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

# FORM 10-Q

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

**For the quarterly period ended March 31, 2026**

**or**

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

**Commission File Number: 000-50768**

# ACADIA PHARMACEUTICALS INC.

**(Exact Name of Registrant as Specified in Its Charter)**

| **Delaware** | **06-1376651** |
|---|---|
| **(State of Incorporation)** | **(I.R.S. Employer Identification No.)** |
| **12830 El Camino Real, Suite 400**<br>**San Diego, California** | **92130** |
| **(Address of Principal Executive Offices)** | **(Zip Code)** |

**(858) 558-2871**
**(Registrant's Telephone Number, Including Area Code)**

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

| Title of Each Class | Trading Symbol | Name of Each Exchange on Which Registered |
|---|---|---|
| **Common Stock, par value $0.0001 per share** | **ACAD** | **The Nasdaq Stock Market LLC** |

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

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

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

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

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

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

Total shares of registrant's common stock outstanding as of the close of business on April 29, 2026:

| Class | Number of Shares Outstanding |
|---|---|
| Common Stock, $0.0001 par value | 171,235,870 |

**ACADIA PHARMACEUTICALS INC.**

**FORM 10-Q**

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## PART I. FINANCIAL INFORMATION

**ITEM 1. FINANCIAL STATEMENTS**

### ACADIA PHARMACEUTICALS INC.
### CONDENSED CONSOLIDATED BALANCE SHEETS
### (in thousands, except share and per share amounts)

| | March 31, 2026 | December 31, 2025 |
|---|---|---|
| | (unaudited) | |
| **Assets** | | |
| Cash and cash equivalents | $ 282,212 | $ 177,695 |
| Investment securities, available-for-sale | 569,246 | 641,991 |
| Accounts receivable, net | 135,350 | 121,457 |
| Interest and other receivables | 13,034 | 26,774 |
| Inventory | 31,574 | 34,670 |
| Prepaid expenses | 64,600 | 59,526 |
| Total current assets | 1,096,016 | 1,062,113 |
| Property and equipment, net | 14,652 | 7,511 |
| Operating lease right-of-use assets | 46,274 | 47,354 |
| Intangible assets, net | 106,171 | 108,893 |
| Restricted cash | 7,846 | 7,845 |
| Long-term inventory | 80,719 | 76,704 |
| Deferred tax assets | 249,624 | 249,879 |
| Other assets | 3,928 | 3,896 |
| Total assets | $ 1,605,230 | $ 1,564,195 |
| **Liabilities and stockholders' equity** | | |
| Accounts payable | $ 12,246 | $ 10,903 |
| Accrued liabilities | 293,278 | 266,211 |
| Total current liabilities | 305,524 | 277,114 |
| Operating lease liabilities | 39,003 | 40,554 |
| Other long-term liabilities | 12,637 | 19,137 |
| Total liabilities | 357,164 | 336,805 |
| Commitments and contingencies (Note 9) | | |
| Stockholders' equity: | | |
| Preferred stock, $0.0001 par value; 5,000,000 shares authorized at March 31, 2026 and December 31, 2025; no shares issued and outstanding at March 31, 2026 and December 31, 2025 | — | — |
| Common stock, $0.0001 par value; 225,000,000 shares authorized at March 31, 2026 and December 31, 2025; 171,086,205 shares and 170,309,376 shares issued and outstanding at March 31, 2026 and December 31, 2025, respectively | 16 | 16 |
| Additional paid-in capital | 3,058,362 | 3,039,315 |
| Accumulated deficit | (1,809,749) | (1,813,386) |
| Accumulated other comprehensive (loss) income | (563) | 1,445 |
| Total stockholders' equity | 1,248,066 | 1,227,390 |
| Total liabilities and stockholders' equity | $ 1,605,230 | $ 1,564,195 |

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

**ACADIA PHARMACEUTICALS INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**
**(in thousands, except per share amounts)**
**(Unaudited)**

| | Three Months Ended March 31, | |
|---|---|---|
| | 2026 | 2025 |
| **Revenues** | | |
| Product sales, net | $ 268,062 | $ 244,317 |
| Total revenues | 268,062 | 244,317 |
| **Operating expenses** | | |
| Cost of product sales | 24,791 | 20,392 |
| Research and development | 76,868 | 78,265 |
| Selling, general and administrative | 171,019 | 126,370 |
| Total operating expenses | 272,678 | 225,027 |
| (Loss) income from operations | (4,616) | 19,290 |
| Interest income, net | 8,055 | 7,901 |
| Other income | 542 | 588 |
| Income before income taxes | 3,981 | 27,779 |
| Income tax expense | 344 | 8,792 |
| Net income | $ 3,637 | $ 18,987 |
| Earnings per share: | | |
| Basic | $ 0.02 | $ 0.11 |
| Diluted | $ 0.02 | $ 0.11 |
| Weighted average common shares outstanding: | | |
| Basic | 170,517 | 166,808 |
| Diluted | 172,706 | 167,668 |

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

**ACADIA PHARMACEUTICALS INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME**
**(in thousands)**
**(Unaudited)**

| | Three Months Ended March 31, | |
|---|---|---|
| | 2026 | 2025 |
| Net income | $ 3,637 | $ 18,987 |
| Other comprehensive income (loss), net of income taxes: | | |
| Unrealized (loss) gain on investment securities | (2,054) | 150 |
| Foreign currency translation adjustments | 46 | (5) |
| Comprehensive income | $ 1,629 | $ 19,132 |

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

**ACADIA PHARMACEUTICALS INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**
**(in thousands)**
**(Unaudited)**

| | Three Months Ended March 31, | |
|---|---|---|
| | 2026 | 2025 |
| **Cash flows from operating activities** | | |
| Net income | $ 3,637 | $ 18,987 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | |
| Stock-based compensation | 14,698 | 11,380 |
| Amortization of premiums and accretion of discounts on investment securities | (453) | (2,116) |
| Amortization of intangible assets | 2,722 | 2,722 |
| Depreciation | 271 | 229 |
| Deferred Income Taxes | (94) | — |
| Changes in operating assets and liabilities: | | |
| Accounts receivable, net | (13,893) | (7,004) |
| Interest and other receivables | 13,740 | (2,015) |
| Inventory | 78 | (10,453) |
| Prepaid expenses | (5,074) | 2,978 |
| Other assets | (32) | (585) |
| Operating lease right-of-use assets | 2,164 | 2,137 |
| Accounts payable | 1,343 | 1,903 |
| Accrued liabilities | 23,557 | (116) |
| Operating lease liabilities | (2,183) | 369 |
| Long-term liabilities | (6,500) | 1,907 |
| Net cash provided by operating activities | 33,981 | 20,323 |
| **Cash flows from investing activities** | | |
| Purchases of investment securities | (15,007) | (156,011) |
| Maturity of investment securities | 86,500 | 130,800 |
| Payment of milestone and contingent payments in connection with asset acquisition | — | (98,838) |
| Purchases of property and equipment | (5,212) | — |
| Net cash provided by (used in) investing activities | 66,281 | (124,049) |
| **Cash flows from financing activities** | | |
| Proceeds from issuance of common stock, net of issuance costs | 4,231 | 1,838 |
| Net cash provided by financing activities | 4,231 | 1,838 |
| Effect of exchange rate changes on cash | 25 | (5) |
| Net increase (decrease) in cash, cash equivalents and restricted cash | 104,518 | (101,893) |
| **Cash, cash equivalents and restricted cash** | | |
| Beginning of period | 185,540 | 328,359 |
| End of period | $ 290,058 | $ 226,466 |
| **Supplemental disclosure of noncash information:** | | |
| Accrued inventory purchases | $ 879 | $ 759 |
| Property and equipment purchases in accrued liabilities | $ 2,200 | $ — |
| Stock-based compensation capitalized | $ 118 | $ 94 |

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

**ACADIA PHARMACEUTICALS INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**
**(in thousands)**
**(Unaudited)**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2026** | **2025** |
| **Total stockholders' equity, beginning balances** | $ 1,227,390 | $ 732,793 |
| Common stock: | | |
| Beginning balance | 16 | 16 |
| Ending balance | 16 | 16 |
| Additional paid-in capital: | | |
| Beginning balance | 3,039,315 | 2,936,871 |
| Issuance of common stock from exercise of stock options and units | 4,231 | 1,838 |
| Stock-based compensation | 14,816 | 11,474 |
| Ending balance | 3,058,362 | 2,950,183 |
| Accumulated deficit: | | |
| Beginning balance | (1,813,386) | (2,204,386) |
| Net income | 3,637 | 18,987 |
| Ending balance | (1,809,749) | (2,185,399) |
| Other comprehensive income (loss): | | |
| Beginning balance | 1,445 | 292 |
| Other comprehensive (loss) income | (2,008) | 145 |
| Ending balance | (563) | 437 |
| **Total stockholders' equity, ending balances** | $ 1,248,066 | $ 765,237 |

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

**ACADIA PHARMACEUTICALS INC.**
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**
**(Unaudited)**

## 1. Organization and Business

Acadia Pharmaceuticals Inc. (the Company), based in San Diego, California, is a biopharmaceutical company focused on turning scientific promise into meaningful innovation that makes the difference for underserved neurological and rare disease communities around the world.

In April 2016, the U.S. Food and Drug Administration (FDA) approved the Company's first drug, NUPLAZID® (pimavanserin), for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis (PDP). NUPLAZID became available for prescription in the United States in May 2016.

In March 2023, the FDA approved the Company's second drug, DAYBUE® (trofinetide), for the treatment of Rett syndrome. DAYBUE became available for prescription in the United States in April 2023.

In October 2024, Health Canada granted marketing authorization of DAYBUE® (trofinetide) for the treatment of Rett syndrome in adult and pediatric patients 2 years of age and older.

In December 2025, the FDA approved DAYBUE® STIX (trofinetide), a dye- and preservative-free powder formulation, for the treatment of Rett syndrome in adult and pediatric patients 2 years and older. DAYBUE STIX was available on a limited basis starting in the first quarter of 2026 followed by a broader launch early in the second quarter of 2026.

In December 2025, the Ministry of Health in Israel approved DAYBUE® (trofinetide) for the treatment of Rett syndrome in adults and pediatric patients 2 years of age and older and weighing at least 9 kg.

## 2. Basis of Presentation and Significant Accounting Policies

*Basis of Presentation*

The accompanying unaudited condensed consolidated financial statements of the Company should be read in conjunction with the audited financial statements and notes thereto as of and for the year ended December 31, 2025 included in the Company's Annual Report on Form 10-K (Annual Report) filed with the Securities and Exchange Commission (the SEC). The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, since they are interim statements, the accompanying unaudited condensed consolidated financial statements do not include all of the information and notes required by GAAP for complete financial statements. In the opinion of management, the accompanying unaudited condensed consolidated financial statements reflect all adjustments (consisting of normal recurring adjustments) that are necessary for a fair statement of the financial position, results of operations, cash flows, and stockholders' equity for the interim periods presented. Interim results are not necessarily indicative of results for a full year. The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the unaudited condensed consolidated financial statements and the accompanying notes. Actual results could differ materially from those estimates.

*Risk and Uncertainties*

Global economic and business activities continue to face widespread macroeconomic uncertainties, including inflation and monetary supply shifts, recession risks, volatility and disruptions in global credit and financial markets, potential disruptions from geopolitical and military conflicts and related sanctions and tariffs and trade tensions. The Company continues to actively monitor the impact of these macroeconomic factors on its financial condition, liquidity, operations and workforce. The extent of the impact of these factors on the Company's operational and financial performance, including its ability to execute its business strategies and initiatives in the expected time frame, will depend on future developments, which are uncertain and cannot be predicted; however, any continued or renewed disruption resulting from these factors could negatively impact the Company's business.

*Cash, Cash Equivalents and Restricted Cash*

The Company considers all highly liquid investments with a maturity date at the date of purchase of three months or less to be cash equivalents.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the unaudited condensed consolidated statements of cash flows that sum to the total of the same such amounts shown in the unaudited condensed consolidated statements of cash flows (in thousands):

| | March 31, 2026 | | March 31, 2025 | |
|---|---|---|---|---|
| | Beginning of period | End of period | Beginning of period | End of period |
| Cash and cash equivalents | $ 177,695 | $ 282,212 | $ 319,589 | $ 217,696 |
| Restricted cash | 7,845 | 7,846 | 8,770 | 8,770 |
| Total cash, cash equivalents and restricted cash shown in the unaudited condensed consolidated statements of cash flows | $ 185,540 | $ 290,058 | $ 328,359 | $ 226,466 |

*Accounts Receivable*

Accounts receivable are recorded net of customer allowances for distribution fees, prompt payment discounts, chargebacks, and credit losses. Allowances for distribution fees, prompt payment discounts and chargebacks are based on contractual terms. The Company estimated the current expected credit losses of its accounts receivable by assessing the risk of loss and available relevant information about collectability, including historical credit losses, existing contractual payment terms, actual payment patterns of its customers, individual customer circumstances, and reasonable and supportable forecast of economic conditions expected to exist throughout the contractual life of the receivable. Based on its assessment, as of March 31, 2026, the Company determined that an allowance for credit loss was not required.

*Inventory*

Inventory is stated at the lower of cost or net realizable value. The Company uses standard cost method to determine the cost basis for its inventory, which approximates actual cost under the first-in, first-out method. Inventory consists of raw material, work in process, and finished goods, including third-party manufacturing costs, freight, and indirect overhead costs. The Company capitalizes inventory costs associated with its products upon regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed. Prior to FDA approval of NUPLAZID in April 2016 and DAYBUE in March 2023, all costs related to the manufacturing of NUPLAZID and DAYBUE were charged to research and development expense in the period incurred. The Company periodically reviews inventory and reduces the carrying value of items to net realizable value for potentially excess, dated or obsolete inventory based on an analysis of forecasted demand compared to quantities on hand and any firm purchase orders, as well as product shelf life.

*Revenues*

The Company operates in one business segment. Results of its operations are reported on a consolidated basis for purposes of segment reporting, consistent with internal management reporting. Revenues consist of net product sales to customers, substantially all of which are sales in North America. Revenues by product are as follows (in thousands):

| | Three Months Ended March 31, | |
|---|---|---|
| | 2026 | 2025 |
| NUPLAZID | $ 166,924 | $ 159,721 |
| DAYBUE | 101,138 | 84,596 |
| Product sales, net | $ 268,062 | $ 244,317 |

*License Fees and Royalties*

The Company expenses amounts paid to acquire licenses associated with products under development when the ultimate recoverability of the amounts paid is uncertain and the technology has no alternative future use when acquired. Acquisitions of technology licenses are charged to expense or capitalized based upon management's assessment regarding the ultimate recoverability of the amounts paid and the potential for alternative future use. The Company has determined that technological feasibility for its product candidates is reached when the requisite regulatory approvals are obtained to make the product available for sale.

Pursuant to the license agreement with Neuren Pharmaceuticals Limited (Neuren), the Company has capitalized a total of $138.8 million as intangible assets following the FDA approval, sale of DAYBUE and sale of a Rare Pediatric Disease Priority Review Voucher (PRV), as disclosed in Note 9. The intangible assets are amortized on a straight-line basis over the estimated useful life of the licensed patents through early 2036. The Company recorded total amortization expense related to these intangible assets of $2.7 million each for the three months ended March 31, 2026 and 2025. As of March 31, 2026, estimated future amortization expense related to the Company's intangible assets was $8.2 million for the remainder of 2026, and $10.9 million for each subsequent year.

Royalties incurred in connection with the Company's license agreement with Neuren, as disclosed in Note 9, are expensed to cost of product sales as revenue from product sales is recognized.

*Intangible Assets*

Finite-lived intangible assets are recorded at cost, net of accumulated amortization, and, if applicable, impairment charges. Amortization of finite-lived intangible assets is recorded over the assets' estimated useful lives on a straight-line basis or based on the pattern in which economic benefits are consumed, if reliably determinable. We review our finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If such intangible assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of intangible assets exceeds the estimated fair value of the intangible assets. No impairment loss was recorded on intangible assets during the three months ended March 31, 2026 and 2025.

*Segment Reporting*

The Company uses "the management approach" in determining reportable operating segments. The management approach considers the internal organization and reporting used by the Company's Chief Operating Decision Maker (CODM) for making operating decisions and assessing performance as the source for determining the Company's reportable segments. The Company determines and presents operating segments based on the information that is internally provided to the Chief Executive Officer (CEO), who is considered the Company's CODM, in accordance with ASC Topic 280*, Segment Reporting*. The Company has determined that it operates as a single business segment, which is the development and commercialization of innovative medicines. Refer to Note 12 – Segment Reporting for further information related to the segment.

**3. Earnings Per Share**

Basic earnings per share is calculated by dividing the net income by the weighted average number of common shares outstanding for the period. Diluted earnings per share is computed by dividing the net income by the weighted average number of common shares and common stock equivalents outstanding for the period determined using the treasury stock method. For purposes of diluted earnings per share calculation, equity awards and employee stock purchase plan rights are considered to be common stock equivalents.

| *(in thousands, except per share data)* | Three Months Ended March 31, 2026 | 2025 |
|---|---|---|
| Net income - basic and diluted | $ 3,637 | $ 18,987 |
| Weighted average shares outstanding: | | |
| Basic | 170,517 | 166,808 |
| Effect of potentially dilutive common shares from: | | |
| Equity awards | 2,065 | 792 |
| Employee stock purchase plan rights | 124 | 68 |
| Diluted | 172,706 | 167,668 |
| | | |
| Earnings per share: | | |
| Basic | $ 0.02 | $ 0.11 |
| Diluted | $ 0.02 | $ 0.11 |
| | | |
| Potentially dilutive shares excluded from per share amounts as their effect would have been anti-dilutive | 11,650 | 18,029 |

**4. Stock-Based Compensation**

The following table summarizes the total stock-based compensation expense included in the Company's unaudited condensed consolidated statements of operations for the periods presented (in thousands):

| | Three Months Ended March 31, 2026 | 2025 |
|---|---|---|
| Cost of product sales | $ 328 | $ 334 |
| Research and development | 4,142 | 3,433 |
| Selling, general and administrative | 10,228 | 7,613 |
| | $ 14,698 | $ 11,380 |

The fair value of each employee stock option and each employee stock purchase plan right granted is estimated on the grant date under the fair value method using the Black-Scholes valuation model, which requires the Company to make a number of assumptions including the estimated expected life of the award and related volatility. The fair value of restricted stock units is estimated based on the market price of the Company's common stock on the date of grant. The estimated fair values of stock options, purchase plan rights, and restricted stock units are then expensed over the requisite service period, which is generally the vesting period. For restricted stock units requiring satisfaction of both market and service conditions, the estimated fair values are generally expensed over the longest of the explicit, implicit and derived service periods. Through 2023, the Company granted performance stock units that vest upon the achievement of certain pre-defined company-specific performance-based criteria. Expense related to these performance stock units is recognized ratably over the expected performance period once the pre-defined performance-based criteria for vesting becomes probable and can vest up to 200 percent of the target number of shares granted. The fair value of these performance stock units are estimated based on the closing market price of the Company's common stock on the date of grant. Beginning in 2024, the structure of the performance stock unit design was revised with a rTSR approach such that awards are earned for the Company's rTSR performance over three-year measurement periods relative to a peer group of companies and the actual numbers of performance stock units that will vest at the end of the performance period may be anywhere from zero to 150 percent of the target number of shares granted. The fair value of these performance stock units is estimated using a Monte Carlo model because the performance target is based on a market condition. Expense related to these performance stock units are recognized ratably over the three-year measurement period.

## 5. Balance Sheet Details

Inventory consisted of the following (in thousands):

| | March 31, 2026 | December 31, 2025 |
|---|---|---|
| Finished goods | $ 33,170 | $ 25,952 |
| Work in process | 4,793 | 2,638 |
| Raw material | 74,330 | 82,784 |
| | $ 112,293 | $ 111,374 |
| Reported as: | | |
| Inventory | $ 31,574 | $ 34,670 |
| Long-term inventory | 80,719 | 76,704 |
| Total | $ 112,293 | $ 111,374 |

Amount reported as long-term inventory primarily consists of raw materials as of March 31, 2026 and December 31, 2025.

Accrued liabilities consisted of the following (in thousands):

| | March 31, 2026 | December 31, 2025 |
|---|---|---|
| Accrued sales allowances | $ 160,804 | $ 140,862 |
| Accrued consulting and professional fees | 43,448 | 29,843 |
| Accrued compensation and benefits | 31,429 | 45,579 |
| Accrued research and development services | 19,284 | 19,094 |
| Current portion of lease liabilities | 11,791 | 11,633 |
| Accrued royalties | 10,399 | 13,314 |
| Other | 16,123 | 5,886 |
| | $ 293,278 | $ 266,211 |

## 6. Investments

The carrying value and amortized cost of the Company's investments, summarized by major security type, consisted of the following (in thousands):

| | March 31, 2026 | | | |
|---|---|---|---|---|
| | Amortized Cost | Unrealized Gains | Unrealized Losses | Estimated Fair Value |
| U.S. Treasury notes | $ 375,342 | $ 379 | $ (237) | $ 375,484 |
| Government sponsored enterprise securities | 194,119 | 42 | (399) | 193,762 |
| | $ 569,461 | $ 421 | $ (636) | $ 569,246 |

| | December 31, 2025 | | | |
|---|---|---|---|---|
| | Amortized Cost | Unrealized Gains | Unrealized Losses | Estimated Fair Value |
| U.S. Treasury notes | $ 429,260 | $ 1,291 | $ — | $ 430,551 |
| Government sponsored enterprise securities | 211,239 | 258 | (57) | 211,440 |
| | $ 640,499 | $ 1,549 | $ (57) | $ 641,991 |

The Company has classified all of its available-for-sale investment securities as current assets on its unaudited condensed consolidated balance sheets based on the highly liquid nature of the investment securities and because these investment securities are considered available for use in current operations. The following table summarizes the contract maturity of the available-for-sale securities:

| | March 31, 2026 | December 31, 2025 |
|---|---|---|
| One year or less | 59% | 51% |
| After one year but within two years | 41% | 49% |
| Total | 100% | 100% |

At March 31, 2026 and December 31, 2025, the Company had 37 and 18 available-for-sale investment securities, respectively, in an unrealized loss position. The following table presents gross unrealized losses and fair value for those available-for-sale investment securities that were in an unrealized loss position as of March 31, 2026 and December 31, 2025, aggregated by investment category and length of time that the individual securities have been in a continuous loss position (in thousands):

| | Less Than 12 Months | | 12 Months or Greater | | Total | |
|---|---|---|---|---|---|---|
| | Estimated Fair Value | Unrealized Losses | Estimated Fair Value | Unrealized Losses | Estimated Fair Value | Unrealized Losses |
| **March 31, 2026** | | | | | | |
| U.S. Treasury notes | $ 113,632 | $ (237) | $ — | $ — | $ 113,632 | $ (237) |
| Government sponsored enterprise securities | 157,845 | (399) | — | — | 157,845 | (399) |
| Total | $ 271,477 | $ (636) | $ — | $ — | $ 271,477 | $ (636) |

| | Less Than 12 Months | | 12 Months or Greater | | Total | |
|---|---|---|---|---|---|---|
| | Estimated Fair Value | Unrealized Losses | Estimated Fair Value | Unrealized Losses | Estimated Fair Value | Unrealized Losses |
| **December 31, 2025** | | | | | | |
| Government sponsored enterprise securities | $ 91,799 | $ (57) | $ — | $ — | $ 91,799 | $ (57) |
| Total | $ 91,799 | $ (57) | $ — | $ — | $ 91,799 | $ (57) |

At each reporting date, the Company performs an evaluation of impairment to determine if any unrealized losses are the result of credit losses. Impairment is assessed at the individual security level. Factors considered in determining whether a loss resulted from a credit loss or other factors include the Company's intent and ability to hold the investment until the recovery of its amortized cost basis, the extent to which the fair value is less than the amortized cost basis, the length of time and extent to which fair value has been less than the cost basis, the financial condition of the issuer, any historical failure of the issuer to make scheduled interest or principal payments, any changes to the rating of the security by a rating agency, any adverse legal or regulatory events affecting the issuer or issuer's industry, any significant deterioration in economic conditions.

