terms of this Section 9 shall control.

   a. To the extent applicable, this Plan shall be interpreted in accordance with Code Section 409A and U.S. Department of Treasury regulations and other interpretive guidance issued thereunder. The intent of the Company is that payments and benefits under this Plan comply with, or be exempt from Code Section 409A and, accordingly, to the maximum extent permitted, this Plan shall be interpreted to be in compliance with such intention. To the extent that any provision in this Plan is ambiguous as to its compliance with or exemption from Code Section 409A, the provision shall be read in such a manner that no payments payable under this Plan shall be subject to an "additional tax" as defined in Section 409A(a)(1)(B) of the Code.

   b. Each installment in a series of Severance Payments and Benefits shall be deemed a separate payment for purposes of Code Section 409A. For purposes of this Plan, to the extent required to ensure the Severance Payments and Benefits comply with, or are exempt from, Code Section 409A, all references to an Eligible Employee's "termination of employment" shall mean his or her Separation from Service.

   c. If an Eligible Employee is a "specified employee" (as determined by the Administrator or its designee in accordance with Treasury Regulation § 1.409A-1(i)) as of his or her Date of Termination, then all Severance Payments that are subject to the requirements of Code Section 409A (determined after taking into account the "short-term deferral" rule in Treasury Regulation § 1.409A-1(b)(4), the "two-year, two-time" rule described in Treasury Regulation § 1.409A-1(b)(9), and any other available exception from such requirements) shall be subject to the six-month delay rule of Code Section 409A(a)(2)(B)(i). Each payment that is subject to such six-month delay rule shall be made, without interest, on the later of (i) the Company's first payroll date that is at least six months after the Eligible Employee's Date of Termination (or, if earlier, as soon as practicable after the Eligible Employee's death) or (ii) the date when such payment would otherwise be due under the terms of the Plan.

   d. To the extent that the payments or benefits under this Plan are "non-qualified deferred compensation" subject to Code Section 409A, if the Release Period spans two calendar years, the payment of any Severance Payments and Benefits shall occur (or commence) on the later of (a) January 1 of the second calendar year, or (b) the the payment date specified herein. To the extent required by Code Section 409A, any reimbursement or in-kind benefit provided under this Plan shall be provided in accordance with the following: (i) the amount of expenses eligible for reimbursement, or in-kind benefits provided during each calendar year cannot affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other calendar year; (ii) any payments in lieu of the benefits shall be paid no later than the end of Eligible Employee's taxable year next following Eligible Employee's taxable year in which the benefit or expense was due to be paid; and (iii) any right to reimbursements or in-kind benefits under this Plan shall not be subject to liquidation or exchange for another benefit.

   e. The Company and its employees and agents make no representation and are providing no advice regarding the taxation of the payments and benefits under this Plan, including with respect to taxes, interest and penalties under Code Section 409A and similar liabilities under state and local tax laws. No indemnification or gross-up is payable under this Plan with respect to any such tax, interest, or penalty under Code Section 409A or similar liability under state or local tax laws applicable to any Eligible Employee.

10. Golden Parachute Limitation. Notwithstanding anything in this Plan to the contrary, if any payment or benefit an Eligible Employee would receive under this Plan or otherwise in connection with a Change in Control (a "***Payment***") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code and (ii) but for this Section 10, be subject to the excise tax imposed by Section 4999 of the Code (the "***Excise Tax***"), then the Payment shall be equal to the Reduced Amount. The "***Reduced Amount***" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment being subject to the Excise Tax or (y) the entire Payment, whichever of (x) or (y), after taking into account all applicable federal, state and local employment taxes, income taxes and the Excise Tax (all computed at the highest applicable marginal rates), results in the Eligible Employee's receipt, on an after-tax basis, of the greater amount. If a reduction is required, it shall occur in the following order: (A) reduction of cash payments that are not deferred compensation subject to Code Section 409A; (B) reduction of cash payments that are deferred compensation subject to Code Section 409A, in reverse order of payment date; (C) cancellation of accelerated vesting of Awards, in reverse order of grant date; and (D) reduction of continued employee benefits. All determinations under this Section 10 shall be made by a nationally recognized accounting or consulting firm selected and paid by the Company, whose determination shall be final and binding on the Eligible Employee and the Company, absent manifest error. In no event shall the Company or any stockholder be liable to any Eligible Employee for any amount not paid by reason of the operation of this Section 10.

11. Claims Procedures. Normally, an Eligible Employee does not need to present a formal claim to receive benefits payable under this Plan. If any person (the "***Claimant***") believes that benefits are being denied improperly, that this Plan is not being operated properly, that fiduciaries of this Plan have breached their duties, or that the Claimant's legal rights are being violated with respect to this Plan, the Claimant must file a formal claim, in writing, with the Administrator. A formal claim must be filed within one (1) year after the date the Claimant first knew or should have known of the facts on which the claim is based, unless the Administrator in writing consents otherwise. The Administrator has adopted procedures for considering claims (which are set forth in Appendix B), which it may amend from time to time, as it sees fit. These procedures shall comply with all applicable legal requirements, and the Administrator shall provide a Claimant, on request, with a copy of such amended claims procedures. These procedures provide that final and binding arbitration shall be the ultimate means of contesting a denied claim (even if the Administrator or its delegates failed to follow the prescribed procedures with respect to the claim such that the claim was deemed denied). The right to receive benefits under this Plan is contingent on a Claimant using the prescribed claims and arbitration procedures to resolve any claim.

12. Miscellaneous.

    a. Assignment; Non-transferability; Successors. No right of an Eligible Employee to any payment or benefit under this Plan shall be subject to assignment, anticipation, alienation, sale, transfer, pledge, encumbrance, attachment, or garnishment by creditors of the Eligible Employee or of any beneficiary of the Eligible Employee. The Company shall require any successor (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets to expressly assume this Plan and agree to perform the Company's obligations under it. The Company shall likewise require any successor to all or substantially all of the business and/or assets of any Affiliate to expressly assume this Plan as it relates to Eligible Employees employed by that Affiliate. For all purposes under this Plan, the term "***Company***" shall include any successor to the Company's and/or Company's Affiliate's business and/or assets which executes and delivers an assumption agreement or which becomes bound by the terms of the Plan by operation of law. All of an Eligible Employee's rights hereunder shall inure to the benefit of, and be enforceable by, his or her personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.

    b. Withholding. The Company shall have the right to deduct from all payments hereunder all taxes that the Company determines are required by law to be withheld therefrom. Regardless of the amount withheld, the recipient of payments, benefits, or other income (including imputed income) under the Plan shall be solely responsible for all taxes owed with respect to such payments, benefits, and other income.

c. No Right To Employment. Nothing in this Plan shall be construed as giving any person the right to be retained in the employment of the Company, nor shall it affect the right of the Company to dismiss an Eligible Employee without any liability except as required by this Plan.

d. Amendment and Termination. The Company, by action of the Administrator, reserves the right to amend or terminate this Plan at any time, without advance notice to any Eligible Employee and without regard to the effect of the amendment or termination on any Eligible Employee or on any other individual. Any amendment or termination of this Plan will be in writing. Notwithstanding the foregoing, the Company may not, without an Eligible Employee's written consent, terminate this Plan, or amend this Plan in any way that adversely affects the rights of any Eligible Employee, in each case, (i) at any time following a Change in Control, (ii) at any time following the execution of a definitive agreement that, if consummated, would result in a Change in Control (unless that agreement terminates without a Change in Control occurring), or (iii) with effect during the three (3)-month period following an Eligible Employee's termination that would constitute a Qualifying Termination if a Change in Control occurs during such 3-month period; any amendment or termination adopted during the periods described in clauses (ii) and (iii) shall be disregarded in determining the rights of any Eligible Employee whose Qualifying Termination occurs in connection with that Change in Control. Any action of the Company in amending or terminating this Plan will be taken in a non-fiduciary capacity. In no event shall any amendment or termination of this Plan affect the Severance Payments or Benefits payable under this Plan to any Eligible Employee whose Qualifying Termination has occurred prior to the effective date of the amendment or termination of this Plan.