As of March 31, 2026, the Company did not intend to sell the investments in unrealized loss position and it was unlikely that the Company will be required to sell the investments before the recovery of their amortized cost basis. The Company has not historically experienced significant losses on its investments. Based on its evaluation, the Company determined its year-to-date credit losses related to its available-for-sale securities were immaterial at March 31, 2026.

**7. Fair Value Measurements**

The Company's investments include cash equivalents and available-for-sale investment securities consisting of money market funds, U.S treasury notes, and government sponsored enterprises in accordance with the Company's investment policy. The Company's investment policy defines allowable investment securities and establishes guidelines relating to credit quality, diversification, and maturities of its investments to preserve principal and maintain liquidity. All investment securities have a credit rating of at least Aa3/AA- or better, or P-1/A-1 or better, as determined by Moody's Investors Service or Standard & Poor's.

The Company's cash equivalents and available-for-sale investment securities are classified within the fair value hierarchy as defined by authoritative guidance. The Company's investment securities classified as Level 1 are valued using quoted market prices. The Company obtains the fair value of its Level 2 financial instruments from third-party pricing services. The pricing services utilize industry standard valuation models whereby all significant inputs, including benchmark yields, reported trades, broker/dealer quotes, issuer spreads, bids, offers, or other market-related data, are observable. The Company validates the prices provided by the third-party pricing services by reviewing their pricing methods and matrices, and obtaining market values from other pricing sources. After completing the validation procedures, the Company did not adjust or override any fair value measurements provided by these pricing services as of March 31, 2026 and December 31, 2025.

The Company has not transferred any investment securities between the classification levels.

The recurring fair value measurements of the Company's financial assets and liabilities measured at March 31, 2026 and December 31, 2025 consisted of the following (in thousands):

| | | Fair Value Measurements at Reporting Date Using | | |
|---|---|---|---|---|
| | March 31, 2026 | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| ***Assets*** | | | | |
| Money market fund | $ 102,834 | $ 102,834 | $ — | $ — |
| U.S. Treasury notes | 375,484 | 375,484 | — | — |
| Government sponsored enterprise securities | 193,762 | — | 193,762 | — |
| Total | $ 672,080 | $ 478,318 | $ 193,762 | $ — |

| | | Fair Value Measurements at Reporting Date Using | | |
|---|---|---|---|---|
| | December 31, 2025 | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| ***Assets*** | | | | |
| Money market fund | $ 24,834 | $ 24,834 | $ — | $ — |
| U.S. Treasury notes | 430,551 | 430,551 | — | — |
| Government sponsored enterprise securities | 211,440 | — | 211,440 | — |
| Total | $ 666,825 | $ 455,385 | $ 211,440 | $ — |

**8. Stockholders' Equity**

***Performance Stock Units***

In March 2024, the Company began to issue performance stock units (PSU) with a market condition that are earned based on the Company's rTSR as compared to a peer group of companies measured over a three-year performance period and continued employment through the performance period. Depending on the actual performance over the measurement period, a rTSR PSU award recipient could receive up to 150% of the granted award. The grant date fair value of such awards is estimated using a Monte Carlo simulation, which includes assumptions such as expected volatility, risk-free interest rate and dividend yield. These unobservable inputs represent a Level 3 measurement because they are supported by little or no market activity and reflect the Company's own assumptions in measuring fair value. The compensation expense for the awards is recognized over the requisite service period regardless of whether the market conditions are achieved and will only be adjusted for pre-vesting forfeitures due to the termination of the recipient's employment with the Company prior to the end of the performance period.

***2024 Equity Incentive Plan***

The Company's 2024 Equity Incentive Plan (the 2024 Plan) became effective upon approval of the stockholders in May 2024. The 2024 Plan permits the grant of awards to employees, non-employee directors and consultants. In addition, the 2024 Plan permits the grant of stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards, and other awards. The 2024 Plan provides that, with limited exceptions, no award will vest until at least 12 months following the date of grant of the award; provided, however, that up to 5% of the aggregate number of shares that may be issued under the 2024 Plan may be subject to awards which do not meet such vesting requirements. The maximum term of any stock option or stock appreciation right awards under 2024 Plan is ten years. All shares that remained eligible for grant under the Company's 2010 Equity Incentive Plan and 2023 Inducement Plan at the time of approval of the 2024 Plan were transferred to the 2024 Plan. At March 31, 2026, there were 9,089,464 shares of common stock available for new grants under the 2024 Plan.

***2024 Inducement Plan***

The Board adopted the Company's 2024 Inducement Plan (Inducement Plan) in September 2024. The Inducement Plan permits the grant of stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other stock-related awards. Stock awards granted under the Inducement Plan may only be made to individuals who did not previously serve as employees or non-employee directors of the Company or an affiliate of the Company. In addition, stock awards must be approved by either a majority of the Company's independent directors or the Compensation Committee. The terms of the Inducement Plan are otherwise substantially similar to the 2024 Plan. The maximum number of shares of Company common stock that may be issued under the Inducement Plan is 2,400,000 shares. At March 31, 2026, there were 302,886 shares available for new grants.

**9. Commitments and Contingencies**

***Collaboration, License and Merger Agreements***

The Company has entered into various collaboration, licensing and merger agreements which provide the Company with rights to certain know-how, technology and patent rights. The agreements generally include upfront license fees, development and commercial milestone payments upon achievement of certain clinical and commercial development and annual net sales milestones, as well as royalties calculated as a percentage of product revenues, with rates that vary by agreement. As of March 31, 2026, the Company may be required to make milestone payments up to $3.6 billion in the aggregate for candidates in its pipeline.

In August 2018, the Company entered into a license agreement with Neuren and obtained exclusive North American rights to develop and commercialize trofinetide for Rett syndrome and other indications. Under the terms of the agreement, the Company paid Neuren an upfront license fee of $10.0 million and it may be required to pay up to an additional $455.0 million in milestone payments based on the achievement of certain development and annual net sales milestones. In addition, the Company will be required to pay Neuren tiered, escalating, double-digit percentage royalties based on net sales. The license agreement was accounted for as an asset acquisition and the upfront cash payment of $10.0 million was expensed to research and development in the third quarter of 2018 as there is no alternative use for the asset. In connection with the FDA approval of DAYBUE, the Company paid a milestone payment of $40.0 million to Neuren following the first commercial sale of DAYBUE pursuant to the license agreement. The Company capitalized the $40.0 million milestone payment as an intangible asset as it was deemed probable of occurring as of March 31, 2023. In addition, the Company was granted a Rare Pediatric Disease PRV following the FDA approval of DAYBUE. Pursuant to the license agreement, the Company is required to pay Neuren one third of the value of the PRV at the time of sale or use of the PRV. The Company capitalized the $29.6 million for the estimated PRV value owed to Neuren as an intangible asset in 2023. In 2024, the Company sold the PRV to a third party for aggregate net proceeds of $146.5 million. Upon sale of the PRV, the Company capitalized an additional $19.2 million for the one third PRV value owed to Neuren as an intangible asset.

In July 2023, the Company expanded its licensing agreement for trofinetide with Neuren to acquire rights to the drug outside of North America as well as global rights in Rett syndrome and Fragile X syndrome to Neuren's development candidate NNZ-2591. Under the terms of the expanded agreement, Neuren received an upfront payment of $100.0 million and is eligible to receive up to an additional $426.3 million in milestone payments based on the achievement of certain commercial and sales milestones for trofinetide outside of North America and up to $831.3 million in milestone payments based on the achievement of certain development and sales milestones for NNZ-2591. In addition, the Company will be required to pay Neuren tiered royalties from the mid-teens to low-twenties percent of trofinetide net sales outside of North America. Percentage royalties related to NNZ-2591 net sales are identical to the trofinetide in each of North America and outside North America. The expanded license agreement was accounted for as an asset acquisition and the upfront cash payment of $100.0 million was expensed to research and development in the third quarter of 2023 as there is no alternative use for the asset.

In January 2022, the Company entered into a license and collaboration agreement with Stoke Therapeutics, Inc. (Stoke) to discover, develop and commercialize novel RNA-based medicines for the potential treatment of severe and rare genetic neurodevelopmental diseases of the central nervous system. Under the collaboration, the two companies will jointly share global research, development and commercialization responsibilities and share 50/50 in all worldwide costs and future profits with respect to a SYNGAP1 program. In addition, Stoke is eligible to receive potential development, regulatory, commercial and sales milestones. In May 2025, the Company determined to discontinue the MECP2 program for Rett syndrome and the undisclosed neurodevelopmental disease program that were originally part of the collaboration. The licenses to the discontinued programs will terminate and the parties will wind down the activities for the two programs. Under the terms of the agreement, the Company paid Stoke a $60.0 million upfront payment which was accounted for as an asset acquisition and was expensed to research and development in the first quarter of 2022 as there is no alternative use for the asset. The Company may be required to pay up to an additional $245.0 million in milestones.

In November 2024, the Company entered into a license agreement with Saniona A/S (Saniona), for the development and commercialization of ACP-711, a highly selective GABAA-α3 positive allosteric modulator. The first indication the Company plans to pursue is development of ACP-711 for essential tremor, a neurological condition that includes shaking or trembling movements in one or more parts of the body. The Company will lead further clinical development, regulatory submissions, and global commercialization efforts for ACP-711 while also providing financial support for Saniona's ongoing Phase 1 study and preparations for Phase 2. Under the terms of the license agreement, the Company paid Saniona an upfront fee of $28.0 million and it may be required to pay up to $582.0 million in milestone payments based on the achievement of certain development and annual net sales milestones. In addition, the Company will be required to pay Saniona tiered royalties of mid-single digits to low double digits on net sales of commercial products that may result from development of ACP-711. The license agreement was accounted for as an asset acquisition and the upfront cash payment of $28.0 million was expensed to research and development in the fourth quarter of 2024 as there is no alternative use for the asset. The potential milestone payments to Saniona consist of up to $147.0 million subject to achievement of development and commercial milestones related to potential first and second indications, and up to $435.0 million subject to achievement of thresholds of annual net sales of ACP-711 worldwide.

***Corporate Credit Card Program***

In connection with the Company's credit card program, the Company established a letter of credit for $3.0 million, which has automatic annual extensions and is fully secured by restricted cash.

***Fleet Program***

In connection with the Company's fleet program, the Company established a letter of credit for $0.4 million, which has automatic annual extensions and is fully secured by restricted cash.

***Legal Proceedings***

*Patent Infringement*

On July 24, 2020, the Company filed complaints against (i) Aurobindo Pharma Limited and its affiliate Aurobindo Pharma USA, Inc. and (ii) Teva Pharmaceuticals USA, Inc. and its affiliate Teva Pharmaceutical Industries Ltd., and on July 30, 2020, the Company filed complaints against (i) Hetero Labs Limited and its affiliates Hetero Labs Limited Unit-V and Hetero USA Inc., (ii) MSN Laboratories Private Ltd. and its affiliate MSN Pharmaceuticals, Inc., and (iii) Zydus Pharmaceuticals (USA) Inc. and its affiliate Cadila Healthcare Limited. These complaints, which were filed in the United States District Court for the District of Delaware, allege infringement of certain of the Company's Orange Book-listed patents covering NUPLAZID (Pimavanserin I Cases).

The Company entered into an agreement effective April 22, 2021 with Hetero settling all claims and counterclaims in the litigation. The agreement allows Hetero to launch its generic pimavanserin product on February 27, 2038, subject to certain triggers for earlier launch. The Hetero case was dismissed by joint agreement on May 3, 2021.

On September 30, 2022, the Company filed a stipulation and proposed order to stay the claims currently asserted against Teva and for Teva to be bound by the result of the litigation rendered against the remaining defendants Aurobindo and MSN, which was ordered by the Court on October 4, 2022.

On October 21, 2022, the Company filed additional complaints against Aurobindo, MSN and Zydus in the United States District Court for the District of Delaware alleging infringement of an additional Orange Book-listed patent covering NUPLAZID (Pimavanserin II Cases).

The Company entered into an agreement, effective March 31, 2023, with Zydus settling all claims and counterclaims in the Pimavanserin I Cases and Pimavanserin II Cases. The agreement allows Zydus to launch its generic pimavanserin 10 mg tablet products on September 23, 2036 and 34 mg capsule products on February 27, 2038, subject to certain triggers for earlier launch. The Zydus case was dismissed by joint agreement on April 5, 2023.

As a result of the above, only MSN remained as an active defendant in the Pimavanserin I Cases. On January 11, 2024, following summary judgment motions, the District Court entered final judgment in the Company's favor that MSN's submission of ANDA No. 214925 was an act of infringement in the Pimavanserin I Case and the '740 patent was not invalid. On January 18, 2024, MSN filed a Notice of Appeal to the United States Court of Appeals for the Federal Circuit from the final judgment entered on January 11, 2024. On June 9, 2025, the Federal Circuit issued a decision affirming the final judgement of the District Court in the Company's favor.

In connection with the Pimavanserin II cases, MSN and Aurobindo are the remaining defendants. A bench trial was conducted from December 3, 2024 to December 6, 2024 in the matter. Post-trial briefing was completed on February 12, 2025. On June 9, 2025, the District Court issued a final judgment in the Company's favor that Aurobindo's ANDA infringes the asserted Nuplazid patent and that the defendants failed to demonstrate such patent is invalid. On June 16, 2025, MSN and Aurobindo filed a Notice of Appeal to the United States Court of Appeals for the Federal Circuit from the final judgment entered on June 9, 2025. Briefing was completed on December 19, 2025. An oral argument has not been scheduled as yet.

On February 14, 2025, the Company filed a complaint against Zydus Lifesciences Limited, Zydus Worldwide DMCC, and Zydus Pharmaceuticals (USA) Inc. (collectively "Zydus") in the United States District Court for the District of Delaware, alleging infringement of certain of the Company's Orange Book-listed patents covering NUPLAZID (Pimavanserin) by Zydus' proposed 34 mg pimavanserin tablet product. On September 9, 2025, Acadia filed a First Amended Complaint alleging that Zydus breached the March 31, 2023 settlement agreement. The case is scheduled for trial commencing November 2, 2026.

*Securities Class Action*

On April 19, 2021, a purported stockholder of the Company filed a putative securities class action complaint (captioned *City of Birmingham Relief Retirement Systems* v. Acadia Pharmaceuticals, Inc., Case No. 21-cv-0762) in the U.S. District Court for the Southern District of California against the Company and certain of the Company's then-current executive officers. On September 29, 2021, the Court issued an order designating lead plaintiff and lead counsel. On December 10, 2021, lead plaintiff filed an amended complaint. The amended complaint generally alleges that defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, by failing to disclose that the materials submitted in support of its sNDA seeking approval of pimavanserin for the treatment of hallucinations and delusions associated with dementia-related psychosis contained statistical and design deficiencies and that the FDA was unlikely to approve the sNDA in its current form. The amended complaint seeks unspecified monetary damages and other relief. On March 11, 2024, the Court granted plaintiffs' motion for class certification and appointment of class representatives and class counsel. The parties concluded discovery on September 24, 2025. The parties submitted pretrial motions on November 12, 2025 and briefing for these motions was completed on February 25, 2026. The Court held a hearing for pretrial motions on April 10, 2026. Remaining pretrial deadlines will be determined pending the Court's rulings on the parties' pretrial motions.

*Opt Out Litigation*

On March 7, 2024, a purported stockholder of the Company filed a complaint (captioned Alger Dynamic Opportunities Fund v. Acadia Pharmaceuticals, Inc., Case No. 24-cv-00451) in the U.S. District Court for the Southern District of California against the Company and one executive officer. The complaint is based on the same underlying allegations as the Securities Class Action described above, and alleged claims under federal and state securities laws, and for common law fraud and negligent misrepresentations. On May 24, 2024, Defendants moved to dismiss the complaint. On October 31, 2024, the Court granted in part and denied in part Defendants' motion to dismiss. The Court dismissed with leave to amend the purported stockholder's state and common law claims, as well as the claim brought under Section 18(a) of the Securities Exchange Act of 1934, as amended. Defendants filed their answer to the Sections 10(b) and 20(a) claims on December 16, 2024. On January 13, 2025, the Court stayed this suit pending the outcome of the Securities Class Action.

*Derivative Suit*

On December 15, 2023, a purported stockholder of the Company filed a derivative action (captioned *Kanner et al v. Biggar et al.*, Case No. 23-cv-2293) in the U.S. District Court for the Southern District of California against certain of the Company's current directors. The Company is named as a nominal defendant. The complaint is based on the same alleged misconduct as the Securities Class Action, and asserts state law claims, on behalf of the Company, against the individual defendants for breach of fiduciary duty, unjust enrichment, abuse of control, waste of corporate assets, and insider trading. The complaint also asserts federal claims under sections 10(b), 21D, and 14(a) of the Securities Exchange Act of 1934, as amended. On December 27, 2023, the action was reassigned to District Judge William Q. Hayes and Magistrate Judge Michael S. Berg due to its relation to the Securities Class Action. On January 30, 2024, the parties jointly requested a stay of the action. The Court granted that request and the action was stayed on February 20, 2024, pending the outcome of our Demand Review Committee's investigation into the underlying claims. The stay was briefly lifted on September 5, 2025 but reinstated on October 17, 2025 and remains in place. On January 15, 2026, the parties informed the Court that they had reached a settlement in principle regarding the derivative claims. Pursuant to the proposed settlement, which is still subject to Court approval, defendants agreed to certain governance reforms and agreed to an award of $1.5 million in attorneys' fees to be paid by the Company's insurance carrier.

Given the unpredictability inherent in litigation, the Company cannot predict the outcome of these matters. The Company is unable to estimate possible losses or ranges of losses that may result from these matters, and therefore it has not accrued any amounts in connection with these matters other than attorneys' fees incurred to date.

**10. Leases**

The Company leases facilities and certain equipment under noncancelable operating leases with remaining lease terms of 1.8 years to 5.2 years, some of which include options to extend for up to two five-year terms. These optional periods were not considered in the determination of the right-of-use asset or the lease liability as the Company did not consider it reasonably certain that it would exercise such options.

The operating lease costs were as follows (in thousands):

| | Three Months Ended March 31, | |
|---|---|---|
| | 2026 | 2025 |
| Operating lease cost | $ 4,149 | $ 4,038 |
| Operating sublease income | (606) | (588) |
| Net operating lease cost | $ 3,543 | $ 3,450 |

Supplemental cash flow information related to the Company's leases were as follows (in thousands):

| | Three Months Ended March 31, | |
|---|---|---|
| | 2026 | 2025 |
| Cash paid for amounts included in the measurement of lease liabilities: | | |
| Operating cash flows from operating leases | $ 3,050 | $ 2,866 |
| Right-of-use assets obtained in exchange for operating lease obligations: | 941 | 6,180 |

The balance sheet classification of the Company's lease liabilities was as follows (in thousands):

| | March 31, 2026 | December 31, 2025 |
|---|---|---|
| Operating lease liabilities | | |
| Current portion included in accrued liabilities | $ 11,791 | $ 11,633 |
| Operating lease liabilities | 39,003 | 40,554 |
| Total operating lease liabilities | $ 50,794 | $ 52,187 |

Maturities of lease liabilities were as follows (in thousands):

| | Operating Leases |
|---|---|
| Remainder of 2026 | $ 9,066 |
| Years ending December 31, | |
| 2027 | 12,130 |
| 2028 | 11,620 |
| 2029 | 11,140 |
| 2030 | 9,096 |
| Thereafter | 3,656 |
| Total lease payments | 56,708 |
| Less: | |
| Imputed interest | (5,914) |
| Total operating lease liabilities | $ 50,794 |

Operating lease liabilities are based on the net present value of the remaining lease payments over the remaining lease term. In determining the present value of lease payments, the Company uses its incremental borrowing rate based on the information available at the lease commencement date. As of March 31, 2026, the weighted average remaining lease term was 5.0 years and the weighted average discount rate used to determine the operating lease liability was 4.9%.

In the fourth quarter of 2018, the Company entered into an agreement to lease the 4$^{th}$ and 5$^{th}$ floors of corporate office space in San Diego, California with total minimum lease payments of $50.4 million over an initial term of 10 years and 9 months. In February 2020, the Company entered into the first amendment to the lease agreement to lease the 2$^{nd}$ floor of corporate office space in San Diego, California with total minimum lease payments of $25.3 million over an initial term of approximately 10 years and 7 months. In March 2020, the Company entered into the second amendment to the lease agreement which increased the total minimum lease payments of the original corporate office space to $51.4 million. In the third quarter of 2020, the lease for the 4$^{th}$ and 5$^{th}$ floors of

corporate office space commenced and the Company capitalized a right of use asset and related lease liability of $40.3 million. In the first quarter of 2021, the lease for the 2nd floor of corporate office space commenced and the Company capitalized a right of use asset and related lease liability of $19.2 million. In connection with this lease and the amendment, the Company established a letter of credit for $3.1 million, which has automatic annual extensions and is fully secured by restricted cash.

In May 2023, the Company entered into an agreement to sublease its 2nd floor of corporate office space in San Diego to a sublessee with a total minimum sublease income of $18.4 million over a term of approximately 7 years and 6 months. The Company delivered full possession of its 2nd floor of corporate office space to the sublessee in August 2023 and began receiving sublease payments in December 2023.

In May 2025, the Company entered into an agreement to lease the 2nd and a portion of the 3rd floors of corporate office space in Princeton, New Jersey (the New Princeton Lease) with total minimum lease payments of $24.5 million over an initial term of 12 years and 2 months. As of March 31, 2026, the New Princeton Lease had not yet commenced. This operating lease is expected to commence in the second quarter of 2026. In connection with this New Princeton Lease agreement, the Company established a letter of credit for $0.6 million, which has automatic annual extensions and is fully secured by restricted cash. The current Princeton office lease will terminate five days after the commencement of the New Princeton Lease.

**11. Income Taxes**

The Company determines its interim income tax provision using an estimated annual effective tax rate applied to year-to-date ordinary income and recognizes the tax effects of discrete items in the period in which those items occur. For the three months ended March 31, 2026 and 2025, the Company recognized an income tax expense of $0.3 million on a pre-tax income of $4.0 million and income tax expense of $8.8 million on a pre-tax income of $27.8 million, respectively, resulting in effective tax rates of 8.6% and 31.6%, respectively. The effective tax rate for the three months ended March 31, 2026 varies from the U.S. federal statutory tax rate of 21% primarily because low pre-tax income for the period amplified the rate effect of discrete tax items recognized in the quarter. The effective tax rate for the three months ended March 31, 2025 varies from the U.S. federal statutory tax rate of 21% due to state income tax expense as a result of current taxable income, offset by valuation allowance.