e. Governing Law. This Plan is a welfare plan subject to ERISA, and it shall be interpreted, administered, and enforced in accordance with that law. To the extent that state law is applicable, the validity, construction, and effect of this Plan and any rules and regulations relating to this Plan shall be determined in accordance with the laws of the State of Nevada, without giving effect to principles of conflicts of laws. If any provision hereof shall be held by a court or arbitrator of competent jurisdiction to be invalid and unenforceable, the remaining provisions shall continue to be fully effective.

f. No Duty to Mitigate. No Eligible Employee shall be required to mitigate, by seeking employment or otherwise, the amount of any payment that the Company becomes obligated to make under this Plan, and, except as expressly provided in this Plan, amounts or other benefits to be paid or provided to an Eligible Employee pursuant to this Plan shall not be reduced by reason of the Eligible Employee's obtaining other employment or receiving similar payments or benefits from another employer.

g. Employment At-Will. Nothing contained in this Plan shall give any Eligible Employee the right to be retained in the employment of the Company or shall otherwise modify the employee's at-will employment relationship with the Company. This Plan is not a contract of employment between the Company and any Eligible Employee.

h. Complete Statement of Plan. This Plan document (which incorporates the applicable Appendix(ces) by reference) contains a complete statement of the Plan's terms and supersedes all prior statements with respect to the Plan's terms. No other evidence, whether written or oral, shall be taken into account in interpreting the provisions of the Plan. In the event of a conflict between a provision in this Plan document and any booklet, brochure, presentation, or other communication (whether written or oral), the provision of this Plan document shall control.

i. No Third-Party Beneficiaries. This Plan shall not give any rights or remedies to any person other than Eligible Employees under this Plan (or their estates or beneficiaries, in the event of an eligible employee's death) and the Company.

j. Funding and Payment of Benefits. This Plan shall be maintained in a manner to be considered "unfunded" for purposes of ERISA. The Company shall be required to make payments only as benefits under this Plan become due and payable. No person shall have any right, other than the right of an unsecured general creditor against the Company, with respect to the benefits payable

under this Plan, or which may be payable under this Plan, to any employee. If the Company, acting in its sole discretion, establishes a reserve or other fund associated with this Plan, no person shall have any right to or interest in any specific amount or asset of such reserve or fund by reason of amounts which may be payable to such person under this Plan, nor shall such person have any right to receive any payment under this Plan except as and to the extent expressly provided in this Plan. The assets in any such reserve or fund shall be part of the general assets of the Company, subject to the control of the Company.

k. Notices. Any notice required or permitted by this Plan shall be in writing and shall be delivered as follows with notice deemed given as indicated: (i) by personal delivery when delivered personally; (ii) by overnight courier upon written verification of receipt; (iii) by email upon acknowledgment of receipt; or (iv) by certified or registered U.S. mail, return receipt requested, upon verification of receipt. Notice shall be sent to an Eligible Employee at the most recent address on the Company's personnel records and to the Company at its principal place of business, or such other address as either party may specify in writing.

IN WITNESS WHEREOF, the Company has adopted the Plan effective as of the effective date set forth above.

VISTAGEN THERAPEUTICS, INC.

By: /s/ Shawn K. Singh

Name: Shawn K. Singh

Title: President and Chief Executive Officer

Appendix A

Vistagen Therapeutics, Inc. CHANGE IN CONTROL executive Severance Plan

EXECUTIVE Severance PAYMENTS AND Benefits

Tier	Base Pay Severance Period	Bonus Severance Period	Benefits Continuation Period (COBRA – Medical, Dental and Vision)	Equity Acceleration Benefits
Tier 1 **Chief Executive Officer**	Per Individual Agreement	Per Individual Agreement	Per Individual Agreement	See Section 6(c)
Tier 2 **Chief Officers (other than Chief Executive Officer)**	12 months	12 months	12 months	See Section 6(c)
Tier 3 **Senior Vice Presidents**	6 months	6 months	6 months	See Section 6(c)
Tier 4 **Vice Presidents**	4 months	4 months	4 months	See Section 6(c)

APPENDIX B

Detailed Claims Procedures

Claims for benefits under the Plan shall be administered in accordance with Section 503 of ERISA and the Department of Labor Regulations thereunder. The Administrator shall make all determinations as to the rights of any participant or other person who makes a claim for benefits under the Plan (a "***Claimant***"). A Claimant may authorize a representative to act on his or her behalf with respect to any claim under the Plan. All procedures shall be designed to afford a Claimant full and fair consideration of his or her claim and appeal.

Initial Claims

All claims shall be presented to the Administrator in writing addressed to the Administrator at the address set forth under "Administrative Information" below. The deadline to submit a claim is set forth in Section 11 of the Plan. If a claim is not timely submitted, it shall be treated as having been irrevocably waived.

Claims Decisions

Within 90 days after receiving a claim, a claims official appointed by the Administrator shall consider the claim and issue his or her determination thereon in writing. If the Administrator or claims official determines that an extension of time is necessary, the claims official may extend the determination period for up to an additional 90 days by giving the Claimant written notice indicating the special circumstances requiring the extension of time prior to the termination of the initial 90 day period and the date by which the Administrator expects to render a decision.

If the claim is granted, the benefits or relief the Claimant seeks shall be provided. If the claim is wholly or partially denied, the claims official shall provide the Claimant with written notice of the denial, setting forth, in a manner calculated to be understood by the Claimant: (1) the specific reason or reasons for the denial; (2) specific references to the Plan provisions on which the denial is based; (3) a description of any additional material or information necessary for the Claimant to perfect the claim, together with an explanation of why the material or information is necessary; and (4) an explanation of the procedures for appealing denied claims and time limits applicable to such procedures, including a statement of the Claimant's right to bring an action under Section 502(a) of ERISA after receiving a final adverse benefit determination upon appeal. If the Claimant can establish that the claims official has failed to respond to the claim in a timely manner, the Claimant may treat the claim as having been denied by the claims official.

Appeals of Denied Claims

Each Claimant shall have the opportunity to appeal the claims official's denial of a claim. All appeals shall be presented to the Administrator in writing at the address set forth above. The appeal will be reviewed by the Administrator or its designee (the "***appeals official***"). A Claimant must appeal a denied claim within 60 days after receipt of written notice of denial of the claim, or within 60 days after it was due if the Claimant did not receive it by its due date. The Claimant shall have the opportunity to submit written comments, documents, records and other information relating to the Claimant's claim. The Claimant (or the Claimant's duly authorized representative) shall be provided upon request and free of charge, reasonable access to, and copies of, all documents, records and other information relevant to the Claimant's claim. The appeals official shall take into account during its review all comments, documents, records and other information submitted by the Claimant relating to the claim, without regard to whether such information was submitted or considered in the initial benefits review. Any claims that the Claimant does not pursue in good faith through the appeals stage, such as by failing to file a timely appeal request, shall be treated as having been irrevocably waived.

Appeals Decisions

The decision by the appeals official shall be made not later than 60 days after the written appeal is received by the Administrator, however, if the appeals official determines that an extension of time is necessary, the appeals official may extend the determination period for up to an additional 60 days by giving the Claimant written notice

prior to the termination of the initial 60 day period indicating the special circumstances requiring the extension of time and the date by which a determination on appeal is expected to be rendered.