**12. Segment Reporting**

Substantially all revenues from the three months ended March 31, 2026 and 2025 were generated from customers in North America. The following table illustrates reported segment revenue, segment profit and significant segment expenses (in thousands):

| | Three Months Ended March 31, | |
|---|---|---|
| | 2026 | 2025 |
| NUPLAZID net revenue | $ 166,924 | $ 159,721 |
| DAYBUE net revenue | 101,138 | 84,596 |
| Total revenues | 268,062 | 244,317 |
| Less: | | |
| Cost of goods sold | 11,665 | 9,211 |
| License fees and royalties | 13,126 | 11,181 |
| Research and development expense: | | |
| External research and development | 48,823 | 54,985 |
| Internal costs[(1)] | 25,544 | 23,280 |
| Upfront and milestone payments | 2,501 | — |
| Total research and development expense | 76,868 | 78,265 |
| Selling, general and administrative | 171,019 | 126,370 |
| Interest income, net | (8,055) | (7,901) |
| Other income | (542) | (588) |
| Income tax expense | 344 | 8,792 |
| Consolidated net income | $ 3,637 | $ 18,987 |

(1) Includes personnel expenses and costs allocated to multiple research and development programs, including benefits, information technology, facilities and inventory.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes thereto included in this Quarterly Report on Form 10-Q (this Quarterly Report), the audited financial statements and notes thereto as of and for the year ended December 31, 2025 included with our Annual Report on Form 10-K, filed with the SEC on February 26, 2026 (our Annual Report). Past operating results are not necessarily indicative of results that may occur in future periods.

This Quarterly Report contains forward-looking statements. These forward-looking statements involve a number of risks and uncertainties. Such forward-looking statements include statements about the benefits to be derived from our products and our product candidates, the potential market opportunities for our products and our product candidates, our strategy for the commercialization of our products, our plans for exploring and developing our products for additional indications, the commercialization of DAYBUE or trofinetide in jurisdictions other than the U.S., our plans and timing with respect to seeking regulatory approvals, the potential commercialization of any of our product candidates that receive regulatory approval, the progress, timing, results or implications of clinical trials and other development milestones and activities involving our products and our product candidates, our strategy for discovering, developing and, if approved, commercializing our product candidates, our existing and potential future collaborations, our estimates of future payments, revenues and profitability, our estimates regarding our capital requirements, future expenses and need for additional financing, the potential or expected impacts of geopolitical and macroeconomic developments, possible changes in legislation, and other statements that are not historical facts, including statements which may be preceded by the words "aims," "anticipates," "believes," "continue," "could," "estimates," "expects," "hopes," "intends," "may," "plans," "potential," "predicts," "pro forma," "projects," "seeks," "should," "will," "would" or similar words. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain. For forward-looking statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Readers of this Quarterly Report are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date on which they are made. We undertake no obligation to update or revise publicly any forward-looking statements except as required by law. Actual events or results may differ materially from our expectations. Important factors that could cause actual results to differ materially from those stated or implied by our forward-looking statements include, but are not limited to, the risk factors set forth under the section captioned "Risk Factors" in this Quarterly Report.

### Overview

#### *Background*

We are a biopharmaceutical company focused on turning scientific promise into meaningful innovation that makes the difference for underserved neurological and rare disease communities around the world.

We have two core franchises in neurological and rare diseases. Our neurological franchise is anchored by the commercial product NUPLAZID (pimavanserin), which is the first and only drug approved by the FDA for the treatment of hallucinations and delusions associated with PDP. Our rare disease franchise is anchored by the commercial product DAYBUE, which is the first and only drug approved for the treatment of Rett syndrome. Net product sales from these two commercial products totaled $268.1 million for the three months ended March 31, 2026, compared with $244.3 million for the three months ended March 31, 2025.

In addition to these commercial products, we have a portfolio of product candidates and research programs that are designed to address significant unmet medical needs in neurological and rare diseases. In order to achieve significant long-term growth, we plan to develop our current portfolio, expand our pipeline of early- and late-stage product candidates and expand into areas of rare disease that are adjacent to our existing franchises, including through strategic business development, and make use of our internal capabilities and knowledge.

Our most advanced current product candidate is remlifanserin for the treatment of Alzheimer's disease psychosis (ADP) and Lewy Body Dementia Psychosis (LBDP). In November 2023, we initiated a Phase 2 study evaluating the efficacy and safety of remlifanserin for the treatment of hallucinations and delusions associated with ADP. We initiated an additional Phase 2 study of remlifanserin in LBDP in September 2025. In the fourth quarter of 2025, we initiated a Phase 2 study of ACP-211 for the treatment of major depressive disorder.

We have several product candidates in earlier stages of development for the treatment of neurological and rare diseases. These include ACP-711 for the treatment of essential tremor, with a Phase 2 study expected to begin in 2026; and ACP-271, a GPR88 agonist, with a first-in-human study in healthy volunteers that initiated in the first quarter of 2026.

We have incurred substantial operating losses since our inception due in large part to expenditures for our research and development activities. As of March 31, 2026, we had an accumulated deficit of approximately $1.8 billion. Contingent on the level of business development activities we may complete as well as pipeline programs we may advance, we may incur operating losses as we incur significant research and development costs and costs for continued commercialization of our products.

We maintain a website at www.acadia.com to which we regularly post copies of our press releases as well as additional information about us. Our filings with the SEC are available free of charge through our website as soon as reasonably practicable after being electronically filed with or furnished to the SEC. Interested persons can subscribe on our website to email alerts that are sent automatically when we issue press releases, file our reports with the SEC or post certain other information to our website. Information contained in our website does not constitute a part of this Quarterly Report or our other filings with the SEC.

**Financial Operations Overview**

***Product Revenues***

Net product sales consist of sales of our products. The FDA approved NUPLAZID in April 2016 for the treatment of hallucinations and delusions associated with PDP and we launched the product in the United States in May 2016. The FDA approved DAYBUE in March 2023 for the treatment of Rett syndrome and we launched the product in the United States in April 2023. Health Canada granted marketing authorization of DAYBUE for the treatment of Rett syndrome in adult and pediatric patients 2 years of age and older in October 2024. The Ministry of Health in Israel approved DAYBUE for the treatment of Rett syndrome in adults and pediatric patients 2 years of age and older and weighing at least 9 kg in December 2025. The FDA approved DAYBUE STIX in December 2025 for the treatment of Rett syndrome and we made the product available on a limited basis in the first quarter of 2026 followed by a broader launch in early Q2 2026. In addition, we currently have contracts with multiple distributors outside the United States that distribute DAYBUE for limited named patient/compassionate use.

***Cost of Product Sales***

Cost of product sales consists of third-party manufacturing costs, freight, duties, and indirect overhead costs associated with sales of our products. Cost of product sales may also include period costs related to certain inventory manufacturing services, excess or obsolete inventory adjustment charges, unabsorbed manufacturing and overhead costs, and manufacturing variances. In addition, cost of product sales may include license fees and royalties. License fees and royalties currently consist of milestone payments capitalized and subsequently amortized under our 2018 license agreement with Neuren. License fees and royalties also include royalties of tiered, escalating, double-digit percentages due to Neuren based upon net sales of DAYBUE.

***Research and Development Expenses***

Our research and development expenses have consisted primarily of fees paid to external service providers, salaries and related personnel expenses, facilities and equipment expenses, and other costs incurred related to pre-commercial product candidates. We charge all research and development expenses to operations as incurred. Our research and development activities have focused on pimavanserin, trofinetide, remlifanserin and other earlier-stage product candidates. In connection with the FDA approval of DAYBUE, we are required to conduct post-marketing work, including a clinical study of renal impairment in healthy volunteers, nonclinical carcinogenicity studies, and nonclinical in vitro and clinical in vivo drug interaction studies. The FDA has released us from one of the five post-marketing requirements (PMRs). In addition, we have fulfilled three of the five PMRs. We will be responsible for all costs incurred for these PMRs. In addition, we expect to incur increased research and development expenses as a result of advancement of our early-stage product candidates.

We use external service providers to manufacture our product candidates and for the majority of the services performed in connection with the preclinical and clinical development of our product candidates. Historically, we have used our internal research and development resources, including our employees and discovery infrastructure, across several projects and many of our costs have not been attributable to a specific project. Accordingly, we have not reported our internal research and development costs on a project-by-project basis. To the extent that external expenses are not attributable to a specific project, they are allocated proportionally to each of the projects.

The following table summarizes our research and development expenses for the three months ended March 31, 2026 and 2025 (in thousands):

| | Three Months Ended March 31, | |
|---|---|---|
| | 2026 | 2025 |
| Costs of external service providers: | | |
| NUPLAZID (pimavanserin) | $ — | $ 3,104 |
| DAYBUE (trofinetide) | 4,746 | 11,782 |
| ACP-101 | 1,908 | 10,056 |
| Remlifanserin | 26,079 | 17,550 |
| Early-stage programs | 16,090 | 12,493 |
| Upfront and milestone payments* | 2,501 | — |
| Subtotal | 51,324 | 54,985 |
| Internal costs | 21,402 | 19,847 |
| Stock-based compensation | 4,142 | 3,433 |
| Total research and development expenses | $ 76,868 | $ 78,265 |

* Includes upfront and milestone consideration as well as transaction costs associated with acquired in-process research and development.

At this time, due to the risks inherent in regulatory requirements and clinical development, we are unable to estimate with certainty the costs we will incur to support the commercialization of DAYBUE or DAYBUE STIX, as well as the further development of our early-stage product candidates. Likewise, we are unable to determine with certainty the anticipated completion dates for our current research and development programs. Clinical development and regulatory approval timelines, probability of success, and development costs vary widely across our development programs. While our current development efforts are primarily focused on advancing the development of remlifanserin and other early-stage product candidates, we anticipate that we will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical success of each product candidate, as well as an ongoing assessment of the commercial potential of each candidate and our financial position. We cannot forecast with any degree of certainty which product candidates will be subject to future collaborative or licensing arrangements, when such arrangements will be secured, if at all, and to what degree any such arrangements would affect our development plans and capital requirements. Similarly, we are unable to estimate with certainty the costs we will incur for post-marketing studies that we committed to conduct in connection with FDA approval of DAYBUE.

We expect our research and development expenses will continue to be substantial as we conduct studies pursuant to our PMRs and pursue the further development of remlifanserin and other early-stage product candidates. The lengthy process of completing clinical trials and supporting development activities and seeking regulatory approval for our product candidates requires the expenditure of substantial resources. Any failure by us or delay in completing clinical trials, or in obtaining regulatory approvals, could cause our research and development expenses to increase and, in turn, have a material adverse effect on our results of operations.

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

Our selling, general and administrative expenses consist of salaries and other related costs, including stock-based compensation expense, for our commercial personnel, including our specialty sales forces, our medical education professionals, and our personnel serving in executive, finance, business development, and business operations functions. Also included in selling, general and administrative expenses are fees paid to external service providers to support our commercial activities associated with our products, professional fees associated with legal and accounting services, costs associated with patents and patent applications for our intellectual property and charitable donations to independent charitable foundations that support Parkinson’s disease patients generally. Changes in selling, general and administrative expenses in future periods are subject to the evolving PDP market dynamics and the Rett syndrome market.

***Income Tax Expense***

Our provision for income taxes, deferred tax assets and liabilities, and reserves for unrecognized tax benefits reflect our best assessment of estimated future taxes to be paid. Judgments and estimates based on interpretations of existing tax laws or regulations are required in determining our provision for income taxes. Changes in tax laws, regulations, or statutory tax rates, and estimates of our future taxable income could impact the deferred tax assets and liabilities provided for in the consolidated financial statements and would require an adjustment to the provision for income taxes. Prior to fiscal year 2025, we maintained a full valuation allowance against our net deferred tax assets (DTAs) due to a history of cumulative losses. However, during the fiscal year ended December 31, 2025, we achieved cumulative three-year profitability. Management determined there is sufficient positive evidence to conclude it is "more likely than not" that deferred taxes are realizable. We therefore reduced the valuation allowance accordingly.

**Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations is based on our unaudited condensed consolidated financial statements. We have identified the accounting policies that we believe require application of management's most subjective judgments, often requiring the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Our actual results may differ substantially from these estimates under different assumptions or conditions. There have been no significant changes to our critical accounting policies and estimates since December 31, 2025. For a description of our critical accounting policies that affect our significant judgments and estimates used in the preparation of our unaudited consolidated financial statements, refer to our Annual Report.

**Results of Operations**

***Fluctuations in Operating Results***

Our results of operations have fluctuated significantly from period to period in the past and are likely to continue to do so in the future. We anticipate that our quarterly and annual results of operations will be impacted for the foreseeable future by several factors, including the progress and timing of expenditures related to our commercial activities associated with our products and the extent to which we generate revenue from product sales, our further development of our early-stage product candidates and the progress and timing of expenditures related to studies of DAYBUE pursuant to our PMRs. Further, we expect our sales allowances to vary from quarter to quarter due to fluctuations in the volume of purchases eligible for government mandated discounts and rebates, as well as changes in discount percentages that may be impacted by potential future price increases and other factors. We cannot predict with certainty what the full impact that geopolitical and macroeconomic developments, including the ongoing military conflict between Ukraine and Russia and in the Middle East, and tariffs and trade tensions may have on our business, results of operations, financial condition and prospects. Due to these fluctuations, we believe that the period-to-period comparisons of our operating results are not a good indication of our future performance.

***Comparison of the Three Months Ended March 31, 2026 and 2025***

*Product Sales, Net*

Net product sales, comprised of NUPLAZID and DAYBUE, were $268.1 million and $244.3 million for the three months ended March 31, 2026 and 2025, respectively.

Net product sales of NUPLAZID were $166.9 million and $159.7 million for the three months ended March 31, 2026 and 2025, respectively. The increase in net product sales of NUPLAZID of $7.2 million was mainly due to the growth in NUPLAZID unit sales in 2026 compared to 2025. Net product sales of DAYBUE were $101.2 million and $84.6 million for the three months ended March 31, 2026 and 2025, respectively. The increase in net product sales of DAYBUE of $16.6 million was primarily due to the growth in DAYBUE unit sales.

The following table provides a summary of activity with respect to our sales allowances and accruals for the three months ended March 31, 2026 (in thousands):

| | Distribution Fees, Discounts & Chargebacks | Co-Pay Assistance | Rebates, Data Fees & Returns | Total |
|---|---|---|---|---|
| Balance as of December 31, 2025 | $ 16,457 | $ (37) | $ 140,440 | $ 156,860 |
| Provision related to current period sales | 34,472 | 1,832 | 46,260 | 82,564 |
| Credits/payments for current period sales | (19,712) | (1,943) | 250 | (21,405) |
| Credits/payments for prior period sales | (16,457) | 37 | (26,384) | (42,804) |
| Balance as of March 31, 2026 | $ 14,760 | $ (111) | $ 160,566 | $ 175,215 |

*Cost of Product Sales*

Cost of product sales was $24.8 million and $20.4 million for the three months ended March 31, 2026 and 2025, respectively, or approximately 9% and 8% of net product sales, respectively. Cost of product sales as a percentage of net product sales remained relatively flat during the three months ended March 31, 2026 as compared to the same period of 2025.

*Research and Development Expenses*

Research and development expenses was $76.9 million and $78.3 million for the three months ended March 31, 2026 and 2025, respectively. The research and development expenses remained relatively flat as compared to the same period of 2025.

*Selling, General and Administrative Expenses*

Selling, general and administrative expenses increased to $171.0 million for the three months ended March 31, 2026 from $126.4 million for the three months ended March 31, 2025. The increase in selling, general and administrative expenses was primarily driven by increased investments to support continued growth of NUPLAZID and DAYBUE.

**Liquidity and Capital Resources**

We have funded our operations primarily with revenues from sales of our products since their approvals, and through sales of our equity securities and interest income. We anticipate that the level of cash used in our operations will fluctuate in future periods depending on the levels of spending required for our ongoing and planned commercial activities for our products, our ongoing and planned development activities for remlifanserin as a treatment for ADP and LBDP, studies to be conducted pursuant to our PMRs, our ongoing and planned development activities for other early- and late-stage product candidates and strategic business development to further expand our portfolio. We expect that our cash, cash equivalents and investment securities, as well as funds generated by anticipated sales of our products, will be sufficient to fund our planned operations through and beyond the next 12 months.

We may require additional financing in the future to fund our operations. Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

- the costs of acquiring additional product candidates or research and development programs;
- the scope, prioritization and number of our research and development programs;
- the ability of our collaborators and us to reach the milestones and other events or developments triggering payments under our collaboration or license agreements, or our collaborators' ability to make payments under these agreements;
- our ability to enter into new collaboration and license agreements;
- the progress in, and the costs of, our ongoing and planned development activities for pimavanserin, post-marketing studies for DAYBUE to be conducted over the next several years, and ongoing and planned commercial activities for our products;
- the costs of our development activities for our product candidates;
- the costs of commercializing our products, including the maintenance and development of our sales and marketing capabilities;
- the costs of establishing, or contracting for, sales and marketing capabilities for our product candidates;

- the amount of U.S. product sales from our products;
- the costs of preparing applications for regulatory approvals for DAYBUE in jurisdictions other than the U.S., for NUPLAZID in additional indications other than PDP and for other product candidates, as well as the costs required to support review of such applications;
- the costs of manufacturing and distributing our products for commercial use in the U.S.;
- our ability to obtain regulatory approval for, and subsequently generate product sales from, our product candidates;
- the extent to which we are obligated to reimburse collaborators or collaborators are obligated to reimburse us for costs under collaboration agreements;
- the costs involved in filing, prosecuting, enforcing, and defending patent claims and other intellectual property rights;
- the costs of maintaining or securing manufacturing arrangements for clinical or commercial production of pimavanserin, trofinetide or other product candidates; and
- the costs associated with litigation, including the costs incurred in defending against any product liability claims that may be brought against us related to our products.

In the past, periods of turmoil and volatility in the financial markets have adversely affected the market capitalizations of many biotechnology companies, and generally made equity and debt financing more difficult to obtain. For example, due to geopolitical and macroeconomic developments, including the Ukraine-Russia military conflict and related sanctions, the ongoing conflicts in the Middle East, tariffs and trade tensions, the global credit and financial markets have experienced extreme volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. These events, coupled with other factors, may limit our access to additional financing in the future. We cannot be certain that additional funding will be available to us on acceptable terms, or at all. If adequate funds are not available when needed, we will be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts. We also may be required to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Additional funding, if obtained, may significantly dilute existing stockholders and could negatively impact the price of our stock.

We have invested a substantial portion of our available cash in money market funds, municipal bonds, and government sponsored enterprises in accordance with our investment policy. Our investment policy defines allowable investments and establishes guidelines relating to credit quality, diversification, and maturities of our investments to preserve principal and maintain liquidity. All investment securities have a credit rating of at least Aa3/AA- or better, or P-1/A-1 or better, as determined by Moody's Investors Service or Standard & Poor's. Our investment portfolio has not been adversely impacted by the disruptions in the credit markets that have occurred in the past. However, if there are future disruptions in the credit markets, there can be no assurance that our investment portfolio will not be adversely affected.

***Material Cash Requirements***

Our material cash requirements in the short and long term consist of the operational, manufacturing, and capital expenditures, a portion of which contain contractual or other obligations. We plan to fund our material cash requirements with our current financial resources together with our anticipated receipts from product sales. On a long-term basis, we manage future cash requirements relative to our long-term business plans.

Our primary uses of cash and operating expenses relate to paying employees and consultants, administering clinical trials, marketing our products, and providing technology and facility infrastructure to support our operations. We also make investments in our office and laboratory facilities to enable continued expansion of our business.

As discussed above, we have entered into various collaboration, licensing and merger agreements which generally include upfront license fees, development and commercial milestone payments upon achievement of certain clinical and commercial development and annual net sales milestones, as well as royalties calculated as a percentage of net product sales, with rates that vary by agreement.

We expect to receive the invoice for rebates under the Inflation Reduction Act of 2022 (IRA) from Medicare Part D unit sales for the period of October 1, 2024 to September 30, 2025 in June 2026. Payment is due 30 days after receiving such invoice; the payment will be set off against the allowance for such rebate that we have accrued up to the date of payment.

***Cash Flows***

At March 31, 2026, we had $851.5 million in cash, cash equivalents, and investment securities, compared to $819.7 million at December 31, 2025. This $31.8 million increase was due to cash provided by operating activities. Net cash provided by operating activities totaled $34.0 million for the three months ended March 31, 2026 compared to $20.3 million for the three months ended March 31, 2025. This increase in cash provided by operations primarily resulted from the increase in product revenue partially offset by an increase in our selling, general and administrative cost.

Net cash provided by investing activities totaled $66.3 million for the three months ended March 31, 2026 compared to $124.0 million of net cash used in investing activities for the three months ended March 31, 2025. The increase in net cash provided by investing activities for the three months ended March 31, 2026 compared to the three months ended March 31, 2025 was primarily due to increased net sales and maturity of investment securities. Also during the three months ended March 31, 2025, there was a net payment of $98.8 million made to Neuren for the sale of the PRV and an annual net sales milestone which we did not have during the same period of 2026.

Net cash provided by financing activities increased to $4.2 million for the three months ended March 31, 2026 compared to $1.8 million for the three months ended March 31, 2025. This increase in net cash provided by financing activities for the three months ended March 31, 2026 was attributable primarily to an increase in proceeds resulting from the exercise of employee stock options and awards.

**Off-Balance Sheet Arrangements**

To date, we have not had any relationships with unconsolidated entities or financial partnerships, such as entities referred to as structured finance or special purpose entities, which are established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As such, we are not materially exposed to any financing, liquidity, market, or credit risk that could arise if we had engaged in these relationships.

**Recent Accounting Pronouncements**

For a discussion of recent accounting pronouncements, refer to Note 2, *Summary of Significant Accounting Policies*, to our consolidated financial statements in our Annual Report.

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

***Interest Rate Risk***

We invest our excess cash in investment-grade, interest-bearing securities. The primary objective of our investment activities is to preserve principal and liquidity. To achieve this objective, we invest in money market funds. U.S. treasury notes, and high quality marketable debt instruments of corporations and government sponsored enterprises with contractual maturity dates of generally less than one year. All investment securities have a credit rating of at least Aa3/AA- or better, or P-1/A-1 or better, as determined by Moody's Investors Service or Standard & Poor's. We do not have any direct investments in auction-rate securities or securities that are collateralized by assets that include mortgages or subprime debt. If a 10 percent change in interest rates were to have occurred on March 31, 2026, this change would not have had a material effect on the fair value of our investment portfolio as of that date. Due to our investment in investment-grade, interest-bearing securities, as of the date of this Quarterly Report on Form 10-Q, we do not expect anticipated changes in interest rates to have a material effect on our interest rate risk in future reporting periods.

## ITEM 4. CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As of March 31, 2026, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of March 31, 2026.

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of any change in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any changes in our internal control over financial reporting that occurred during our latest fiscal quarter 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

The information required to be set forth under this Item 1 is incorporated by reference to the section titled "Legal Proceedings" in Note 9 to the unaudited condensed consolidated financial statements included in this Quarterly Report.

### ITEM 1A. RISK FACTORS

*You should consider carefully the following information about the risks described below, together with the other information contained in this Quarterly Report and in our other public filings in evaluating our business. The risk factors set forth below that are marked with an asterisk (*) did not appear as separate risk factors in, or contain changes to the similarly titled risk factor included in, Item 1A of our Annual Report. If any of the following risks actually occurs, our business, financial condition, results of operations, and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline.*

**Summary Risk Factors**

We face risks and uncertainties related to our business, many of which are beyond our control. In particular, risks associated with our business include:

- Our prospects are highly dependent on the successful commercialization of our products. To the extent we cannot establish, maintain or increase sales of our products, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.
- Our products may not gain maximal acceptance among physicians, patients, caregivers and the medical community, thereby limiting our potential to generate revenues.
- Our ability to generate product revenues will be diminished if coverage for our products from commercial or government payors is not provided, is decreased or if patients have unacceptably high out-of-pocket requirements.
- Our products are subject to ongoing regulatory requirements that could cause us significant expense and delay or limit our ability to generate sales revenues.
- We rely on a limited network of third-party distributors and pharmacies to market and sell our products. If this approach ceases to be effective, commercialization of our products may be adversely affected, and our products may not be profitable.
- Drug development is a long, expensive and unpredictable process with a high risk of failure, and there is no guarantee that our products or product candidates will be successful in ongoing or future clinical trials or obtain regulatory approval.
- The regulatory approval processes in the European Union (EU) and outside North America are lengthy, time consuming and inherently unpredictable, and, if we do not obtain regulatory approval of trofinetide outside North America, we will not be able to market trofinetide outside North America, which will limit our trofinetide commercial revenues.
- Expanded access or compassionate use programs could subject us to additional risks.
- Delays, suspensions, variations and terminations in our clinical trials for our product candidates could result in increased costs to us and delay our ability to generate product revenues.
- If we are unable to attract, retain, and motivate key management, research and development, and sales and marketing personnel, our drug development programs, our research and discovery efforts, and our commercialization plans may be delayed and we may be unable to successfully commercialize our products, or develop our product candidates.
- If we fail to develop, acquire or in-license other product candidates or products, our business and prospects would be limited. Even if we obtain rights to other product candidates or products, we will incur a variety of costs and may never realize the anticipated benefits.
- We may require additional financing in the future to fund our operations. If we cannot raise additional financing in the future, we may be unable to fund our business plan and our future research, development, commercial and manufacturing efforts.
- We expect that our results of operations will fluctuate, which may make it difficult to predict our future performance from period to period.

- Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.
- Our ability to use net operating loss carryforwards and certain other tax attributes to offset future taxable income or taxes may be limited.
- Tax authorities could reallocate our taxable income among our subsidiaries, which could increase our overall tax liability.
- Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.
- International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.
- We or the third parties upon whom we depend may be adversely affected by catastrophic events, such as earthquakes, fires or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.
- We have incurred, and expect to continue to incur, significant costs as a result of laws, regulations and standards relating to various aspects of our business, including corporate governance, work force initiatives and other matters, and failure to comply with such laws, regulations and standards could adversely affect our business.
- Our business involves the use of hazardous materials, and we and our third-party manufacturers and suppliers must comply with environmental, health and safety laws and regulations, which can be expensive and restrict how we do, or interrupt our, business.

**Risks Related to Our Products and Product Candidates**

***Our prospects are highly dependent on the successful commercialization of our products. To the extent we cannot establish, maintain or increase sales of our products, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.***

We have two products that are approved for commercialization in the U.S.: NUPLAZID and DAYBUE. The successful commercialization of such products is subject to many risks, and there is no guarantee that we will be able to maintain or increase sales of such products. Our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline because of many factors, some of which are outside our control, including, but not limited to, the following:

- the extent to which patients, caregivers and physicians recognize and diagnose the indications for which our products are approved and accept and adopt our products as a treatment for such indications;
- the scope and terms of the FDA's approval of our products, including the inclusion of a boxed warning for NUPLAZID or other warnings and precautions for our products;
- physicians may not prescribe our products and patients may be unwilling to use our products, due to a number of factors, including if coverage is not provided, coverage changes in the future, reimbursement is inadequate to cover a significant portion of the cost, negative or changing perceptions of each product's clinical profile and clinical benefits or due to the prevalence and severity of any adverse side effects;
- the experiences of those adopting our products earlier could have significant impact on future adoption of our products by other physicians, patients and caregivers, either favorably or unfavorably, based on clinical benefits and side effects experienced;
- any new clinical data, post-approval studies or real world results, including in jurisdictions other than the U.S., could result in the FDA making changes to the product label or withdrawal from the market, and could impact regulatory approvals for other indications in the U.S. or other jurisdictions, if any, any of which could result in significant expense and delay or limit our ability to generate sales revenues;
- our products are becoming available to a larger number of patients and patients' experiences and results with our products may not be consistent with, or may be more negative when compared to, the experiences and results of those treated in our clinical trials;
- successful expansion and development of our commercial team and sales forces; and
- any negative publicity related to our products.

Additionally, our success is dependent on our ability to obtain regulatory approval for, and successfully commercialize, trofinetide in jurisdictions outside the U.S., including the EU. We will face in jurisdictions outside the U.S., such as the EU, if approved for marketing, risks and uncertainties similar to the risks and uncertainties faced in the U.S. with respect to commercialization outside of the U.S., including, but not limited to, government reimbursement of the cost of trofinetide. If the commercialization of our products and future sales is less successful than expected or perceived as disappointing, our stock price could decline significantly and the long-term success of our products and our company could be harmed.

***Our products may not gain maximal acceptance among physicians, patients, caregivers and the medical community, thereby limiting our potential to generate revenues.***

The degree of market acceptance by physicians, healthcare professionals, patients, caregivers and third-party payors of our products, and our profitability and growth, will depend on a number of factors, including:

- the ability to provide acceptable evidence of safety and efficacy;
- the scope of the approved indication(s) for the product;
- the inclusion of any warnings or contraindications in the product label;
- the relative convenience and ease of administration;
- the relative timing, or perceived timing, in which patients experience outcomes;
- the prevalence and severity of any actual or expected adverse side effects;
- the availability of alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- our ability to increase awareness of our approved products through marketing efforts;
- pricing and cost effectiveness, which may be subject to regulatory control;
- effectiveness of our or our collaborators' sales and marketing strategy;
- publicity concerning us, our products or competing products and treatments; and
- our ability to obtain and maintain sufficient third-party insurance coverage or adequate reimbursement levels.

If a product does not provide a treatment regimen that is at least as beneficial as the current standard of care or otherwise does not provide patient benefit, that product will not achieve market acceptance and will not generate sufficient revenues to achieve or maintain profitability. With respect to our products specifically, successful commercialization will depend on whether and to what extent physicians, patients, caregivers, long-term care facilities and pharmacies, over whom we have no control, determine to utilize our products. NUPLAZID is available in the U.S. to treat hallucinations and delusions associated with PDP, and DAYBUE is available in the U.S. to treat Rett syndrome, both indications for which no other FDA-approved pharmaceutical treatments currently exist. DAYBUE is also the first and only product approved in Canada and Israel for the treatment of Rett syndrome.

As there are no approved competitors for our products, it is particularly difficult to estimate the market potential for our products and how physicians, patients, caregivers, long-term care facilities and payors will respond to changes in the price of our products. Industry sources and analysts have a divergence of estimates for the near- and long-term market potential of our products, and a variety of assumptions directly impact the estimates for our products' market potential, including assumptions regarding the prevalence of PDP and Rett syndrome, the rate of diagnosis of PDP and Rett syndrome, the prevalence and rate of hallucinations and delusions in patients diagnosed with PDP with respect to NUPLAZID, the rate of physician adoption, the potential impact of payor restrictions, and patient adherence and compliance rates. Small differences in these assumptions can lead to widely divergent estimates of the market potential of our products.

For example, with respect to NUPLAZID, certain research suggests that patients with Parkinson's disease may be hesitant to report symptoms of PDP to their treating physicians for a variety of reasons, including apprehension about societal stigmas relating to mental illness. Research also suggests that physicians who typically treat patients with Parkinson's disease may not ask about or identify symptoms of PDP. For these reasons, even if PDP occurs in high rates among patients with Parkinson's disease, it may be underdiagnosed. Even if PDP is diagnosed, physicians may not prescribe treatment for hallucinations and delusions associated with PDP, and if they do prescribe treatment, they may prescribe drugs other than NUPLAZID, even though they are not approved in PDP. Further, NUPLAZID may take several weeks to show efficacy. Even if NUPLAZID is prescribed for the treatment of hallucinations and delusions associated with PDP, patients may stop taking NUPLAZID because they may not see results in the timeframe they desire or expect.

Similarly, even if DAYBUE is prescribed for the treatment of Rett syndrome, issues may arise with respect to patient acceptance, adherence, persistence and compliance rates for a variety of reasons, including due to the expected clinical benefits or expected and actual side effects a patient might incur. If patients do not adhere to the recommended dosing of DAYBUE, or do not maintain the recommended dosing of DAYBUE for sufficient periods of time, patients and physicians may believe that DAYBUE is less effective, and as a result they may discontinue taking it and prescribing it. Additionally, if physicians or patients titrate DAYBUE below the recommended doses, patients may not experience the desired outcomes, and physicians or patients may develop negative beliefs about the effectiveness of DAYBUE and/or discontinue its use.

The label for NUPLAZID also contains a "boxed" warning related to particularly important prescribing information, and the FDA reminded healthcare providers to be aware of the risks described in the NUPLAZID prescribing information following its observation of potentially concerning prescribing patterns. There has also been attention to publicly reported deaths of patients that were prescribed NUPLAZID, and the FDA conducted an evaluation of available information about NUPLAZID. Perceptions that NUPLAZID is unsafe, even if unfounded, may discourage physicians from prescribing or patients from taking NUPLAZID.

The commercial success of our products depends on acceptance by patients, caregivers and physicians, and there are a number of factors that could skew our or others' estimates about prescribing behaviors and market adoption. If we fail to gain the acceptance of patients, caregivers and physicians, or if our estimates are inaccurate, these events could negatively impact our business, results of operations, financial condition and prospects.

***Our ability to generate product revenues will be diminished if coverage for our products from commercial or government payors is not provided, is decreased or if patients have unacceptably high out-of-pocket requirements.***

Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors, including governmental healthcare programs, such as Medicare and Medicaid, managed care organizations and commercial payors, among others, to reimburse all or part of the costs associated with their prescription drugs. Coverage and adequate reimbursement from third-party payors are critical to product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor drug products when lower cost therapeutic alternatives are already available or subsequently become available. Even with coverage for our products, the resulting reimbursement payment rates might not be adequate or may require out-of-pocket obligations, such as deductibles and co-pay or coinsurance payments, that patients find unacceptably high. Patients may not use our products if coverage is not provided or reimbursement is inadequate to cover a significant portion of its cost.

In addition, the market for our products depends significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly alternative is available, even if not approved for the indication for which our products are approved.

Legislators, policymakers and healthcare insurance funds in the EU may continue to propose and implement cost-containing measures to keep healthcare costs down. These measures could include limitations on the prices we would be able to charge for product candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third-party payors. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

Third-party payors, whether governmental or commercial, whether in the U.S. or globally, are developing increasingly sophisticated methods of controlling healthcare costs. The current environment is putting pressure on companies to price products below what they may feel is appropriate. For example, the U.S. Department of Health and Human Services ("HHS") imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. In addition, HHS has been empowered to negotiate the price of certain single-source drugs that have been on the market for at least 7 years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to 20 products will be selected

by HHS for the Medicare Drug Price Negotiation Program. Based upon the current law, we believe that 2029 is the earliest year NUPLAZID could be subject to a negotiated price, as we expect to apply and qualify for the small biotech exception, which provides an exemption from selection until 2027 (for initial price negotiation in 2029). In 2029, if selected, we expect that the price negotiation for NUPLAZID would be limited as we qualify as a "specified small manufacturer" and will receive the discount phase-in for NUPLAZID in years 2029 and 2030. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our current and any future product candidates that we develop, which could have an adverse effect on our operating results and our overall financial condition. Selling our products at less than an optimized price would impact our revenues and could impact our overall success as a company. We have changed, and may continue to change, the price of our products from time to time, however, we do not know if the price we have selected, or may select in the future, for our products is or will be the optimized price. Additionally, we do not know whether and to what extent third-party payors will react to any possible future changes in the price of our products. In the U.S., no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Outside the U.S., reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. Further, one payor's determination to provide coverage and reimbursement for a product does not ensure that other payors will also provide coverage and reimbursement for the product. Therefore, coverage and reimbursement for our products both in the U.S. and outside may differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage will be obtained. Coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

In most international markets, where the government is the primary payor, manufacturers must operate in an environment of government-directed cost-containment programs – designs such as price controls, international reference pricing, mandatory discounts and rebates, regulatory hurdles and restrictions on physician-level prescribing. In these markets, healthcare services and determination of a product's pricing and reimbursement are impacted by government control. For example, the EU provides options for EU Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU Member State may approve a specific price for the medicinal product, it may refuse to reimburse a product at the price set by the manufacturer or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Many EU Member States also periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies in a Health Technology Assessment (HTA).

An HTA of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. On January 12, 2025, Regulation No 2021/2282 on HTA entered into application through a phased implementation. It is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products. The HTA Regulation establishes a framework for joint clinical assessments, joint scientific consultations, and the early identification of emerging health technologies. This regulation permits EU Member States to use common HTA tools, methodologies, and procedures across the EU and requires them to rely on EU-level joint clinical assessment reports for the clinical components of their national HTA evaluations. Individual EU Member States continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. As implementation of the HTA Regulation is phased in and key methodological and procedural guidance continues to evolve, there remains uncertainty regarding the evidence requirements, timing, and impact of joint clinical assessments on national reimbursement processes. The new framework may result in additional or differently structured evidentiary expectations, misalignment between assessment and regulatory timelines, or delays in national decisions. Any adverse or delayed HTA outcomes, or divergent national reimbursement decisions, could negatively affect our ability to obtain or maintain favorable pricing and reimbursement status for any product candidates, if approved. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.

So, for present and future considerations, if we are unable to obtain coverage of, and adequate payment levels for, our products we may market to third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer them and patients may decline to purchase them. This in turn could affect our ability to successfully commercialize our products or any other products we may market, and thereby adversely impact our profitability, results of operations, financial condition, and future success.

***Our products are subject to ongoing regulatory requirements that could cause us significant expense and delay or limit our ability to generate sales revenues.***

In connection with the FDA approval of DAYBUE, we agreed to the following PMRs: a clinical study of renal impairment in healthy volunteers, nonclinical carcinogenicity studies and nonclinical in vitro and clinical in vivo drug interaction studies. The FDA has released us from one of the five PMRs. In addition, we have fulfilled three of the five PMRs. The results of any post-marketing study may cause the FDA to update the label, request additional studies and/or require risk mitigation plans.

The manufacturing processes, labeling, packaging, export, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for our products will also continue to be subject to extensive and ongoing regulatory requirements in the U.S. and in other foreign countries in which we operate, engage third-party manufacturers and obtain marketing approvals. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practices (cGMPs), licensing requirements, good clinical practices, international council for harmonization guidelines and good laboratory practices, each of which are regulations and guidelines enforced by regulatory authorities for all of our nonclinical and clinical development and for any clinical trials that we conduct post-approval.

Discovery of any issues post-approval, including any safety concerns, such as carcinogenicity, unexpected side effects or drug-drug interaction problems, adverse events of unanticipated severity or frequency, or concerns over misuse or abuse of the product, problems with the facilities where the product is manufactured, tested, packaged or distributed, or failure to comply with regulatory requirements, may result in, among other things, restrictions on our products or on us, including:

- withdrawal or variation of approval, addition of warnings or narrowing of the approved indication in the product label;
- requirement of a Risk Evaluation and Mitigation Strategy to mitigate the risk of off-label use in populations where the FDA may believe that the potential risks of use may outweigh its benefits;
- voluntary or mandatory recalls;
- warning letters;
- suspension, variation or termination of any ongoing clinical studies;
- refusal by the FDA or comparable foreign regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension, variation or revocation of product approvals;
- restrictions on operations, including restrictions on the marketing or manufacturing of the product or the imposition of costly new manufacturing requirements;
- material fines or other types of penalties; or
- seizure or detention, or refusal to permit the import or export of products.

If any of these actions were to occur, we may have to discontinue the commercialization of the applicable product, limit our sales and marketing efforts, conduct further post-approval studies, and/or discontinue or change any other ongoing or planned clinical studies, which in turn could result in significant expense and delay or limit our ability to generate sales revenues.

***We rely on a limited network of third-party distributors and pharmacies to market and sell our products. If this approach ceases to be effective, commercialization of our products may be adversely affected, and our products may not be profitable.***

Our strategy includes distributing NUPLAZID in the U.S. and DAYBUE or trofinetide, as applicable, in the U.S. and other jurisdictions in which marketing is approved solely through a limited network of third-party specialty distributors, specialty pharmacies or other third-party partners. While we have entered into agreements with each of these distributors and pharmacies to distribute NUPLAZID in the U.S. and DAYBUE in the U.S. and other jurisdictions in which marketing is approved, we will need to enter into similar agreements in any jurisdictions in which trofinetide is approved, and such distributors and pharmacies may not perform as agreed or they may terminate their agreements with us. Also, we may need to enter into agreements with additional distributors, pharmacies or other entities, and there is no guarantee that we will be able to do so on commercially reasonable terms or at all.

In the event we are unable to maintain and, if needed, expand, our network of third-party specialty distributors and specialty pharmacies, our ability to continue commercializing our products would be limited, and our products may not be profitable.

***Drug development is a long, expensive and unpredictable process with a high risk of failure, and there is no guarantee that our products or product candidates will be successful in ongoing or future clinical trials or obtain regulatory approval.****

Preclinical testing and clinical trials are long, expensive and unpredictable processes that can be subject to delays. Preliminary, initial, top-line or interim results of clinical trials do not necessarily predict final results and such results 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 results. In addition, success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials even after promising results in earlier trials. Of the large number of product candidates in development, only a small percentage result in the submission of an NDA to the FDA or comparable regulatory filing to regulatory authorities in other jurisdictions, and even fewer are approved for marketing. Even if clinical trials are completed, we or our collaborators may not submit applications for required authorizations to manufacture and/or market potential products or any such application may not be reviewed and approved by the appropriate regulatory authorities in a timely manner, if at all.

Our clinical trials face a number of risks, and our product candidates may fail regardless of whether our collaborators successfully complete the clinical trials and apply for such required authorizations for a number of reasons, including:

- a product candidate may fail to receive the regulatory clearances required to market them as drugs;
- a product candidate may be subject to proprietary rights held by others requiring the negotiation of a license agreement prior to marketing;
- a product candidate may be difficult or expensive to manufacture on a commercial scale;
- a product candidate may have adverse side effects that make their use less desirable;
- a product candidate may fail to compete with product candidates or other treatments commercialized by competitors;
- a product candidate may not prove to be efficacious or safe;
- patients may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested;
- the results of clinical trials may not be consistent with positive results of earlier trials; and
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities.

Our drug development programs are at various stages of development and the historical rate of failures for product candidates in our industry is extremely high. We have had several clinical studies that did not achieve statistical significance on certain endpoints, including the unsuccessful Phase 3 ADVANCE-2 study of pimavanserin for the treatment of the negative symptoms of schizophrenia in March 2024, the unsuccessful Phase 2 study of pimavanserin for the treatment of irritability associated with autism spectrum disorder in pediatric populations (Pediatric Phase 2 Trial) in October 2024 and the unsuccessful Phase 3 COMPASS PWS study of intranasal carbetocin for the treatment of hyperphagia in Prader-Willi Syndrome in September 2025. At this time, we are not planning to conduct any additional clinical studies for any new indications for pimavanserin or any additional clinical studies with intranasal carbetocin.

An unfavorable outcome in any of our ongoing or future development efforts for trofinetide or in the post-marketing studies for DAYBUE could be a major set-back for the programs and for us, generally. In particular, an unfavorable outcome in our trofinetide programs or in the post-marketing studies for DAYBUE, may require us to delay, devote additional substantial resources to, reduce the scope of, or eliminate the affected program and could have a material adverse effect on us and the value of our common stock. Also, although we have submitted a marketing application for the approval of trofinetide in the EU, there is no guarantee we will receive regulatory approval.

We are currently conducting studies with our product candidates. Even if we complete all planned clinical trials for our product candidates on schedule, such completion does not guarantee that we will obtain regulatory approval from the regulatory authorities. The results of our clinical trials may not meet the requirements for approval, or regulatory authorities may interpret the data differently than we do. In addition, completion of clinical trials does not ensure that regulatory authorities will view the results as sufficient to demonstrate safety, efficacy, or clinical benefit. For example, regulators may disagree with the design or implementation of our clinical trials, the appropriateness or relevance of endpoints of our clinical trials, duration of our clinical trials, whether the patient

population is sufficiently representative of the desired indication in their geography or at all, the nature or existence of comparative data, size and duration of safety database, and our interpretation of meaningfulness and/or generalizability of findings. Consequently, the successful completion of clinical trials may not be predictive of a positive outcome with any or all regulatory authorities. If we are unable to develop, or obtain marketing approval for, or, if approved, successfully commercialize our product candidates, we may not be able to generate sufficient revenue and our business operations and financial performance may be materially and adversely affected.

***The regulatory approval processes in the EU and outside North America are lengthy, time consuming and inherently unpredictable, and if we do not obtain regulatory approval of trofinetide outside North America, we will not be able to market trofinetide outside North America, which will limit our trofinetide commercial revenues.****

In the U.S., the EU and many foreign countries, we are not permitted to market our product candidates until we receive regulatory approval from the FDA, European Commission or comparable foreign regulatory authorities. DAYBUE was approved in 2023 in the U.S. by the FDA, in 2024 in Canada by Health Canada, and in 2025 in Israel by the Ministry of Health.

The process of obtaining regulatory approval of medicinal products in the EU and elsewhere, is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, and regulatory authorities have substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed.

Prior to obtaining approval to commercialize trofinetide in the EU or internationally, we must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the European Medicines Agency (EMA), the European Commission or comparable foreign regulatory authorities, that trofinetide is safe and effective for its intended uses. Results from non-clinical studies and clinical trials can be interpreted in different ways. Even if we believe the non-clinical or clinical data for trofinetide are promising, such data may not be sufficient to support approval by the European Commission or comparable foreign regulatory authorities. For example, in January 2025, we submitted a marketing authorization application (MAA) for the approval of trofinetide for the treatment of Rett syndrome in the EU, and in January 2026 we were informed by the EMA's Committee for Medicinal Products for Human Use (CHMP) of a negative trend vote on our MAA for trofinetide for the treatment of Rett syndrome, following a CHMP oral explanation which led to a negative CHMP opinion in February 2026. We requested a re-examination of the CHMP's opinion, however, the results of the re-examination may not be favorable to us and our ability to ultimately obtain approval for trofinetide for the treatment of Rett syndrome may be negatively impacted.