However, if the appeals official is a committee that meets at least quarterly, then the decision by the appeals official shall be made not later than the date of the meeting that immediately follows the Plan's receipt of an appeal request, unless the appeal request is filed within 30 days preceding the date of such meeting. In such case, a benefit determination may be made by no later than the date of the second meeting following the Plan's receipt of the appeal request. If special circumstances require a further extension of time for processing, a benefit determination shall be rendered no later than the third meeting of the appeals official following the Plan's receipt of the appeal request. If such an extension of time for review is required, the appeals official shall provide the Claimant with written notice of the extension, describing the special circumstances and the date as of which the benefit determination will be made, prior to the commencement of the extension. The appeals official shall notify the Claimant of the benefit determination as soon as possible but not later than 5 days after it has been made.

The appeal decision shall be in writing, shall be set forth in a manner calculated to be understood by the Claimant and shall include the following: (1) the specific reason or reasons for the denial; (2) specific references to the Plan provisions on which the denial is based; (3) a statement that the Claimant is entitled to receive, upon request and free of charge, reasonable access to, and copies of, all documents, records and other information relevant to the Claimant's claim; and (4) a statement of the employee's right to bring an action under Section 502(a) of ERISA. If a Claimant does not receive the appeal decision by the date it is due, the Claimant may deem the appeal to have been denied. Subject to applicable law and the provisions of Section 4(b) of this Plan (including, without limitation, the de novo standard of review applicable upon or after a Change in Control), any decision made in accordance with the claims procedures in this Appendix B is final and binding on all parties and shall be given the maximum possible deference allowed by law.

Exhaustion; Arbitration

No arbitration or other proceeding may be commenced to recover benefits under the Plan until the claim and appeal rights described in the Plan have been exhausted and the Plan benefits requested in such appeal have been denied in whole or in part; provided, however, that if the Plan fails to establish or follow claims procedures consistent with the requirements of 29 C.F.R. § 2560.503-1, a Claimant shall be deemed to have exhausted the administrative remedies available under the Plan and shall be entitled to pursue arbitration on the basis that the Plan has failed to provide a reasonable claims procedure. Any dispute, controversy, or claim relating to benefits under the Plan that remains after exhaustion of those procedures shall be resolved exclusively by final and binding arbitration before a single arbitrator, administered by the American Arbitration Association under its employment dispute resolution rules, with the arbitration held at South San Francisco, CA. The Company shall pay all fees and costs unique to arbitration. The arbitrator shall apply the standard of review required by the Plan and applicable law (including, for the avoidance of doubt, the de novo standard of review set forth in Section 4(b) of the Plan when applicable), and the evidence presented may be strictly limited to the evidence timely presented to the Administrator and the appeals official; provided, however, that when the de novo standard of review set forth in Section 4(b) applies, the arbitrator shall not be limited to the administrative record and may consider additional evidence as appropriate. Judgment on the award may be entered in any court of competent jurisdiction, and nothing in the Plan limits a party's right to compel arbitration or to enforce an award. Any arbitration must be commenced by the earlier of: (a) one year after the final decision regarding the appeal or (b) one year after the participant or other Claimant began receiving payment of the Plan benefits at issue.

APPENDIX C
Statement of ERISA Rights

Eligible Employees are entitled to certain rights and protections under ERISA. ERISA provides that all Eligible Employees shall be entitled to:

Receive Information About Your Plan and Benefits

1. Examine, without charge, at the Administrator's office and at other specified locations, such as worksites, all documents governing the Plan and a copy of the latest annual report (Form 5500 Series) filed by the Plan with the U.S. Department of Labor and available at the Public Disclosure Room of the Employee Benefits Security Administration.

2. Obtain, upon written request to the Administrator, copies of documents governing the operation of the Plan and copies of the latest annual report (Form 5500 Series) and any updated summary plan description. The Administrator may make a reasonable charge for the copies.

3. Receive a summary of the Plan's annual financial report, if any. The Administrator is required by law to furnish each Eligible Employee with a copy of this summary annual report.