The EMA or comparable foreign regulatory authorities may also require us to conduct additional preclinical studies or clinical trials for trofinetide either prior to or post-approval or may object to elements of our clinical development program. If we were required to conduct such additional preclinical studies or clinical trials, the EMA or comparable foreign regulatory authorities may not agree with our interpretation of the results and we may not receive approval for trofinetide for the desired indication, or marketing of trofinetide, if approved, may be subject to additional requirements.

Trofinetide could fail to receive regulatory approval for many reasons, including the following:

- the EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials, the appropriateness or relevance of endpoints of our clinical trials, duration of our clinical trials, whether the patient population is sufficiently representative of the desired indication, the nature or existence of comparative data, size and duration of safety database, and our interpretation of meaningfulness and/or generalizability of findings;
- the EMA or comparable foreign regulatory authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the EU or the applicable foreign jurisdiction;
- we may be unable to demonstrate to the satisfaction of the EMA or comparable foreign regulatory authorities that trofinetide is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the EMA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that trofinetide's clinical and other benefits outweigh its safety risks to the satisfaction of the EMA or comparable foreign regulatory authorities;

- the EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to obtain regulatory approval in the EU or elsewhere for the proposed indication in the proposed population; and
- the approval policies or regulations of the EMA, the European Commission or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Any of the above events could prevent us from achieving market approval of trofinetide and could substantially increase the costs of commercializing trofinetide.

Of the large number of drugs in development, only a small percentage successfully complete European Commission or comparable foreign regulatory approval processes and are commercialized. Even if we receive approval for trofinetide, the European Commission or comparable foreign regulatory authorities may grant approval contingent on the performance of costly additional clinical trials, including post-approval clinical trials, and/or the implementation of risk management strategies, which may be required to ensure safe use of the drug after approval. The European Commission or comparable foreign regulatory authorities also may approve trofinetide for a more limited indication or patient population than we originally requested, and the European Commission or comparable foreign regulatory authorities may not approve the labeling that we believe is necessary or desirable for the successful commercialization of trofinetide. As a result, any approval may fail to create the value we were expecting trofinetide to generate. Further, if we do not receive marketing approval for trofinetide in the EU or other jurisdictions outside of North America, including Japan, we will not be able to commercialize trofinetide in such jurisdictions at all.

If the results or timing of regulatory filings, the regulatory process, regulatory developments, clinical trials or preclinical studies, or other activities, actions or decisions related to DAYBUE or trofinetide do not meet our or others' expectations, the market price of our common stock could decline significantly and the long-term success of the product and our company could be harmed.

***Expanded access or compassionate use programs could subject us to additional risks.***

We currently provide and may provide in the future access to unapproved products or product candidates outside of clinical trials through expanded access or compassionate use programs (sometimes referred to as named patient or right to try programs). These patients generally have life-threatening or severe illnesses for which there are no alternative therapies or they have exhausted all other available therapies, and unapproved products or product candidates may be provided to eligible patients based upon the request of healthcare professionals as allowed by country specific laws and regulations. There are a number of risks that we may face as a result of our expanded access or compassionate use programs. For example, the risk for serious adverse events in certain of these patient populations is high, which, if those adverse events are determined (or perceived) to be drug-related, could have a negative impact on the safety profile of our products and product candidates and cause significant delays, result in an inability to successfully commercialize our products and materially harm our business.

In certain jurisdictions, we may provide our product for a charge, and in others, we may be required to provide our products free of charge if we participate in expanded access or compassionate use programs. In other jurisdictions we may be required to return some or all of the revenue we may generate through our expanded access or compassionate use programs if the appropriate foreign regulatory authority ultimately does not approve our products or product candidates for marketing in the jurisdiction of our expanded access or compassionate use programs. If this were to occur, it could materially and adversely affect our business operations and financial performance.

***Delays, suspensions, variations and terminations in our clinical trials for our product candidates could result in increased costs to us and delay our ability to generate product revenues.***

The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organizations (CROs) and clinical trial sites;
- manufacturing sufficient quantities of a product candidate;
- obtaining clearance from the FDA to commence clinical trials pursuant to an Investigational New Drug application;
- obtaining approval to conduct clinical trials in countries or jurisdictions outside the United States pursuant to evolving regional and local regulations (e.g., EU Clinical Trials Regulation (EU No. 536/2014));

- obtaining institutional review board approval or a positive Ethics Committee opinion to conduct a clinical trial at a prospective clinical trial site; and
- patient recruitment, which is a function of many factors, most of which is outside our control, including the size of the patient population, the nature of the protocol (including limitations in the protocol that further limit the size of the potential trial population), the proximity of patients to clinical trial sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial.

Once a clinical trial has begun, it may be delayed, suspended, varied or terminated due to a number of factors, including:

- competition for internal and external resources, including clinical sites and study patients, that we may choose to allocate to other programs;
- ongoing discussions with regulatory authorities regarding the scope or design of our clinical trials or requests by them for supplemental information with respect to our clinical trial results;
- imposition of clinical holds by regulatory authorities, institutional review boards or Ethics Committees;
- failure to conduct clinical trials in accordance with regulatory requirements or other irregularities in clinical trial conduct;
- inability to monitor patients adequately during or after treatment;
- difficulty monitoring multiple study sites;
- patient enrollment, which is a function of many factors, most of which is outside our control, including the size of the patient population, the nature of the protocol (including limitations in the protocol that further limit the size of the potential trial population such as, for example, our Phase 2 RADIANT study, which is subject to certain defined enrollment criteria that has caused enrollment to take longer than expected), the proximity of patients to clinical trial sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial;
- lower than anticipated screening or retention rates of patients in clinical trials;
- serious adverse events or side effects experienced by participants; and
- insufficient supply or deficient quality of product candidates or other materials necessary for the conduct of our clinical trials.

In addition, enrollment and retention of patients in, or the ability to receive results from, clinical trials could be disrupted by geopolitical or macroeconomic developments. For example, as a result of the conflict between Ukraine and Russia, we experienced temporary delays in accessing historical records of certain clinical trial sites located in Russia. It is possible that enrollment in future studies, could be impacted due to the same or similar geopolitical or macroeconomic developments. If patients withdraw from our trials, miss scheduled doses or follow-up visits or otherwise fail to follow trial protocols, or if our trial results are otherwise disrupted or disputed due to such developments, the integrity of data from our trials may be compromised or not accepted by the FDA or other regulatory authorities, which would represent a significant setback for the applicable program.

Many of these factors may also ultimately lead to denial of regulatory approval of a current or potential future product candidate. If we experience delays, suspensions or terminations in a clinical trial, clinical trial materials or investigational products, the commercial prospects for the related product candidate will be harmed, and our ability to generate product revenues will be delayed.

***If we are unable to attract, retain, and motivate key management, research and development, and sales and marketing personnel, our drug development programs, our research and discovery efforts, and our commercialization plans may be delayed and we may be unable to successfully commercialize our products, or develop our product candidates.***

Our success depends on our ability to attract, retain, and motivate highly qualified management, scientific, and commercial personnel. In particular, our development programs depend on our ability to attract and retain highly skilled development personnel, especially in the fields of neurological and rare diseases. We are currently hiring, and in the future we expect to need to continue to hire, additional personnel as we expand our research and development efforts for our products and product candidates, and commercial activities for our products. We face competition for experienced management, scientists, clinical operations personnel, commercial and other personnel from numerous companies and academic and other research institutions across all jurisdictions in which our products may be commercialized. Many of the other biotechnology and pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may

be more appealing to high quality candidates than that which we have to offer. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize products and product candidates, if approved, will be limited. If we are unable to attract and retain the necessary personnel, it will significantly impede our commercialization efforts for our products, and the achievement of our research and development objectives.

All of our employees are "at will" employees, which means that any employee may quit at any time and we may terminate any employee at any time. We do not carry "key person" insurance covering members of senior management.

**Risks Related to Our Business**

***If we fail to develop, acquire or in-license other product candidates or products, our business and prospects would be limited. Even if we obtain rights to other product candidates or products, we will incur a variety of costs and may never realize the anticipated benefits.***

Part of our corporate strategy is to develop, acquire or in-license businesses, technologies, product candidates or products that we believe are a strategic fit with our business. The success of this strategy depends in large part on the combination of our regulatory, development and commercial capabilities and expertise and our ability to identify, select and acquire or in-license clinically-enabled product candidates for the treatment of neurological and rare diseases, or for therapeutic indications that complement or augment our current products and product candidates, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. Identifying, selecting and acquiring or in-licensing promising product candidates requires substantial technical, financial and human resources expertise, and we may not be successful in identifying acquisition targets, completing proposed acquisitions and integrating any acquired businesses, technologies, services or products into our current infrastructure. Efforts to do so may not result in the actual acquisition or in-license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. If we are unable to identify, select and acquire or license suitable product candidates from third parties on terms acceptable to us, our business and prospects will be limited.

The process of integrating any acquired business, technology, service, or product may result in unforeseen operating difficulties and expenditures and may divert significant management attention from our ongoing business operations. As a result, we will incur a variety of costs in connection with an acquisition and may never realize its anticipated benefits. Moreover, any product candidate we identify, select and acquire or license may require additional, time-consuming development or regulatory efforts prior to commercial sale, including preclinical studies, if applicable, and extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to the risk of failure that is inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities. In addition, any such products that are approved may not be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective or desired than other commercially available alternatives.

***We may require additional financing in the future to fund our operations. If we cannot raise additional financing in the future, we may be unable to fund our business plan and our future research, development, commercial and manufacturing efforts.***

We have funded our operations primarily with revenues from sales of our products since their approvals, and through sales of our equity securities and interest income. We anticipate that the level of cash used in our operations will fluctuate in future periods depending on the levels of spending required for our ongoing and planned commercial activities for our products, our ongoing and planned development activities for remlifanserin as a treatment for ADP and LBDP, studies to be conducted pursuant to our PMRs, our ongoing and planned development activities for other early- and late-stage product candidates and strategic business development to further expand our portfolio. We expect that our cash, cash equivalents and investment securities, as well as funds generated by anticipated sales of our products, will be sufficient to fund our planned operations through and beyond the next 12 months.

We may require additional financing in the future to fund our operations. Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

- the costs of acquiring additional product candidates or research and development programs;
- the scope, prioritization and number of our research and development programs;
- the ability of our collaborators and us to reach the milestones and other events or developments triggering payments under our collaboration or license agreements, or our collaborators' ability to make payments under these agreements;
- our ability to enter into new collaboration and license agreements;

- the progress in, and the costs of, our ongoing and planned development activities for pimavanserin, post-marketing studies for DAYBUE to be conducted over the next several years, and ongoing and planned commercial activities for our products;
- the costs of our development activities for our product candidates;
- the costs of commercializing our products, including the maintenance and development of our sales and marketing capabilities;
- the costs of establishing, or contracting for, sales and marketing capabilities for our product candidates;
- the amount of U.S. product sales from our products;
- the costs of preparing applications for regulatory approvals for DAYBUE in jurisdictions other than the U.S. and for other product candidates, as well as the costs required to support review of such applications;
- the costs of manufacturing and distributing our products for commercial use in the U.S.;
- our ability to obtain regulatory approval for, and subsequently generate product sales from our product candidates;
- the extent to which we are obligated to reimburse collaborators or collaborators are obligated to reimburse us for costs under collaboration agreements;
- the costs involved in filing, prosecuting, enforcing, and defending patent claims and other intellectual property rights;
- the costs of maintaining or securing manufacturing arrangements for clinical or commercial production of pimavanserin, trofinetide or other product candidates; and
- the costs associated with litigation, including the costs incurred in defending against any product liability claims that may be brought against us related to our products.

In the past, periods of turmoil and volatility in the financial markets have adversely affected the market capitalizations of many biotechnology companies, and generally made equity and debt financing more difficult to obtain. For example, as a result of geopolitical and macroeconomic developments, the global credit and financial markets have experienced extreme volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. These events, coupled with other factors, may limit our access to additional financing in the future if needed, and could have a material adverse effect on our ability to access sufficient funding. We cannot be certain that additional funding will be available to us on a timely basis, on acceptable terms, or at all. If additional funds are not available, we will be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts. We also may be required to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Additional funding, if necessary and obtained, may significantly dilute existing stockholders and could negatively impact the price of our stock.

***We expect that our results of operations will fluctuate, which may make it difficult to predict our future performance from period to period.***

Our operating results have fluctuated in the past and are likely to do so in future periods. Some of the factors that could cause our operating results to fluctuate from period to period include:

- the success of our commercialization of our products;
- the impact of geopolitical and macroeconomic developments, international tariffs, general political, health and economic conditions, as well as any related political or economic responses and counter-responses or otherwise by various global actors or the general effect on the global economy and supply chain, pandemics or epidemics, economic slowdowns, recessions, inflation, high interest rates and tightening of credit markets on our business;
- the status and cost of our PMRs for DAYBUE;
- the variation in our gross-to-net adjustments from quarter to quarter, primarily because of the fluctuation in our share of the donut hole for Medicare Part D patients;
- the status and cost of development and commercialization of our product candidates, if approved, including compounds being developed under our collaborations;
- whether we acquire or in-license additional product candidates or products, and the status of development and commercialization of such product candidates, if approved, or products;

- whether we are required to make payments due to achieving specified milestones under any licensing or similar agreements or otherwise make payments under these agreements;
- the incurrence of preclinical or clinical expenses that could fluctuate significantly from period to period, including reimbursement obligations pursuant to our collaboration agreements;
- the initiation, termination, or reduction in the scope of our collaborations or any disputes regarding these collaborations;
- the timing of our satisfaction of applicable regulatory requirements;
- the rate of expansion of our clinical development, other internal research and development efforts, and pre-commercial and commercial efforts;
- the effect of competing technologies and products and market developments;
- the costs associated with litigation, including the costs incurred in defending against any product liability claims that may be brought against us related to our products or our product candidates; and
- general and industry-specific economic conditions.

We believe that comparisons from period to period of our financial results are not necessarily meaningful and should not be relied upon as indications of our future performance.

From time to time, we provide guidance relating to our expectations for total revenue, net sales of our products and certain expense line items based on estimates and the judgment of management at the time. If, for any reason, our actual total revenue, net sales or expenses differ materially from our guidance, we may have to revise our previously announced financial guidance. If we revise previously announced financial guidance, such revisions may not reflect actual results due to, among other things, being based on our management's estimates and judgments at the time. If we change, update or fail to meet any element of such guidance, our stock price could decline.

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

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, legislation referred to as the OBBBA, enacted in 2025, along with prior U.S. federal tax reform legislation, enacted many significant changes to the U.S. taxation of business entities, including, among other changes, changes to the taxation of income derived from international operations, changes in the deduction and amortization of research and development expenditures, and limitations on the deductibility of business interest. For example, for tax years beginning after December 31, 2024, the OBBBA restores the tax deductibility of domestic research and development expenses in the year incurred, which expenses had been required under prior legislation to be capitalized and subsequently amortized over five years. The OBBBA did not change the tax treatment of expenses incurred in research and development activities conducted outside the United States, which expenses continue to be required to be capitalized and amortized over 15 years. We are evaluating the potential impacts this and other changes under the OBBBA may have on our business. Future guidance from the Internal Revenue Service and other tax authorities with respect to any legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation or sunset in future years. In addition, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

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

Portions of our net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. U.S. federal net operating losses incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating loss carryforwards in a taxable year is limited to 80% of taxable income in such year. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50 percent change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have experienced ownership changes in the past and we may experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California imposed limits on the usability of California state net operating losses to offset taxable income in tax years beginning after 2023 and before 2027. As a result, if we earn net taxable income, we may be unable to use all or a material portion of our net operating loss carryforwards and other tax attributes, which could potentially result in increased future tax liability to us and adversely affect our future cash flows.

***Tax authorities could reallocate our taxable income among our subsidiaries, which could increase our overall tax liability.***

The amount of taxes we pay in different jurisdictions depends on the application of the tax laws of various jurisdictions, including the United States, to our international business activities, tax rates, new or revised tax laws, or interpretations of tax laws and policies, and our ability to operate our business in a manner consistent with our corporate structure and intercompany arrangements. In 2015, we licensed worldwide intellectual property rights related to pimavanserin in certain indications to Acadia Pharmaceuticals GmbH, our wholly owned Swiss subsidiary (Acadia GmbH), and in July 2020 we licensed additional related rights to Acadia GmbH. Our goals for the establishment of Acadia GmbH, and the licensing of worldwide intellectual property rights for pimavanserin, include building a platform for long-term operational and financial efficiencies, including tax-related efficiencies. The taxing authorities of the jurisdictions in which we operate may challenge our methodologies for pricing intercompany transactions pursuant to our intercompany arrangements or disagree with our determinations as to the income and expenses attributable to specific jurisdictions. In addition, future changes in U.S. and non-U.S. tax laws, including implementation of international tax reform relating to the tax treatment of multinational corporations, if enacted, may reduce or eliminate any potential financial efficiencies that we hoped to achieve by establishing this operational structure. Additionally, taxing authorities, such as the U.S. Internal Revenue Service, may audit and otherwise challenge these types of arrangements, and have done so with other companies in the pharmaceutical industry. If any such challenge or disagreement were to occur or change in tax law were enacted, we could be required to pay additional taxes, interest and penalties, which could result in one-time tax charges, higher effective tax rates, reduced cash flows and lower overall profitability of our operations. Our financial statements could fail to reflect adequate reserves to cover such a contingency. Similarly, a taxing authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions.

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

Our results of operations could be adversely affected by general conditions in the U.S. and global economies, the U.S. and global financial markets and adverse macroeconomic developments. U.S. and global market and economic conditions have been, and continue to be, disrupted and volatile due to many factors, including international tariffs, material shortages and related manufacturing and supply chain challenges, shutdowns of the federal government and the resulting effects on its regulatory agencies, geopolitical developments (as well as any related political or economic responses and counter-responses or otherwise by various global actors or the general effect on the global economy and manufacturing and supply chain), and the responses by central banking authorities to control inflation, among others. General business and economic conditions that could affect our business, financial condition or results of operations include fluctuations in economic growth, debt and equity capital markets, liquidity of the global financial markets, the availability and cost of credit, investor and consumer confidence, and the strength of the economies in which we, our collaborators, our manufacturers and our suppliers operate.

A severe or prolonged global economic downturn could result in a variety of risks to our business. For example, high inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital on acceptable terms, if at all. In addition, reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks. Risks of a prolonged global economic downturn are particularly true in Europe, which is undergoing a continued severe economic crisis. A weak or declining economy could also strain our suppliers and manufacturers, possibly resulting in supply and clinical trial disruption. 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.

***International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.***

We operate in a global economy, and our business depends on a global supply chain for the development, manufacturing, and distribution of our pharmaceutical products, and for the advancement of our preclinical and clinical development programs. There is inherent risk, based on the complex relationships among the U.S. and the countries in which we conduct our business, that political, diplomatic, and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty.

We source significant quantities of active pharmaceutical ingredients (APIs), precursor chemicals, and specialized equipment from international suppliers, with substantial reliance on foreign manufacturers, including China. Tariff policies, particularly those affecting China and pharmaceutical products, could materially increase our costs and reduce our profitability, including as a result of our inability to adjust pricing in formulary-based markets. Recent and potential future changes in international trade policies, including U.S.-China trade relations and pharmaceutical-specific tariffs, present material risks to our operations and financial performance.

Recent policy discussions have included potential targeted tariffs or other trade measures specifically aimed at pharmaceutical products and ingredients as part of broader healthcare cost control or national security initiatives. For example, the Bureau of Industry and Security, U.S. Department of Commerce, has initiated an investigation to determine whether pharmaceutical ingredients, including finished drug product, manufactured outside the United States pose a national security risk and should be subject to additional tariffs. Unlike consumer goods, pharmaceuticals face unique regulatory, technology and capacity constraints that make rapid supply chain adjustments particularly difficult and costly. Should the current tariffs hold or additional tariffs be imposed specifically targeting pharmaceutical imports, our production costs could rise significantly, and it would be difficult and costly to qualify alternative sources within another country with a lower tariff rate or within the United States, as developing and qualifying alternative sources typically requires substantial lead time and substantial investment and regulatory approvals. Moreover, the dynamic and unpredictable tariff and trade landscape creates substantial uncertainty and significant planning challenges for our operations and to our CMOs' long term capital investment plans. Changes in tariff classifications, country-of-origin requirements, or customs procedures can occur with limited notice. This uncertainty complicates our long-term investment decisions regarding manufacturing facilities, supply chain optimization, and research and development locations.

Unlike many industries, our ability to pass increased costs to customers is limited by the structure of pharmaceutical pricing and reimbursement systems. Many of our products are included in formularies with pricing established through annual or multi-year contracts with commercial, third-party payors and pharmacy benefit managers, and reimbursement methodologies established by government programs, such as Medicare and Medicaid. These arrangements typically include fixed pricing terms that were determined prior to the implementation of the recently announced tariffs and well ahead of payors' fiscal cycles (typically 12-18 months ahead of a calendar year). As a result, and depending on their timing and scope, tariff-induced cost increases may be difficult or impossible to pass through to customers until the 2027 calendar year at the earliest, perhaps even a year later.

Current or future tariffs will also result in increased research and development expenses, including with respect to increased costs associated with APIs, raw materials, laboratory equipment and research materials and components. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence and negatively impact our business, results of operations, financial condition and growth prospects.

The complexity of announced or future tariffs may also increase the risk that we or our suppliers may be subject to civil or criminal enforcement actions in the United States or foreign jurisdictions related to compliance with trade regulations. Foreign governments may also adopt non-tariff measures, such as procurement preferences or informal disincentives to engage with, purchase from or invest in U.S. entities, which may limit our ability to compete internationally and attract non-U.S. investment, employees, customers and suppliers. Foreign governments may also take other retaliatory actions against U.S. entities, such as decreased intellectual property protection, increased enforcement actions, or delays in regulatory approvals, which may result in heightened international legal and operational risks. In addition, the United States and other governments have imposed and may continue to impose additional sanctions, such as trade restrictions or trade barriers, which could restrict us from doing business directly or indirectly in or with certain countries or parties and may impose additional costs and complexity to our business.

Trade disputes, tariffs, restrictions and other political tensions between the United States and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability, and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition, and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions, or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and prospects. In addition, tariffs and other trade developments have and may continue to heighten the risks related to the other risk factors described elsewhere in this report.

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

We depend on our employees, consultants, and CROs, as well as regulatory agencies and other parties, for the continued operation of our business. While we maintain disaster recovery plans, those plans may not adequately protect us. Despite any precautions that we or any third parties on whom we depend take for catastrophic events, including earthquakes, fires or other natural disasters, these events could result in significant disruptions to our research and development, clinical trials, manufacturing and the commercialization of our products. Long-term disruptions in the infrastructure caused by these types of events, particularly involving geographies in which we or third parties on whom we depend have offices or manufacturing, distribution or clinical trial sites, could adversely affect our businesses, including as a result of the affected third parties' decision to deprioritize their service commitments to us. Although we carry business interruption insurance policies and typically have provisions in our contracts that protect us in certain events, our coverage might not include or be adequate to compensate us for all losses that may occur. Any catastrophic event affecting us or the third parties on whom we depend could have a material adverse effect on our business, results of operations, financial condition and prospect.

***We have incurred, and expect to continue to incur, significant costs as a result of laws, regulations and standards relating to various aspects of our business, including corporate governance, work force initiatives and other matters, and failure to comply with such laws, regulations and standards could adversely affect our business.***

Laws, regulations and standards affecting various aspects of our business, including as a result of provisions of the Dodd-Frank Wall Street Reform and Consumer Protection Act that was enacted in July 2010, the provisions of the Sarbanes-Oxley Act of 2002 (SOX), rules adopted or proposed by the SEC and by The Nasdaq Stock Market and executive orders, have resulted in, and will continue to result in, significant costs to us as we evaluate the implications of these laws, regulations and standards and respond to their requirements. Certain laws, regulations and standards are subject to varying interpretations in some 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, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure, policies and governance practices. For example, in the future, if we are not able to issue an evaluation of our internal control over financial reporting, as required, or we or our independent registered public accounting firm determine that our internal control over financial reporting is not effective, this shortcoming could have an adverse effect on our business and financial results and the price of our common stock could be negatively affected. Further, new laws, regulations and standards could make it more difficult or more costly for us to operate our business, including obtaining certain types of insurance (such as director and officer liability insurance), and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the coverage that is the same or similar to our current coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors and board committees, and as our executive officers. If we fail, or are perceived to fail, to comply with these laws, regulations and standards, our reputation may be harmed and we might be subject to litigation, sanctions, investigations or other regulatory proceedings, which would adversely affect our financial results and our business. We cannot predict or estimate the total amount of the costs we may incur or the timing of such costs to comply with these laws, regulations and standards.

***Our business involves the use of hazardous materials, and we and our third-party manufacturers and suppliers must comply with environmental, health and safety laws and regulations, which can be expensive and restrict how we do, or interrupt our, business.***

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the generation, storage, use and disposal of hazardous materials, including the components of our products and product candidates and other hazardous compounds and wastes. We and our manufacturers and suppliers are subject to environmental, health and safety laws and regulations governing, among other matters, the use, manufacture, generation, storage, handling, transportation, discharge and disposal of these hazardous materials and wastes and worker health and safety. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination or injury, which could result in an interruption of our commercialization efforts, research and development efforts and business operations, damages and significant cleanup costs and liabilities under applicable environmental, health and safety laws and regulations. We also cannot guarantee that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials and wastes generally comply with the standards prescribed by these laws and regulations. We may be held liable for any resulting damages costs or liabilities, which could exceed our resources, and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental, health and safety laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. Failure to comply with these environmental, health and safety laws and regulations may result in substantial fines, penalties or other sanctions. We do not currently carry hazardous waste insurance coverage.

***Our management has broad discretion over the use of our cash and we may not use our cash effectively, which could adversely affect our results of operations.***

Our management has significant flexibility in applying our cash resources and could use these resources for corporate purposes that do not increase our market value, or in ways with which our stockholders may not agree. We may use our cash resources for corporate purposes that do not yield a significant return or any return at all for our stockholders, which may cause our stock price to decline.

**Risks Related to Our Relationships with Third Parties**

***We depend on collaborations with third parties to develop certain of our product candidates and may need to enter into future collaborations to develop and commercialize certain of our product candidates.***

We depend on collaborations with third parties to develop certain of our product candidates and may need to enter into future collaborations to develop and commercialize certain of our product candidates. In addition, we may choose to rely on collaborations in the future for our products or other product candidates, including for the commercialization of DAYBUE in selected markets outside of the U.S.

Our collaborators may fail to develop or effectively commercialize products using our product candidates, if approved, or technologies because they:

- do not have sufficient resources or decide not to devote the necessary resources due to internal constraints such as limited cash or human resources or a change in strategic focus;
- may not properly maintain, enforce or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- terminate the arrangement or allow it to expire, which would delay the development and commercialization and may increase the cost of developing and commercializing our products or product candidates, if approved;
- may sell, transfer or divest assets or programs related to our partnered product or product candidates;
- may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement;
- decide to pursue a competitive product developed outside of the collaboration; or
- cannot obtain the necessary regulatory approvals.

Collaborations are complex and time-consuming to negotiate and document. Given the current economic and industry environment, it is possible that competition for new collaborators may increase. We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all. If we are unable to find new collaborations, we may not be able to continue advancing our programs alone.

***Our collaborations may be subject to conflicts or disputes, which could have a material adverse effect on our business, results of operations and financial condition.***

Conflicts may arise in our collaborations due to one or more of the following:

- disputes or breaches with respect to payments that we believe are due under the applicable agreements, particularly in the current environment when companies, including large established ones, may be seeking to reduce external payments;
- disputes on strategy as to what development or commercialization activities should be pursued under the applicable agreements;
- disputes as to the responsibility for conducting development and commercialization activities pursuant to the applicable collaboration, including the payment of costs related thereto;
- disagreements with respect to ownership of intellectual property rights;
- unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities, or to permit public disclosure of these activities;
- delay or reduction of a collaborator's development or commercialization efforts with respect to our product candidates, if approved; or
- termination or non-renewal of the collaboration.

Conflicts arising with our collaborators could impair the progress of our product candidates, harm our reputation, result in a loss of revenues, reduce our cash position, and cause a decline in our stock price.

In addition, in our past collaborations, from time to time, we have agreed not to conduct independently, or with any third party, any research that is directly competitive with the research conducted under the applicable program. Any collaborations we establish in the future may have the effect of limiting the areas of research that we may pursue, either alone or with others. Conversely, the terms of any collaboration we may establish in the future might not restrict our collaborators from developing, either alone or with others, products or product candidates in related fields that are competitive with the products or product candidates that are the subject of these collaborations. Competing products and product candidates, either developed by our collaborators or to which our collaborators have rights, may result in the allocation of resources by our collaborators to competing products and product candidates, and their withdrawal of support for our products and product candidates or may otherwise result in lower demand for our potential products and product candidates.

In addition, disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, if approved, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the related product candidates, if approved, which would have a material adverse effect on our business.

***We rely on third parties to conduct our clinical trials and perform data collection and analysis, which may result in costs and delays that prevent us from successfully commercializing product candidates, if approved.***

Although we design and manage our current preclinical studies and clinical trials, we currently do not have the ability to conduct clinical trials for our product candidates on our own. We rely on CROs, medical institutions, clinical investigators, and contract laboratories to perform data collection and analysis and other aspects of our clinical trials. In addition, we also rely on third parties to assist with our preclinical studies, including studies regarding biological activity, safety, absorption, metabolism, and excretion of product candidates. Some of these third parties may experience shutdowns or other disruptions as a result of adverse geopolitical or macroeconomic developments and therefore may be unable to provide the level of service that we have received in the past.

Our preclinical activities or clinical trials may be delayed, suspended, or terminated if:

- these third parties do not successfully carry out their contractual duties or fail to meet regulatory obligations or expected deadlines;
- these third parties need to be replaced; or
- the quality or accuracy of the data obtained by these third parties is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons.

Failure to perform by these third parties may increase our development costs, delay our ability to obtain regulatory approval, and delay or prevent the commercialization of our product candidates, if approved. We currently use several CROs to perform services for our preclinical studies and clinical trials. While we believe that there are numerous alternative sources to provide these services, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without delays, additional expenditures, or at all, any of which could negatively affect our business, results of operations, financial condition and prospects.

***We currently depend, and in the future will continue to depend, on third parties to manufacture our products and product candidates. If these manufacturers fail to provide us or our collaborators with adequate supplies of clinical trial materials and commercial product or fail to comply with the requirements of regulatory authorities, we may be unable to develop or commercialize our products or product candidates, if approved.***

We have no manufacturing facilities and only limited experience as an organization in the manufacturing of drugs or in designing drug-manufacturing processes. We have contracted with third-party manufacturers to produce, in collaboration with us, our products and product candidates.

We have contracted with Patheon to manufacture NUPLAZID 10 mg tablet and 34 mg capsule drug product and DAYBUE for commercial use, Catalent to manufacture NUPLAZID 34 mg drug product for commercial use in the U.S., Bend to manufacture DAYBUE for commercial use, and Halo to manufacture trofinetide DAYBUE STIX 5g, 6g, and 8g drug product stick packs for commercial use in the U.S. Additionally, we have contracted with Siegfried to manufacture API to be used in the manufacture of NUPLAZID drug product for commercial use, and Corden, FIS and Flamma to manufacture API to be used in the manufacture of DAYBUE drug product for commercial use. However, we have not entered into any agreements with any alternate suppliers for 10 mg NUPLAZID drug product or NUPLAZID API. We may face delays or increased costs in our supply chain that could jeopardize the commercialization of our products. While we currently have sufficient API for both NUPLAZID and DAYBUE and NUPLAZID and DAYBUE finished products on hand to continue our commercial and clinical operations as planned, depending on the effects of geopolitical and macroeconomic developments and whether such developments cause disruptions, we may face such delays or costs in future years. If any third party in our supply or distribution chain for materials or finished product is adversely impacted by geopolitical and macroeconomic developments, including rapid changes in U.S. trade policy, such as the imposition of tariffs and trade barriers as well as potential retaliatory measures taken by other governments, our supply chain may be disrupted, limiting our ability to manufacture, test and distribute our products for commercial sales and our product candidates for our clinical trials and research and development operations. For example, it takes approximately two years for our third-party manufacturers to produce DAYBUE API, and a supply chain disruption in DAYBUE API would cause delays or increased costs to us that could jeopardize the commercialization of DAYBUE.

Even though we have agreements with third parties for the manufacture of our products, the FDA or comparable foreign regulatory authorities may not approve the facilities of such manufacturers, the manufacturers may not perform as agreed, or the manufacturers may terminate their agreements with us. If any of the foregoing circumstances occur, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, maintain or obtain, as applicable, regulatory approval for or market our products or product candidates. While we believe that there will be alternative sources available to manufacture our products and product candidates, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without delays or additional expenditures. We cannot estimate these delays or costs with certainty but, if they were to occur, they could cause a delay in our development and commercialization efforts, which would have a negative effect on our business, results of operations, financial condition and prospects.

The manufacturers of our products and product candidates, including Patheon, Calatent, Bend, Halo, Siegfried, Corden, FIS and Flamma, are obliged to operate in accordance with FDA-mandated and comparable foreign regulatory authorities' cGMPs, and we have limited control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel to ensure compliance with cGMPs. In addition, the facilities used by our third-party manufacturers to manufacture our products and product candidates must be approved by the FDA pursuant to inspections that will be conducted prior to any grant of regulatory approval by the FDA. Similar requirements apply abroad. If any of our third-party manufacturers are unable to successfully manufacture material that conforms to our specifications and the FDA's or comparable foreign regulatory authorities' strict regulatory requirements, or pass regulatory inspection, they will not be able to secure or maintain approval for the manufacturing facilities. We, or our contract manufacturers, any future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA, competent authorities of EU Member States or other comparable foreign regulatory authorities, to monitor and ensure compliance with cGMP. Despite our efforts to audit and verify regulatory compliance, one or more of our third-party manufacturing vendors may be found on regulatory inspection by the FDA, competent authorities of EU Member States or other comparable foreign regulatory authorities to be noncompliant with cGMP regulations. Additionally, a failure by any of our third-party manufacturers to establish and follow cGMPs or to document their adherence to such practices may lead to significant delays in clinical trials or in obtaining regulatory approval of product candidates, or result in issues maintaining regulatory approval of our products and any product candidate that receives regulatory approval, negatively impact our commercialization of our products, or lead to significant delays in the launch and commercialization of any other products we may have in the future. Failure by our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including shutdown of the third-party vendor or invalidation of drug product lots or processes, fines, injunctions, civil penalties, failure of regulatory authorities to grant pre-market approval of drugs, delays, suspension, variation or withdrawal of approvals, seizures or recalls of products, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our products, if approved, and significantly harm our business, financial condition, results of operations and prospects.

The manufacture of pharmaceutical products requires significant capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. We cannot assure you that any issues relating to the manufacture of our products or product candidates will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to commercialize our products, or provide our products or product candidates to patients in clinical trials, would be jeopardized. Any delay or interruption in our ability to meet commercial demand for our products and any other approved products will result in the loss of potential revenues and could adversely affect our ability to gain market acceptance for these products. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

Failures or difficulties faced at any level of our supply chain could materially adversely affect our business and delay or impede the development and commercialization of our products or product candidates, if approved, and could have a material adverse effect on our business, results of operations, financial condition and prospects. Further, changes in federal policy could affect the geopolitical landscape and could give rise to circumstances that negatively affect our business. The third parties that manufacture our products and product candidates have manufacturing activities located in Canada, the European Union and Switzerland. The U.S. has implemented, and has proposed to further implement, tariffs that may affect the availability of imported raw materials used in the production of our products and/or increase the costs of our third-party manufacturers and the expense to us to produce our products and product candidates. Additionally, other governments have enacted, and may continue to enact, retaliatory measures in response to such tariffs. If such actions were to materially affect us or our third-party manufacturers, we may not be able to successfully commercialize our products, which would have an adverse effect on our results of operations.

***We may not be able to continue or fully exploit our collaborations with outside scientific and clinical advisors, which could impair the progress of our clinical trials and our research and development efforts.***

We work with scientific and clinical advisors at academic and other institutions who are experts in the field of neurological and rare diseases. They assist us in our research and development efforts and advise us with respect to our clinical trials. These advisors are not our employees and may have other commitments that would limit their future availability to us. Although our scientific and clinical advisors generally agree not to engage in competing work, if a conflict of interest arises between their work for us and their work for another entity, we may lose their services, which may impair our reputation in the industry and delay the development or commercialization of our product candidates, if approved.

**Risks Related to Our Intellectual Property**

***Our ability to compete may decline if we do not adequately protect our proprietary rights.***

Our commercial success depends on obtaining and maintaining intellectual property rights to our products and product candidates and technologies, as well as successfully defending these rights against third-party challenges. Successful challenges to, or misappropriation of, our intellectual property could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. To protect our intellectual property, we rely on a combination of patents, trade secret protection and contracts requiring confidentiality and nondisclosure. If our patents are successfully challenged, we may face generic competition prior to the expiration dates of our U.S. Orange Book listed patents. In addition, potential competitors have in the past and may in the future file an Abbreviated New Drug Application (ANDA) with the FDA for generic versions of NUPLAZID, seeking approval prior to the expiration of our patents. In response, we have filed complaints against these companies alleging infringement of certain of our Orange Book-listed patents covering NUPLAZID and DAYBUE. For a more detailed description of these matters, see the section captioned “Legal Proceedings” elsewhere in this report. While we intend to defend the validity of such patents vigorously, and will seek to use all appropriate methods to prevent their infringement, such efforts are expensive and time consuming. Any substantial decrease in the revenue and income derived from our products would have an adverse effect on our results of operations.

With regard to patents, although we control numerous patent applications worldwide with respect to pimavanserin and trofinetide, not all of our patent applications resulted in an issued patent, or they resulted in an issued patent that is susceptible to challenge by a third party. Our ability to obtain, maintain, and/or defend our patents covering our product candidates and technologies is uncertain due to a number of factors, including:

- we may not have been the first to make the inventions covered by our pending patent applications or issued patents;
- we may not have been the first to file patent applications for our product candidates or the technologies we rely upon;
- others may develop similar or alternative technologies or design around our patent claims to produce competitive products that fall outside of the scope of our patents;
- our disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;
- we may not seek or obtain patent protection in all countries that will eventually provide a significant business opportunity;
- any patents issued to us or our collaborators may not provide a basis for commercially viable products, may not provide us with any competitive advantages, or are easily susceptible to challenges by third parties;
- our proprietary technologies may not be patentable;
- changes to patent laws that limit the exclusivity rights of patent holders or make it easier to render a patent invalid;
- recent decisions by the U.S. Supreme Court limiting patent-eligible subject matter;
- litigation regarding our patents may include challenges to the validity, enforceability, scope and term of one or more patents;
- the passage of The Leahy-Smith America Invents Act (the America Invents Act), introduced new procedures for challenging pending patent applications and issued patents; and
- technology that we may in-license may become important to some aspects of our business; however, we generally would not control the patent prosecution, maintenance or enforcement of any such in-licensed technology.

Even if we have or obtain patents covering our product candidates or technologies, we may still be barred from making, using and selling our product candidates or technologies because of the patent rights of others. Others have or may have filed, and in the future are likely to file, patent applications covering compounds, assays, genes, gene products or therapeutic products that are similar or identical to ours. There are many issued U.S. and foreign patents relating to genes, nucleic acids, polypeptides, chemical compounds or therapeutic products, and some of these may encompass reagents utilized in the identification of candidate drug compounds or compounds that we desire to commercialize. Numerous U.S. and foreign issued patents and pending patent applications owned by others exist in the area of neurological diseases and the other fields in which we are developing products. These could materially affect our freedom to operate. Moreover, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, that may later result in issued patents that our product candidates or technologies may infringe. These patent applications may have priority over patent applications filed by us.

We regularly conduct searches to identify patents or patent applications that may prevent us from obtaining patent protection for our proprietary compounds or that could limit the rights we have claimed in our patents and patent applications. Disputes may arise regarding the ownership or inventorship of our inventions. For applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the U.S. Patent and Trademark Office (U.S. PTO), to determine who was the first to invent the invention at issue. It is difficult to determine how such disputes would be resolved. Applications containing a claim not entitled to priority before March 16, 2013, are not subject to interference proceedings due the change brought by the America Invents Act to a "first-to-file" system. However, a derivation proceeding can be brought by a third-party alleging that the inventor derived the invention from another.

Periodic maintenance fees on any issued patent are due to be paid to the U.S. PTO and foreign patent agencies in several stages over the lifetime of the patent. The U.S. PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Some of our academic institutional licensors, research collaborators and scientific advisors have rights to publish data and information to which we have rights. We generally seek to prevent our collaborators from disclosing scientific discoveries until we have the opportunity to file patent applications on such discoveries, but in some cases, we are limited to relatively short periods to review a proposed publication and file a patent application. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborations, then our ability to receive patent protection or protect our proprietary information may be impaired.

***Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.***

Because we operate in the highly technical field of drug discovery and development of small molecule drugs, we rely in part on trade secret protection in order to protect our proprietary technology and processes. However, trade secrets are difficult to protect. We enter into confidentiality, nondisclosure, and intellectual property assignment agreements with our corporate partners, employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. These agreements also 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. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time consuming and the outcome is unpredictable. In addition, courts outside the U.S. may be less willing to protect trade secrets. We also have not entered into any noncompete agreements with any of our employees. Although each of our employees is required to sign a confidentiality agreement with us at the time of hire, we cannot guarantee that the confidential nature of our proprietary information will be maintained in the course of future employment with any of our competitors. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

***A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time-consuming and costly, and an unfavorable outcome could harm our business.***

There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including post-issuance review proceedings before the U.S. PTO or oppositions and other comparable proceedings in foreign jurisdictions.

Central provisions of the America Invents Act went into effect on September 16, 2012 and on March 16, 2013. The America Invents Act includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications are being filed, prosecuted and litigated. For example, the America Invents Act enacted proceedings involving post-issuance patent review procedures, such as inter partes review (IPR), and post-grant review, that allow third parties to challenge the validity of an issued patent in front of the U.S. PTO Patent Trial and Appeal Board. Each proceeding has different eligibility criteria and different patentability challenges that can be raised. IPRs permit any person (except a party who has been litigating the patent for more than a year) to challenge the validity of the patent on the grounds that it was anticipated or made obvious by prior art. Patents covering pharmaceutical products have been subject to attack in IPRs from generic drug companies and from hedge funds. If it is within nine months of the issuance of the challenged patent, a third party can petition the U.S. PTO for post-grant review, which can be based on any invalidity grounds and is not limited to prior art patents or printed publications.

In post-issuance proceedings, U.S. PTO rules and regulations generally tend to favor patent challengers over patent owners. For example, unlike in district court litigation, claims challenged in post-issuance proceedings are given their broadest reasonable meaning, which increases the chance a claim might be invalidated by prior art or lack support in the patent specification. As another example, unlike in district court litigation, there is no presumption of validity for an issued patent, and thus, a challenger's burden to prove invalidity is by a preponderance of the evidence, as opposed to the heightened clear and convincing evidence standard. As a result of these rules and others, statistics released by the U.S. PTO show a high percentage of claims being invalidated in post-issuance proceedings. Moreover, with few exceptions, there is no standing requirement to petition the U.S. PTO for inter partes review or post-grant review. In other words, companies that have not been charged with infringement or that lack commercial interest in the patented subject matter can still petition the U.S. PTO for review of an issued patent. Thus, even where we have issued patents, our rights under those patents may be challenged and ultimately not provide us with sufficient protection against competitive products or processes.

We may be exposed to future litigation by third parties based on claims that our product candidates, technologies or activities infringe the intellectual property rights of others. In particular, there are many patents relating to specific genes, nucleic acids, polypeptides or the uses thereof to identify product candidates. Some of these may encompass genes or polypeptides that we utilize in our drug development activities. If our drug development activities are found to infringe any such patents, and such patents are held to be valid and enforceable, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from using the patented genes or polypeptides for the identification or development of drug compounds. There are also many patents relating to chemical compounds and the uses thereof. If our compounds are found to infringe any such patents, and such patents are held to be valid and enforceable, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from making, using or selling the patented compounds.

In addition to the patent infringement lawsuits against the filers of ANDAs pertaining to NUPLAZID, we may need to resort to litigation to enforce other patents issued to us, protect our trade secrets or determine the scope and validity of third-party proprietary rights. From time to time, we may hire scientific personnel formerly employed by other companies involved in one or more areas similar to the activities conducted by us. Either we or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of their prior affiliations. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. We may not be able to afford the costs of litigation. Any legal action against us or our collaborators could lead to:

- payment of damages, which could potentially be trebled if we are found to have willfully infringed a party's patent rights;
- injunctive or other equitable relief that may effectively block our ability to further develop, commercialize, and sell products; or
- we or our collaborators having to enter into license arrangements that may not be available on commercially acceptable terms, or at all.

As a result, we could be prevented from commercializing current or future products.

Furthermore, because of the substantial amount of pre-trial document and witness 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. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. Securities analysts and investors have in the past, and may again in the future perceive these results to be negative, it could have a substantial adverse effect on the trading price of our common stock.

***The patent applications of pharmaceutical and biotechnology companies involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our patent position.***

The strength of patents in the pharmaceutical and biotechnology field can be highly uncertain and involve complex legal and factual questions. The U.S. PTO's interpretation of the Supreme Court's decisions and the standards for patentability it sets forth are uncertain and could change in the future. Consequently, the issuance and scope of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. U.S. patents and patent applications may also be subject to interference proceedings as mentioned above, and U.S. patents may be subject to reexamination and post-issuance proceedings in the U.S. PTO (and foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent office), which proceedings could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. Similarly, opposition or invalidity proceedings could result in loss of rights or reduction in the scope of one or more claims of a patent in foreign jurisdictions. In addition, such interference, reexamination, post-issuance and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes.