Prudent Actions by Plan Fiduciaries

In addition to creating rights for Eligible Employees, ERISA imposes duties upon the people who are responsible for the operation of the Plan. The people who operate the Plan, called "fiduciaries" of the Plan, have a duty to do so prudently and in the interest of the Eligible Employees and their beneficiaries. No one, including any employer or any other person, may fire an Eligible Employee or otherwise discriminate against an Eligible Employee in any way to prevent the Eligible Employee from obtaining a benefit under this Plan or exercising the Eligible Employee's rights under ERISA.

Enforce Your Rights

If an Eligible Employee's claim for a benefit under this Plan is denied or ignored, in whole or in part, the Eligible Employee has a right to know why this was done, to obtain copies of documents relating to the decision without charge, and to appeal any denial, all within certain time schedules. Under ERISA, there are steps the Eligible Employee can take to enforce the above rights. For instance, if the Eligible Employee requests a copy of Plan documents or the latest annual report from the Plan and do not receive them within 30 days, the Eligible Employee may file suit in a Federal court. In such a case, the court may require the Administrator to provide the materials and pay the Eligible Employee up to $110 a day until the Eligible Employee receives the materials, unless the materials were not sent because of reasons beyond the control of the Administrator. If the Eligible Employee has a claim for benefits which is denied or ignored, in whole or in part, the Eligible Employee may file suit in a state or Federal court. In addition, if the Eligible Employee disagrees with the Plan's decision or lack thereof concerning the qualified status of a domestic relations order or a medical child support order, the Eligible Employee may file suit in Federal court. If it should happen that fiduciaries of the Plan misuse the Plan's money, or if the Eligible Employee is discriminated against for asserting the Eligible Employee's rights, the Eligible Employee may seek assistance from the U.S. Department of Labor, or the Eligible Employee may file suit in a Federal court. The court will decide who should pay court costs and legal fees. If the Eligible Employee is successful, the court may order the person the Eligible Employee has sued to pay these costs and fees. If the Eligible Employee loses, the court may order the Eligible Employee to pay these costs and fees (for example, if it finds the Eligible Employee's claim is frivolous). Under the Plan, benefit claims and appeals must be pursued through the claims, appeal, and arbitration procedures described in Section 11 of the Plan and Appendix B before any legal action is filed.

Assistance with Your Questions

If an Eligible Employee has any questions about the Plan, the Eligible Employee should contact the Administrator. If an Eligible Employee has any questions about this statement or about the Eligible Employee's rights under ERISA, or if an Eligible Employee needs assistance in obtaining documents from the Administrator, the Eligible

Employee should contact the nearest office of the Employee Benefits Security Administration, U.S. Department of Labor, listed in the Eligible Employee's telephone directory or the Division of Technical Assistance and Inquiries, Employee Benefits Security Administration, U.S. Department of Labor, 200 Constitution Avenue N.W., Washington, D.C. 20210. The Eligible Employee may also obtain certain publications about the Eligible Employee's rights and responsibilities under ERISA by calling the publications hotline of the Employee Benefits Security Administration.

ADMINISTRATIVE INFORMATION

Name of Plan:	Vistagen Therapeutics, Inc. Change in Control Severance Plan
Plan Sponsor and Administrator, including address and telephone:	Vistagen Therapeutics, Inc. 343 Allerton Avenue South San Francisco, CA 94080
Name and address of person designated as agent for service of process:	SVP, Human Resources Vistagen Therapeutics, Inc. Service of legal process may also be made upon the Administrator.
Direct questions regarding the plan to:	SVP, Human Resources Vistagen Therapeutics, Inc.
Type of Administration:	Self-Administered
Basis on which Plan records are kept:	Calendar year: January 1 to December 31
Type of Plan:	Unfunded welfare benefit severance plan
Plan Number:	
EIN:	
Funding:	The Plan is unfunded. Plan benefits are paid as needed from the general assets of the Company.

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.

November 13, 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.

November 13, 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 September 30, 2026, 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.

November 13, 2026

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

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