In addition, changes in or different interpretations of patent laws in the U.S. and foreign countries may permit others to use our discoveries or to develop and commercialize our technology and products without providing any compensation to us or may limit the number of patents or claims we can obtain. In particular, there have been proposals to shorten the exclusivity periods available under U.S. patent law that, if adopted, could substantially harm our business. The product candidates that we are developing are protected by intellectual property rights, including patents and patent applications. If any of our product candidates becomes a marketable product, we will rely on our exclusivity under patents to sell the compound and recoup our investments in the research and development of the compound. If the exclusivity period for patents is shortened, then our ability to generate revenues without competition will be reduced and our business could be materially adversely impacted. The laws of some countries do not protect intellectual property rights to the same extent as U.S. laws and those countries may lack adequate rules and procedures for defending our intellectual property rights. For example, some countries, including many in Europe, do not grant patent claims directed to methods of treating humans and, in these countries, patent protection may not be available at all to protect our products and product candidates. In addition, U.S. patent laws may change which could prevent or limit us from filing patent applications or patent claims to protect our products and/or technologies or limit the exclusivity periods that are available to patent holders. For example, the America Invents Act (2012) included a number of significant changes to U.S. patent law. These included changes to transition from a "first-to-invent" system to a "first-to-file" system and to the way issued patents are challenged. These changes may favor larger and more established companies that have more resources to devote to patent application filing and prosecution. It is still not clear what, if any, impact the America Invents Act will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend our issued patents.

If we fail to obtain and maintain patent protection and trade secret protection of our product candidates, proprietary technologies and their uses, we could lose our competitive advantage and competition we face would increase, reducing our potential revenues and adversely affecting our ability to attain or maintain profitability.

**Risks Related to Government Regulation and Our Industry**

***Healthcare reform measures may negatively impact our ability to sell NUPLAZID, DAYBUE or our product candidates, if approved, profitably.****

In both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our products, as described in greater detail in the Government Regulation section of our Annual Report on Form 10-K filed on February 26, 2026.

For example, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA), as well as other 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 may receive for any of our approved products. The ACA, among other things, expanded and increased industry rebates for drugs covered by Medicaid, made changes to the coverage requirements under Medicare Part D, Medicare's prescription drug benefits program, and broadened access to health insurance. There have been legal and political challenges and amendments to certain aspects of the ACA.

For example, on July 4, 2025, the OBBBA was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies. It is unclear how any healthcare reform measures of the current administration will impact the ACA and our business.

Other legislative changes have been proposed and adopted in the U.S. since the ACA. For example, through the process created by the Budget Control Act of 2011, there are automatic reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments, including the Infrastructure Investment and Jobs Act and the Consolidated Appropriations Act of 2023, will remain in effect through 2032 unless additional Congressional action is taken.

An expansion in the government's role in the U.S. healthcare industry may increase existing congressional or governmental agency scrutiny on price increases, such as the ones we have implemented for NUPLAZID, cause general downward pressure on the prices of prescription drug products, lower reimbursements for providers using our products, reduce product utilization and adversely affect our business and results of operations.

The current administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, the Centers for Medicare & Medicaid Services (CMS) and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct to consumer platform, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions include, for example: (1) directives to reduce agency workforce and program cuts; (2) directing HHS and other agencies to lower prescription drug costs for Medicare through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products; (3) imposing tariffs on certain imported pharmaceutical products; and (4) as part of the Make America Healthy Again (MAHA) Commission's recent Strategy Report, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on PBM payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In the event Most-Favored-Nation pricing for pharmaceutical products is implemented and applicable to the products that we commercialize outside of the U.S., our revenue opportunities may be adversely affected, as our U.S. pricing would have to be reduced to the lowest price paid for the applicable product outside of the U.S. In such event, we may choose to forgo the ex-U.S. market to preserve more favorable U.S. pricing. In June 2024, the U.S. Supreme Court's Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass healthcare related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

Individual states in the U.S. have also increasingly passed legislation and implemented regulations designed to control pharmaceutical 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. Any such approved importation plans, if implemented, may result in lower drug prices for products covered by those programs.

In the EU, on January 12, 2025, Regulation (EU) 2021/2282 on HTA entered into application through a phased implementation. It is intended to increase cooperation among EU Member States in assessing clinical aspects of health technologies, including new medicinal products, by establishing a framework for joint clinical assessments, joint scientific consultations, and the early identification of emerging health technologies. The HTA Regulation permits EU Member States to use common tools, methodologies, and procedures and requires them to rely on EU-level joint clinical assessment reports for the clinical components of their national HTA evaluations. EU Member States, however, remain responsible for assessing non-clinical aspects, such as economic, ethical, and social considerations, and for making pricing and reimbursement decisions at the national level. As implementation of the HTA Regulation is phased in and key methodological and procedural guidance continues to evolve, there remains uncertainty regarding the evidence requirements, timing, and impact of joint clinical assessments on national reimbursement processes. The new framework may result in additional or differently structured evidentiary expectations, misalignment between assessment and regulatory timelines, or delays in national decisions. Any adverse or delayed HTA outcomes, or divergent national reimbursement decisions, could

negatively affect our ability to obtain or maintain favorable pricing and reimbursement status for any product candidates, if approved. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.

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.

***We are subject, directly and indirectly, to federal, state and foreign healthcare laws and regulations, including healthcare fraud and abuse laws, false claims laws, physician payment transparency laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.****

Our operations are directly, and indirectly through our customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal False Claims Act, and physician payment sunshine laws and regulations. These laws may impact, among other things, our clinical research, sales, marketing, grants, charitable donations, and education programs and constrain the business or financial arrangements with healthcare providers, physicians, charitable foundations that support Parkinson's disease patients generally, and other parties that have the ability to directly or indirectly influence the prescribing, ordering, marketing, or distribution of our products for which we obtain marketing approval. In addition, we and any current or potential future collaborators, partners or service providers are or may become subject to data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business, including laws and regulations that apply to our processing of personal data or the processing of personal data on our behalf. Finally, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. 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 U.S. federal civil and criminal false claims laws, including the civil False Claims Act, which can be enforced through civil whistleblower or *qui tam* actions, and civil monetary penalties laws, which impose criminal and civil penalties on individuals or entities for, among other things, knowingly presenting, or causing to be presented to the U.S. federal government, claims for payment or approval that are false or fraudulent or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes criminal and civil liability for, among other things, 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 statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. 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;
- HIPAA, and its implementing regulations, and as amended again by the Final HIPAA Omnibus Rule, Modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act (HITECH) and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, published in January 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information on covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers as well as their business associates, individuals or entities that perform certain services involving the use or disclosure of individually identifiable health information on behalf of a covered entity and their subcontractors that use, disclose or otherwise process individually identifiable health information;
- the U.S. Federal Food, Drug and Cosmetic Act (FDCA), which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- the U.S. federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act", which was enacted as part of the ACA and its implementing regulations and requires certain 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 CMS information related to certain payments and other transfers of value made to physicians (as defined to include doctors of medicine, dentists, optometrists, podiatrists and chiropractors under such law), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members; and
- analogous state and local laws and regulations, including: some state and local laws which require certain regulatory licenses to manufacture or distribute our products commercially and/or the registration of pharmaceutical sales representatives in the jurisdiction; state and foreign anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and local laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. For example, contributions to third-party charitable foundations are a current area of significant governmental and congressional scrutiny, and we could face action if a federal or state governmental authority were to conclude that our charitable contributions to foundations that support Parkinson's disease patients generally are not compliant. 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 civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and/or oversight, and the curtailment or restructuring of our operations. Moreover, while we do not bill third-party payors directly and our customers make the ultimate decision on how to submit claims, from time-to-time, for our products, we may provide reimbursement guidance to patients and healthcare providers. If a government authority were to conclude that we provided improper advice and/or encouraged the submission of a false claim for reimbursement, we could face action against us by government authorities. If any of the physicians, healthcare professionals, or other providers or entities with whom we expect to do business is found to be not 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, it could adversely affect our ability to operate our business and our results of operations.

Outside the U.S., interactions between pharmaceutical companies and healthcare professionals are also governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment, any of which could adversely affect our ability to operate our business and our results of operations.

***We and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.***

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, sensitive third-party data, business plans, transactions, financial information and medical information collected by our patient access management team (collectively, sensitive data). Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. Additionally, numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 (CCPA) requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for fines for intentional violations and allows private litigants affected by certain data breaches to recover significant statutory damages. Although some U.S. comprehensive privacy laws exempt some data processed in the context of clinical trials, these laws may increase compliance costs and potential liability with respect to other personal data we may maintain about California residents. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more jurisdictions to pass similar laws in the future.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the European Union's General Data Protection Regulation (EU GDPR), United Kingdom's GDPR (UK GDPR) (collectively, the GDPR), Switzerland's Federal Act on Data Protection (FADP), Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or LGPD) (Law No. 13,709/2018), China's Personal Information Protection Law (PIPL), and Canada's Personal Information Protection and Electronic Documents Act (PIPEDA) impose strict requirements for processing personal data. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR / 17.5 million pounds sterling under the UK GDPR or 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions have adopted and may continue to adopt similarly stringent data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere, the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data to recipients outside Europe for allegedly violating the GDPR's cross-border data transfer limitations. Additionally, companies that transfer personal data to recipients outside of the EEA and/or UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators individual litigants and activist groups.

Our employees and personnel use generative artificial intelligence (AI) technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws and regulations regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

In addition to data privacy and security laws, we may be contractually subject to industry standards adopted by industry groups and may become subject to additional such obligations in the future. We are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy policies, marketing materials, and other statements, such as statements related to compliance with certain certifications or self-regulatory principles, regarding artificial intelligence, data privacy and security. Regulators in the United States are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Additionally, under various privacy laws and other obligations, we may be required to obtain certain consents to process personal data. For example, some of our data processing practices may be challenged under wiretapping laws, if we obtain consumer information from third parties through various methods, including chatbot and session replay providers, cookies or via third-party marketing pixels. These practices may be subject to increased challenges by class action plaintiffs. Our inability or failure to obtain consent for these practices could result in adverse consequences, including class action litigation and mass arbitration demands.

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties with whom we work may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties with whom we work fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans or restrictions on processing personal data; and orders to destroy or not use personal data. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to loss of customers; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

***If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the U.S., we could be subject to additional reimbursement requirements, fines, sanctions and exposure under other laws which could have a material adverse effect on our business, results of operations and financial condition.***

We participate in the Medicaid Drug Rebate Program, as administered by CMS, and other federal and state government pricing programs in the U.S., such as the Medicare Part D Prescription Drug Inflation Rebate Program, and we may participate in additional government pricing programs in the future. These programs generally require us to pay rebates or otherwise provide discounts to government payors in connection with drugs that are dispensed to beneficiaries/recipients of these programs. In some cases, such as with the Medicaid Drug Rebate Program, the rebates are based on pricing that we report on a monthly and quarterly basis to the government agencies that administer the programs. Pricing requirements and rebate/discount calculations are complex, vary among products and programs, and are often subject to interpretation by governmental or regulatory agencies and the courts. The requirements of these programs, including, by way of example, their respective terms and scope, change frequently. For example, American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacturer price (AMP), for single source and innovator multiple source drugs, effective January 1, 2024. Responding to current and future changes may increase our costs, and the complexity of compliance will be time consuming. Invoicing for rebates is provided in arrears, and there is frequently a time lag of up to several months between the sales to which rebate notices relate and our receipt of those notices, which further complicates our ability to accurately estimate and accrue for rebates related to the Medicaid program as implemented by individual states. Thus, we may not be able to identify all factors that may cause our discount and rebate payment obligations to vary from period to period, and our actual results may differ significantly from our estimated allowances for discounts and rebates. Changes in estimates and assumptions, including accruals that are less than our ultimate payment obligations, may have a material adverse effect on our business, results of operations and financial condition.

In addition, the HHS Office of Inspector General and other Congressional, enforcement and administrative bodies have recently increased their focus on pricing requirements for products, including, but not limited to the methodologies used by manufacturers to calculate AMP, and best price (BP), for compliance with reporting requirements under the Medicaid Drug Rebate Program. We are liable for errors associated with our submission of pricing data and for any overcharging of government payors. For example, failure to submit monthly/quarterly AMP and BP data on a timely basis could result in significant civil monetary penalties for each day the submission is late beyond the due date. Failure to make necessary disclosures and/or to identify overpayments could result in allegations against us under the civil False Claims Act and other laws and regulations. Any required refunds to the U.S. government or responding to a government investigation or enforcement action would be expensive and time consuming and could have a material adverse effect on our business, results of operations and financial condition. In addition, in the event that the CMS were to terminate our rebate agreement, no federal payments would be available under Medicaid or Medicare for our covered outpatient drugs.

***We could face liability if a regulatory authority determines that we are promoting our products for any "off-label" uses.***

The FDA, Health Canada, the European Commission, competent authorities of individual EU Member States and other comparable foreign regulatory authorities and industry self-regulatory bodies strictly regulate the marketing and promotional claims that are made about drug and biologic products. In particular, a company may not promote "off-label" uses for its drug products. An off-label use is the use of a product for an indication, patient population, or manner that is not described in the product's approved labeling and that differs from those approved by the applicable regulatory authorities. Physicians and other persons qualified to prescribe medicinal products, on the other hand, may, in certain jurisdictions including the U.S., prescribe products for off-label uses. Although the FDA and certain comparable foreign regulatory authorities do not generally regulate a physician's or other person qualified to prescribe's choice of drug treatment made in the such person's independent medical judgment, they do restrict promotional communications from pharmaceutical companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. A company that is found to have promoted off-label use of its product may be subject to significant liability, including civil and criminal sanctions.

We intend to comply with the requirements and restrictions of the FDA and comparable foreign regulatory authorities, governmental authorities and regulatory bodies in the jurisdictions that approve our products or product candidates with respect to our promotion of our products, but such authorities may nevertheless make us the target of an investigation or prosecution based on our marketing and promotional practices. As a result, we may be subject to criminal and civil liability for the promotion of off-label uses. In addition, our management's attention could be diverted to handle any such alleged violations, all of which could have a material adverse effect on our business, results of operations, financial condition and reputation.

A significant number of pharmaceutical companies have been the target of inquiries and investigations by various U.S. federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including by the Department of Justice (DOJ), and various U.S. Attorneys' Offices, the HHS Office of Inspector General, the FDA, the Federal Trade Commission and various state Attorneys General offices. These investigations have alleged violations of various U.S. federal and state laws and regulations, including claims asserting antitrust violations, violations of the FDCA, the civil False Claims Act, the Prescription Drug Marketing Act, anti-kickback laws, and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. If the FDA, DOJ, or any other governmental agency initiates an enforcement action against us, or if we are the subject of a qui tam suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects, and reputation.

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as direct-to-consumer advertising of prescription medicinal products, are established in EU law. However, the details are governed by regulations in individual EU Member States and can differ from one country to another. If the EU or an applicable EU Member State were to determine that we violated an applicable law or regulation, we could be subject to lawsuits, regulatory actions, penalties and other adverse consequences that would have an adverse effect on our revenue, business, financial prospects, and reputation.

***Changes at the FDA and other government agencies could delay or prevent new products from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, layoffs and statutory, regulatory, and policy changes. Average review times at the agency 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, including executive and congressional priorities, the impacts of which are inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical government employees and stop critical activities to the extent they are not funded by existing available user fees. In addition, the current administration has enacted substantial reductions in force at various government agencies that, if applied in a material way, could significantly reduce the FDA's and other agencies' capacities to perform their functions in a manner consistent with past practices and could negatively impact our business. Repeated or prolonged government shutdowns or material layoffs of agency personnel could significantly impact the ability of the FDA to timely review and process our regulatory submissions, and negatively impact other government operations on which we rely, which could have a material adverse effect on our business.

***We are subject to stringent regulation in connection with the marketing of our products, which could delay the development, approval and commercialization of our products.***

The pharmaceutical industry is subject to stringent regulation by the FDA and other regulatory agencies in the U.S. and by comparable foreign regulatory authorities in other jurisdictions. Neither we nor our collaborators can market a pharmaceutical product in the U.S. until it has completed rigorous preclinical testing and clinical trials and an extensive regulatory clearance process implemented by the FDA. Satisfaction of regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product, and requires substantial resources. Even if regulatory approval is obtained, the FDA and comparable foreign regulatory authorities may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, and/or marketing of such products, and requirements for post-approval studies, including additional research and development and clinical trials. These limitations may limit the size of the market for the product or result in the incurrence of additional costs. Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenues from the particular product candidate, if approved.

Outside the U.S., the ability to market a product is contingent upon receiving approval from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing, and reimbursement vary widely from country to country. Only after the appropriate regulatory authority is satisfied that adequate evidence of safety, quality, and efficacy has been presented will it grant a marketing authorization (MA). Approval by the FDA does not automatically lead to the approval by regulatory authorities outside the U.S. and, similarly, approval by regulatory authorities outside the U.S. will not automatically lead to FDA approval.

In addition, U.S. and foreign government regulations control access to and use of some human or other tissue samples in our research and development efforts. U.S. and foreign government agencies may also impose restrictions on the use of data derived from human or other tissue samples. Accordingly, if we fail to comply with these regulations and restrictions, the commercialization of our product candidates, if approved, may be delayed or suspended, which may delay or impede our ability to generate product revenues.

The policies of the FDA and other regulatory authorities may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidates in any additional indications or territories, or further restrict or regulate post-approval activities. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR introduces, among other changes, a centralized application system, coordinated review procedures, expanded reporting and increased transparency obligations. The new requirements, together with evolving guidance from EU authorities, may impose additional operational burdens on us and our CROs and could result in delays in trial initiation, increased compliance costs, or other disruptions to our development programs.

In addition, on December 11, 2025, the European Commission, the Parliament and the European Council reached a political agreement on a comprehensive overhaul of EU pharmaceutical legislation (the Pharma Package). The reform has been under negotiation since the European Commission submitted its proposal in April 2023. This package, comprised of a new directive and regulation to replace existing legislation, aims to modernize the EU framework. The political agreement is still subject to formal approval by the European Parliament and Council. If approved in the form proposed, the Pharma Package will, among other changes, reduce the baseline market protection period by one year, with limited opportunities for extensions, capped at a maximum of eleven years; reshape the incentives regime for orphan medicinal products, by introducing "breakthrough" orphan medicinal products (those addressing diseases with no available medicinal treatment), which will benefit from 11 years of market exclusivity; and expand the "Bolar" exemption to permit generic and biosimilar manufacturers to conduct preparatory activities for regulatory submissions, including pricing and reimbursement, and participate in procurement tenders while patent protection remains in force. A decrease in market exclusivity opportunities for our product candidates in the EU, combined with the expanded Bolar exemption, could open them to generic or biosimilar competition earlier than under the current regime, potentially impacting reimbursement status and the commercial prospects of our product candidates

***If our competitors develop and market products that are more effective than our products, they may reduce or eliminate our commercial opportunity.***

Competition in the pharmaceutical and biotechnology industries is intense and expected to increase. We face, and will continue to face, intense competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, both in the U.S. and abroad. We compete, or will compete, with existing and new products being developed by our competitors. Some of these competitors have products or are pursuing the development of pharmaceuticals that target the same diseases and conditions that our research and development programs target.

For example, the use of NUPLAZID for the treatment of PDP competes with off-label use of various antipsychotic drugs, including the generic drugs quetiapine, clozapine, risperidone, aripiprazole, and olanzapine. In addition, DAYBUE competes indirectly with off-label usage of branded and generic prescription medications targeted at individual symptoms of Rett syndrome, including antiepileptics, antipsychotics, antidepressants and benzodiazepines. Further, there are several currently disclosed programs in development for Rett syndrome. UCB S.A. has announced plans to initiate a Phase 3 clinical trial of fenfluramine in patients with Rett syndrome during 2026. Taysha Gene Therapies is conducting pivotal clinical trial of a AAV9 intrathecal delivered gene therapy to treat Rett syndrome. Neurogene has initiated a pivotal clinical trial of its investigational adeno-associated virus gene therapy candidate, NGN-401, delivered using intracerebroventricular administration to treat Rett Syndrome. Several academic institutions and pharmaceutical companies are currently conducting clinical trials for the treatment of various symptoms of Rett syndrome, including Unravel Bio and Vanderbilt University Medical Center, which are jointly conducting an early-stage study with vorinostat (RVL-001).

Other competitors may have a variety of drugs in development or awaiting approval from the FDA or comparable foreign regulatory authorities that could reach the market and become established before we have a product to sell for the applicable disorder. Our competitors may also develop alternative therapies that could further limit the market for any drugs that we may develop. Many of our competitors are using technologies or methods different or similar to ours to identify and validate drug targets and to discover novel small molecule drugs. Many of our competitors and their collaborators have significantly greater experience than we do in the following:

- identifying and validating targets;
- screening compounds against targets;
- preclinical studies and clinical trials of potential pharmaceutical products;
- obtaining FDA and other regulatory approvals; and
- commercializing pharmaceutical products.

In addition, many of our competitors and their collaborators have substantially greater advantages in the following areas: capital resources, research and development resources, manufacturing capabilities, sales and marketing, and production facilities. Smaller companies also may prove to be significant competitors, particularly through proprietary research discoveries and collaboration arrangements with large pharmaceutical and established biotechnology companies. Many of our competitors have products that have been approved or are in advanced development and may develop superior technologies or methods to identify and validate drug targets and to discover novel small molecule drugs. Our competitors, either alone or with their collaborators, may succeed in developing technologies or drugs that are more effective, safer, more affordable, or more easily administered than ours and may achieve patent protection or commercialize drugs sooner than us. Our competitors may also develop alternative therapies that could further limit the market for any drugs that we may develop. Our failure to compete effectively could have a material adverse effect on our business.

***If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our products, or development or commercialization of our product candidates, if approved.***

We face an inherent risk of product liability as a result of the commercial sales of our products and the clinical testing of our product candidates. For example, we may be sued if any of our products allegedly cause injury or are found to be otherwise unsuitable for administration in humans. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates, if approved. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products or product candidates, if approved;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize our products or product candidates, if approved; and
- a decline in our stock price.

Although we currently have product liability insurance that covers our clinical trials and the commercialization of our products, we may need to increase and expand this coverage, including if we commence larger scale trials and if our product candidates are approved for commercial sale. This insurance may be prohibitively expensive or may not fully cover our potential liabilities. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of products that we or our collaborators develop. If we determine that it is prudent to increase our product liability coverage, we may be unable to obtain such increased coverage on acceptable terms or at all. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. Our liability could exceed our total assets if we do not prevail in a lawsuit from any injury caused by our drug products. Product liability claims could have a material adverse effect on our business and results of operations.

***If our information technology systems or data, or those of third parties with whom we work, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions, interruptions to operations or clinical trials, reputational harm, litigation, fines and penalties, disruptions of our business operations, and a loss of customers or sales.***

In the ordinary course of our business, we, or the third parties with whom we work, process proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property, and trade secrets.

Cyberattacks, malicious internet-based activity, online and offline fraud and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties with whom we work. These threats are prevalent, continue to rise, and are becoming increasingly difficult to detect. These threats come from a variety of sources, including traditional computer "hackers," hacktivists, threat actors, personnel misconduct or error (such as through theft or misuse), organized criminal threat actors, sophisticated nation-states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties with whom we work may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to, social engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunction, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, telecommunications failures, earthquakes, fire, flood, and other similar threats.

Ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, disruption of clinical trials or otherwise affecting our ability to provide our products or product candidates, loss of sensitive data (including data related to clinical trials) and income, significant extra expenses to restore data or systems, reputational harm and the diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments (including, for example, if applicable laws or regulations prohibit such payments). Remote work has increased risks to our information technology systems and data, as our employees work from home, utilizing network connections, computers and devices outside our premises, including at home, while in transit or in public locations. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely on third-party service providers and technologies to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, drug suppliers, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. Our ability to monitor these third parties' information security practices and posture (including whether any unremediated vulnerabilities exist or have been exploited) is limited, and these third parties may not have adequate information security measures in place. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised. For example, we were made aware of a cyberattack against one of the largest prescription processors in the country in February 2024 that impacted the ability for our specialty pharmacy partners to have payors provide authorizations for patient refills and new patient starts for certain of our products. In April 2024, we were notified by a third-party patient support service provider of a data security incident that involved personal data of NUPLAZID patients.

It may be difficult and/or costly to detect, investigate, mitigate, contain and remediate a security incident. Our efforts to investigate, mitigate, contain and remediate a security incident may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain and remediate a security incident could result in outages, data losses and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems. For example, threat actors may use an initial compromise of one part of our environment to gain access to other parts of our environment, or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information security systems (such as our hardware and/or software, including that of third parties with whom we work). We and the third parties with whom we work may not, however, detect and remediate all such vulnerabilities including on a timely basis. For example, we have identified certain vulnerabilities in our information systems, and we take steps designed to mitigate the risks associated with known vulnerabilities. These steps include implementing compensating controls and other protective measures. Further, we and the third parties with whom we work may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats could cause, and in some cases have in the past caused, a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties with whom we work. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to provide our products.

We may expend significant resources or fundamentally change our business activities and practices (including our clinical trials) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data.

Applicable data privacy and security obligations may require us, or we may choose, to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents, or to implement other requirements, such as providing credit monitoring or identity theft protection services. Such disclosures and related actions are costly, and the disclosure or the failure to comply with applicable requirements could lead to adverse consequences. If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may prevent or cause customers to stop using our products, deter new customers from using our products, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations.

In addition, our insurance coverage may not be adequate or sufficient in type or amount to protect us from or to mitigate liabilities arising out of our privacy and security practices. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive data about us from public sources, data brokers or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive information of the Company could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative AI technologies.

**Risks Related to Our Common Stock**

***Our stock price historically has been, and is likely to remain, highly volatile.****

The market prices for securities of biotechnology companies in general, and drug discovery and development companies in particular, have been highly volatile and may continue to be highly volatile in the future. From the period between January 2, 2026 to April 29, 2026, the closing price of our common stock has ranged from a low of $20.32 per share to a high of $27.51 per share. Furthermore, especially as we and our market capitalization have grown, the price of our common stock has been increasingly affected by quarterly and annual comparisons with the valuations and recommendations of the analysts who cover our business. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- the success of our commercialization of our products;
- the status and cost of development and commercialization of our products and product candidates, if approved, including compounds being developed under our collaborations;
- whether we acquire or in-license additional product candidates or products, and the status of development and commercialization of such product candidates, if approved, or products;
- the status and cost of development and commercialization of trofinetide for indications other than Rett syndrome and in jurisdictions outside North America;
- any other communications or guidance from the FDA or other regulatory authorities that pertain to our products or product candidates;
- the status and cost of our PMRs for DAYBUE;
- the initiation, termination, or reduction in the scope of our collaborations or any disputes or developments regarding our collaborations;
- market conditions or trends related to biotechnology and pharmaceutical industries, or the market in general;
- announcements of technological innovations, new products, or other material events by our competitors or us, including any new products that we may acquire or in-license;
- disputes or other developments concerning our proprietary and intellectual property rights;

- fluctuations in our operating results;
- changes in, or failure to meet, securities analysts' or investors' expectations of our financial performance;
- our failure to meet applicable Nasdaq listing standards and the possible delisting of our common stock from the Nasdaq Stock Market;
- additions or departures of key personnel;
- discussions of our business, products, financial performance, prospects, or stock price by the financial and scientific press and online investor communities such as blogs and chat rooms;
- public concern as to, and legislative action with respect to, genetic testing or other research areas of biopharmaceutical companies, the pricing and availability of prescription drugs, or the safety of drugs and drug delivery techniques;
- regulatory developments in the U.S. and in foreign countries;
- changes in the structure of healthcare payment systems;
- the announcement of, or developments in, any litigation matters;
- disruptions caused by geopolitical or macroeconomic developments or other business interruptions, as well as any related political or economic responses and counter-responses or otherwise by various global actors or the general effect on the global economy and supply chain; and
- economic and political factors, including but not limited to economic and financial crises, wars, terrorism, and political unrest.

In the past, following periods of volatility in the market price of a particular company's securities, securities class action litigation has been brought against that company. For example, we, and certain of our current and former officers and directors, are subject to numerous lawsuits related to prior statements about NUPLAZID and our sNDA seeking approval of pimavanserin for the treatment of hallucinations and delusions associated with DRP, as described in "Legal Proceedings". If we are not successful in defense of these claims, we may have to make significant payments to, or other settlements with, our stockholders and their attorneys. Even if such claims are not successful, the litigation has resulted in additional costs in the past and could result in further substantial costs and diversion of our management's attention and resources in the future, which could have a material adverse effect on our business, operating results or financial condition.

***If we or our stockholders sell substantial amounts of our common stock, the market price of our common stock may decline.***

A significant number of shares of our common stock are held by a small number of stockholders. Sales of a significant number of shares of our common stock, or the expectation that such sales may occur, could significantly reduce the market price of our common stock. In connection with our March 2014 public offering of common stock, we agreed to provide resale registration rights for the shares of our common stock held by entities affiliated with one of our principal stockholders and two of our directors, Julian C. Baker and Dr. Stephen R. Biggar, which we refer to as the Baker Entities. In connection with our January 2016 public offering of common stock, we entered into a formal registration rights agreement with the Baker Entities to provide for these rights (2016 Registration Rights Agreement). Under the 2016 Registration Rights Agreement, we agreed that, if at any time and from time to time, the Baker Entities demand that we register their shares of our common stock for resale under the Securities Act of 1933, as amended (the Securities Act), we would be obligated to effect such registration. On May 23, 2025, the SEC declared effective a registration statement that we filed on May 9, 2025 covering the sale of up to 43,576,075 shares of our common stock, which includes 492,407 shares of our common stock issuable upon the exercise of warrants that were owned by the Baker Entities as of April 30, 2025, and which represented approximately 26 percent of our outstanding shares at the time. In February 2026, following its expiration, we replaced the 2016 Registration Rights Agreement by entering into a new registration rights agreement with the Baker Entities (2026 Registration Rights Agreement). Our registration obligations under the 2026 Registration Rights Agreement, which cover all securities now held or later acquired by the Baker Entities, will be in effect for up to 10 years, and include our obligation to facilitate certain underwritten public offerings and block trades of our securities by the Baker Entities in the future. If the Baker Entities sell a large number of our securities, or the market perceives that the Baker Entities intend to sell a large number of our securities, this could adversely affect the market price of our securities, including our common stock. We also may elect to sell from time to time an indeterminate number of securities on our own behalf pursuant to a registration statement or in a private placement. The price of our securities may decline as a result of the sale of the securities, including shares of our common stock, included in any of these registration statements or future financings.

***If our officers, directors, and largest stockholders choose to act together, they may be able to significantly influence our management and operations, acting in their best interests and not necessarily those of our other stockholders.***

Our directors, executive officers and holders of 5% or more of our outstanding common stock and their affiliates beneficially own a substantial portion of our outstanding common stock. As a result, these stockholders, acting together, have the ability to significantly influence all matters requiring approval by our stockholders, including the election of all of our board members, amendments to our certificate of incorporation, going-private transactions, and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of our other stockholders.

***Anti-takeover provisions in our charter documents and under Delaware law may make an acquisition of us more complicated and may make the removal and replacement of our directors and management more difficult.***

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may delay or prevent a change in control, discourage bids at a premium over the market price of our common stock and adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. These provisions may also make it difficult for stockholders to remove and replace our board of directors and management. These provisions:

- establish that members of the board of directors may be removed only for cause upon the affirmative vote of stockholders owning at least a majority of our capital stock;
- authorize the issuance of "blank check" preferred stock that could be issued by our board of directors to increase the number of outstanding shares and prevent or delay a takeover attempt;
- limit who may call a special meeting of stockholders;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings;
- prohibit our stockholders from making certain changes to our amended and restated certificate of incorporation or amended and restated bylaws except with $66^{2/3}$% stockholder approval; and
- provide for a board of directors with staggered terms.

We are also subject to provisions of the General Corporation Law of the State of Delaware that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for three years unless the holder's acquisition of our stock was approved in advance by our board of directors. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders.

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

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or employees to our company or our stockholders, (iii) any action asserting a claim against our company or any director, officer or other employee arising pursuant to any provision of the General Corporation Law of the State of Delaware or our amended and restated certificate of incorporation or bylaws, (iv) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or bylaws; (v) any action as to which the General Corporation Law of the State of Delaware confers jurisdiction on the Court of Chancery of the State of Delaware; and (vi) any action asserting a claim against our company governed by the internal affairs doctrine. This choice of forum provision does not apply to suits brought to enforce a duty or liability created by the Securities Act.

This choice of forum provision may limit a stockholder's ability to bring certain claims in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. If a court were to find this choice of forum provision to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

***We do not intend to pay dividends on our common stock in the foreseeable future; as such, you must rely on stock appreciation for any return on your investment.***

To date, we have not paid any cash dividends on our common stock, and we do not intend to pay any dividends in the foreseeable future. Instead, we intend to retain any future earnings to fund the development and growth of our business. For this reason, the success of an investment in our common stock, if any, will depend on the appreciation of our common stock, which may not occur. There is no guarantee that our common stock will appreciate, and therefore, a holder of our common stock may not realize a return on his or her investment.

**ITEM 5. OTHER INFORMATION**

During the Company's last fiscal quarter, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated any "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as those terms are defined in Item 408 of Regulation S-K.

## ITEM 6. EXHIBITS

| Exhibit Number | Description |
|---|---|
| 3.1 | Amended and Restated Certificate of Incorporation, as amended (incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q, filed August 6, 2015). |
| 3.2 | Certificate of Amendment of Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.2 to the Registrant's Annual Report on Form 10-K, filed February 25, 2021). |
| 3.3 | Amended and Restated Bylaws, effective on and after April 15, 2025 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed April 16, 2025). |
| 4.1 | Form of common stock certificate of the Registrant (incorporated by reference to Exhibit 4.1 to Registration Statement No. 333-52492). |
| 4.2 | Form of Amended and Restated Warrant to Purchase Common Stock issued to purchasers in a private placement on December 17, 2012 (incorporated by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K, filed on February 27, 2019). |
| 10.1 | Non-Employee Director Compensation Policy, effective March 3, 2026. |
| 10.2 | Registration Rights Agreement, dated February 24, 2026, among the Registrant and the investors listed on Schedule A thereto (incorporated by reference to Exhibit 10.25 to the Registrant's Annual Report on Form 10-K, filed February 26, 2026). |
| 31.1 | Certification of Catherine Owen Adams, Chief Executive Officer, pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2 | Certification of Mark C. Schneyer, Executive Vice President and Chief Financial Officer, pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1[a] | Certification of Catherine Owen Adams, Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 32.2[a] | Certification of Mark C. Schneyer, Executive Vice President and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101 | The following financial statements from the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2026, filed on May 6, 2026, formatted in iXBRL (Inline Extensible Business Reporting Language), are filed herewith: (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Comprehensive Income, (iv) Condensed Consolidated Statements of Cash Flows, (v) Condensed Consolidated Statements of Stockholders' Equity and (vi) Notes to Condensed Consolidated Financial Statements. |
| 104 | Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101) |

[a] The information in Exhibits 32.1 and 32.2 shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act (including this report), unless the Registrant specifically incorporates the foregoing information into those documents by reference.

**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.

**Acadia Pharmaceuticals Inc.**

Date: May 6, 2026

By: /s/ Mark C. Schneyer
Mark C. Schneyer
Executive Vice President and Chief Financial Officer
(on behalf of the registrant and as the registrant's Principal Financial Officer)

**Exhibit 10.1**

**ACADIA PHARMACEUTICALS INC.**

**NON-EMPLOYEE DIRECTOR COMPENSATION POLICY**

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Each member of the Board of Directors (the "***Board***") of Acadia Pharmaceuticals Inc. (the "***Company***") who is not also serving as an employee of the Company or any of its subsidiaries (each such member, a "***Non-Employee Director***") will, automatically and without further action by the Board or the Compensation Committee of the Board (the "***Compensation Committee***"), receive the compensation described in this Non-Employee Director Compensation Policy (as amended, this "***Policy***"). A Non-Employee Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash is to be paid or equity awards are to be granted, as the case may be.

This Policy is effective as of March 3, 2026 (the "***Effective Date***") and may be amended at any time in the sole discretion of the Board or the Compensation Committee.

**Annual Cash Retainer**

Each Non-Employee Director will automatically, and without further action by the Board or the Compensation Committee, receive annual cash compensation in equal quarterly installments, payable in arrears on the last day of each fiscal quarter in which the service occurred, as set forth in the tables below. All annual cash retainers are vested upon payment.

If a Non-Employee Director joins the Board or a committee of the Board at a time other than the first day of a fiscal quarter, the quarterly installment for each annual cash retainer set forth below will be pro-rated based on days served in the applicable fiscal quarter. Similarly, if a Non-Employee Director leaves a committee of the Board at any time other than the last day of the fiscal quarter (but remains a member of the Board), the quarterly installment for each annual committee member service retainer (and committee chair service retainer, if applicable) set forth below will be pro-rated based on days served in the applicable fiscal quarter and the Company shall adjust all future quarterly installments of the annual cash retainers to account for such service.

| | | |
|---|---|---|
| Annual Board Service Retainer: | | |
| All Non-Employee Directors | $ | 50,000 |
| Board Chair (in addition to Non-Employee Director Board Service Retainer) | $ | 40,000 |
| | | |
| Annual Committee Member Service Retainer: | | |
| Member of the Audit Committee | $ | 12,500 |
| Member of the Compensation Committee | $ | 10,000 |
| Member of the Nominating and Corporate Governance Committee | $ | 7,500 |
| Member of the Scientific Advisory Committee | $ | 10,000 |
| | | |
| Annual Committee Chair Service Retainer (in addition to Committee Member Service Retainer): | | |
| Chair of Audit Committee | $ | 12,500 |
| Chair of Compensation Committee | $ | 10,000 |
| Chair of Nominating and Corporate Governance Committee | $ | 7,500 |
| Chair of Scientific Advisory Committee | $ | 10,000 |

In addition to the foregoing annual cash retainers, the Board or the Compensation Committee at the recommendation of the Board, may approve annual committee member service retainers (and annual committee chair service retainers) for any newly created committee of the Board.

**Equity Compensation**

The equity compensation set forth below will be granted under the Company's 2024 Equity Incentive Plan (as may be amended from time to time and including any successor plan thereto, the "***Plan***"). All equity awards granted under this Policy will be nonstatutory stock options and restricted stock unit awards ("***RSU Awards***"). All nonstatutory stock options granted under this Policy will have an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying common stock on the date of grant, and a term of 10 years from the date of grant (subject to earlier termination in connection with a termination of service, as provided in the Plan).

1. Initial Grant: For each Non-Employee Director who is first elected or appointed to the Board following the Effective Date, on the date of such Non-Employee Director's initial election or appointment to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Non-Employee Director will be automatically, and without further action by the Board or the Compensation Committee, granted a nonstatutory stock option (an "***Initial Option Grant***") and an RSU Award (an "***Initial RSU Grant***," together with the Initial Option Grant, the "***Initial Grant***") with an aggregate target fair value equal to $200,000 (the "***Initial Grant Maximum Value***") as follows:

    a. an Initial Option Grant to purchase a number of shares of common stock of the Company equal to 50% of the Initial Grant Maximum Value; and

    b. an Initial RSU Grant covering a number of shares of common stock of the Company equal to 50% of the Initial Grant Maximum Value.

    The number of shares subject to the Initial Option Grant and the Initial RSU Grant shall be calculated by dividing (a) the Initial Grant Maximum Value attributable to the Initial Option Grant and the Initial RSU Grant, respectively, by (b) the product of (i) the fair value percentage of such award, as determined by the Company under ASC 718 on the date of grant, and (ii) the volume-weighted average closing trading price of the common stock of the Company over the 15 consecutive trading days ending with the date of grant (the "***15-Day VWAP***"), rounding up to the nearest whole share. The shares subject to the Initial Grant will vest in equal annual installments over three years following the date of grant such that the Initial Grant will be fully vested on the third anniversary of the date of grant, subject to the Non-Employee Director's Continuous Service (as defined in the Plan) through each such vesting date.

2. Annual Grant: On the date of each annual meeting of the Company's stockholders (an "***annual meeting***") held after the Effective Date, each Non-Employee Director (whether a member of the Board prior to such annual meeting or first appointed at such annual meeting) who continues to serve as a non-employee member of the Board following such annual meeting will be automatically, and without further action by the Board or the Compensation Committee, granted a nonstatutory stock option (an "***Annual Option Grant***") and an RSU Award (an "***Annual RSU Grant***," and together with the Annual Option Grant, the "***Annual Grant***") with an aggregate target fair value equal to $400,000 (the "***Annual Grant Maximum Value***"), as follows:

    a. an Annual Option Grant to purchase a number of shares of common stock of the Company equal to 50% of the Annual Grant Maximum Value; and

    b. an Annual RSU Grant covering a number of shares of common stock of the Company equal to 50% of the Annual Grant Maximum Value.

The number of shares subject to the Annual Option Grant and the Annual RSU Grant shall be calculated by dividing (a) the Annual Grant Maximum Value attributable to the Annual Option Grant and the Annual RSU Grant, respectively, by (b) the product of (i) the fair value percentage of such award, as determined by the Company under ASC 718 on the date of grant, and (ii) the 15-Day VWAP, rounding up to the nearest whole share. The shares subject to the Annual Option Grant will vest in four equal installments, with the first three installments vesting on each of the first three quarterly anniversaries of the date of grant and the fourth and final installment vesting on the earlier of one year following the date of grant or the date of the next annual meeting (such earlier date, the "Annual Vest Date"), and the Annual RSU Grant will vest in full upon the Annual Vest Date, in each case subject to the Non-Employee Director's Continuous Service (as defined in the Plan) through each such vesting date.

A new Non-Employee Director who joins the Board other than on the date of an annual meeting shall receive an Annual Grant, provided that (a) such Annual Grant shall be pro-rated by multiplying the Annual Grant Maximum Value by a quotient, the numerator of which is equal to the number of days between the date such new Non-Employee Director joins the Board and the one-year anniversary of the most recently held annual meeting, and the denominator of which is 365, and (b) the portion of such Annual Grant that is an Annual Option Grant will vest in equal parts on the remaining vesting dates for the Annual Option Grants made to Non-Employee Directors at the most recent annual meeting (i.e., if there are two vesting dates remaining, the pro-rated Annual Option Grant will vest 50% on each of those vesting dates), and the portion of such Annual Grant that is an Annual RSU Grant will vest in full upon the Annual Vest Date, in each case subject to the Non-Employee Director's Continuous Service through each such vesting date.

3. Deferral of RSU Awards: Unless and until otherwise determined by the Board, each Non-Employee Director may elect to defer the delivery of shares in settlement of any future RSU Award that is granted pursuant to this Policy and that would otherwise be delivered to such Non-Employee Director on or following the date such RSU Award vests pursuant to the terms of this Policy, until, at such Non-Employee Director's election:

    a. the earlier of (i) the fifth anniversary of the date of grant of such RSU Award, (ii) the date that is 30 days following the date on which the director ceases to serve as a member of the Board or otherwise provide services to the Company and (iii) a change in control, subject to such rules, conditions and procedures as shall be determined by the Board, in its sole discretion;

    b. the earlier of (i) the tenth anniversary of the date of grant of such RSU Award, (ii) the date that is 30 days following the date on which the director ceases to serve as a member of the Board or otherwise provide services to the Company and (iii) a change in control, subject to such rules, conditions and procedures as shall be determined by the Board, in its sole discretion; or

    c. the earlier of (i) the date that is 30 days following the date on which the director ceases to serve as a member of the Board or otherwise provide services to the Company and (ii) a change in control, subject to such rules, conditions and procedures as shall be determined by the Board, in its sole discretion.

**Non-Employee Director Compensation Limit**

Notwithstanding anything else in this Policy to the contrary, in no event shall the aggregate value of all compensation granted or paid, as applicable, to any Non-Employee Director exceed the limitations set forth in Section 3(d) of the Plan.

**Reimbursement of Expenses**

Upon presentation of documentation of such expenses reasonably satisfactory to the Company, each Non-Employee Director is entitled to be reimbursed for reasonable travel and other expenses incurred in connection with attending meetings of the Board and any committee of the Board on which he or she serves.

**Additional Requirements**

In making any future changes to compensation payable to Non-Employee Directors, the Board or the Compensation Committee will evaluate the practices of the peer group of companies that serve as references for executive compensation benchmarking, as well as then current general best practices regarding director compensation.

The Compensation Committee will review this Policy on at least a biennial basis and engage an independent compensation consultant to assist in such review.

Furthermore, the Company will not permit compensation to be paid to Non-Employee Directors for their service as such other than as provided for in this Policy, unless there are extraordinary circumstances as determined by the Compensation Committee or the Board.

All payments to Non-Employee Directors will be disclosed in accordance with applicable law, regulations and exchange or national market system requirements.

**Approved by the Board of Directors: March 3, 2026**
**Effective: March 3, 2026**

**Exhibit 31.1**

**CERTIFICATION**
**Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Catherine Owen Adams, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Acadia Pharmaceuticals 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 this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 6, 2026

/s/ Catherine Owen Adams

**Catherine Owen Adams**
**Chief Executive Officer**
(Registrant's Principal Executive Officer)

**Exhibit 31.2**

**CERTIFICATION**
**Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Mark C. Schneyer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Acadia Pharmaceuticals 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 this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 6, 2026

/s/ Mark C. Schneyer

**Mark C. Schneyer**
**Executive Vice President and Chief Financial Officer**
(Registrant's Principal Financial Officer)

**Exhibit 32.1**

**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 of Acadia Pharmaceuticals Inc. (the "Company") on Form 10-Q for the quarterly period ended March 31, 2026, as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), I, Catherine Owen Adams, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"); and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Date: May 6, 2026

/s/ Catherine Owen Adams

**Catherine Owen Adams**
**Chief Executive Officer**
(Registrant's Principal Executive Officer)

This certification shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of Section 18 of the Exchange Act. Such certification shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

**Exhibit 32.2**

**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 of Acadia Pharmaceuticals Inc. (the "Company") on Form 10-Q for the quarterly period ended March 31, 2026, as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), I, Mark C. Schneyer, Executive Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"); and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Date: May 6, 2026

/s/ Mark C. Schneyer

**Mark C. Schneyer**
**Executive Vice President and Chief Financial Officer**
(Registrant's Principal Financial Officer)

This certification shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of Section 18 of the Exchange Act. Such certification shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.