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 September 30, 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 **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 October 28, 2026:

Class	Number of Shares Outstanding
Common Stock, $0.0001 par value	172,828,972

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)

	September 30, 2026	December 31, 2025
	(unaudited)	
Assets		
Cash and cash equivalents	$ 322,365	$ 177,695
Investment securities, available-for-sale	654,081	641,991
Accounts receivable, net	161,017	121,457
Interest and other receivables	17,298	26,774
Inventory	40,360	34,670
Prepaid expenses and other current assets	73,305	59,526
Total current assets	1,268,426	1,062,113
Property and equipment, net	18,403	7,511
Operating lease right-of-use assets	67,468	47,354
Intangible assets, net	135,483	108,893
Restricted cash	7,846	7,845
Long-term inventory	66,484	76,704
Deferred tax assets	226,719	249,879
Other assets	3,322	3,896
Total assets	$ 1,794,151	$ 1,564,195
Liabilities and stockholders' equity		
Accounts payable	$ 16,330	$ 10,903
Accrued liabilities	315,887	266,211
Total current liabilities	332,217	277,114
Operating lease liabilities	57,322	40,554
Other long-term liabilities	17,123	19,137
Total liabilities	406,662	336,805
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized at September 30, 2026 and December 31, 2025; no shares issued and outstanding at September 30, 2026 and December 31, 2025	—	—
Common stock, $0.0001 par value; 225,000,000 shares authorized at September 30, 2026 and December 31, 2025; 172,789,550 shares and 170,309,376 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	17	16
Additional paid-in capital	3,115,141	3,039,315
Accumulated deficit	(1,724,725)	(1,813,386)
Accumulated other comprehensive (loss) income	(2,944)	1,445
Total stockholders' equity	1,387,489	1,227,390
Total liabilities and stockholders' equity	$ 1,794,151	$ 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 September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Revenues				
Product sales, net	$ 342,291	$ 278,633	$ 918,312	$ 787,516
Total revenues	342,291	278,633	918,312	787,516
Operating expenses				
Cost of product sales	35,090	21,647	88,197	62,773
Research and development	76,282	87,829	234,705	244,045
Selling, general and administrative	159,201	133,401	490,472	393,278
Total operating expenses	270,573	242,877	813,374	700,096
Income from operations	71,718	35,756	104,938	87,420
Interest income, net	8,421	8,246	24,466	23,390
Other income	300	593	1,489	1,775
Income before income taxes	80,439	44,595	130,893	112,585
Income tax expense (benefit)	26,915	(27,184)	42,232	(4,847)
Net income	$ 53,524	$ 71,779	$ 88,661	$ 117,432
Earnings per share:				
Basic	$ 0.31	$ 0.43	$ 0.52	$ 0.70
Diluted	$ 0.31	$ 0.42	$ 0.51	$ 0.69
Weighted average common shares outstanding:				
Basic	172,545	168,836	171,563	167,837
Diluted	175,466	170,650	173,770	169,156

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 September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Net income	$ 53,524	$ 71,779	$ 88,661	$ 117,432
Other comprehensive income (loss), net of income taxes:				
Unrealized (loss) gain on investment securities	(2,023)	598	(4,496)	693
Foreign currency translation adjustments	37	(15)	107	4
Comprehensive income	$ 51,538	$ 72,362	$ 84,272	$ 118,129

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)

	Nine Months Ended September 30,	
	2026	2025
Cash flows from operating activities		
Net income	$ 88,661	$ 117,432
Adjustments to reconcile net income to net cash provided by operating activities:		
Stock-based compensation	49,089	38,900
Amortization of premiums and accretion of discounts on investment securities	(642)	(4,754)
Amortization of intangible assets	8,410	8,167
Depreciation	1,393	669
Loss on disposal of assets	166	—
Deferred Income Taxes	24,077	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(39,561)	(17,111)
Interest and other receivables	9,433	(17,626)
Inventory	5,334	(13,305)
Prepaid expenses and other current assets	(13,740)	(5,187)
Other assets	574	(2,006)
Operating lease right-of-use assets	7,012	6,471
Accounts payable	5,443	5,555
Accrued liabilities	9,565	49,126
Operating lease liabilities	(6,935)	(3,597)
Long-term liabilities	(2,014)	(4,167)
Net cash provided by operating activities	146,265	158,567
Cash flows from investing activities		
Purchases of investment securities	(276,665)	(534,951)
Maturity of investment securities	259,805	387,779
Payment of milestone and contingent payments in connection with asset acquisition	—	(98,838)
Purchases of property and equipment	(11,541)	(685)
Net cash used in investing activities	(28,401)	(246,695)
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	26,596	27,217
Net cash provided by financing activities	26,596	27,217
Effect of exchange rate changes on cash	211	19
Net increase (decrease) in cash, cash equivalents and restricted cash	144,671	(60,892)
Cash, cash equivalents and restricted cash		
Beginning of period	185,540	328,359
End of period	$ 330,211	$ 267,467
Supplemental disclosure of noncash information:		
Accrued inventory purchases	$ 814	$ 863
Accrued property and equipment purchases	$ 910	$ —
Accrued milestone and contingent payments in connection with asset acquisition	$ 35,000	$ —
Stock-based compensation capitalized	$ 142	$ 233

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 September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Total stockholders' equity, beginning balances	$ 1,306,609	$ 822,382	$ 1,227,390	$ 732,793
Common stock:				
Beginning balance	16	16	16	16
Issuance of common stock from exercise of stock options and units	1	—	1	—
Ending balance	17	16	17	16
Additional paid-in capital:				
Beginning balance	3,085,800	2,980,693	3,039,315	2,936,871
Issuance of common stock from exercise of stock options and units	11,870	9,423	22,613	23,943
Issuance of common stock pursuant to employee stock purchase plan	—	—	3,982	3,274
Stock-based compensation	17,471	13,105	49,231	39,133
Ending balance	3,115,141	3,003,221	3,115,141	3,003,221
Accumulated deficit:				
Beginning balance	(1,778,249)	(2,158,733)	(1,813,386)	(2,204,386)
Net income	53,524	71,779	88,661	117,432
Ending balance	(1,724,725)	(2,086,954)	(1,724,725)	(2,086,954)
Other comprehensive (loss) income:				
Beginning balance	(958)	406	1,445	292
Other comprehensive (loss) income	(1,986)	583	(4,389)	697
Ending balance	(2,944)	989	(2,944)	989
Total stockholders' equity, ending balances	$ 1,387,489	$ 917,272	$ 1,387,489	$ 917,272

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), 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.

In August 2026, the European Commission (EC) granted marketing authorization for DAYBU® (trofinetide) for the treatment of neurobehavioral symptoms of Rett syndrome in adults and pediatric patients aged five and older.

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. Unless the context requires otherwise, DAYBUE, DAYBUE STIX, and DAYBU are collectively referred to as DAYBUE products.

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):

	Nine Months Ended September 30, 2026		Nine Months Ended September 30, 2025	
	Beginning of period	End of period	Beginning of period	End of period
Cash and cash equivalents	$ 177,695	$ 322,365	$ 319,589	$ 257,996
Restricted cash	7,845	7,846	8,770	9,471
Total cash, cash equivalents and restricted cash shown in the unaudited condensed consolidated statements of cash flows	$ 185,540	$ 330,211	$ 328,359	$ 267,467

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 September 30, 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 the 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 September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
NUPLAZID	$ 202,158	$ 177,530	$ 552,214	$ 505,730
DAYBUE products	140,133	101,103	366,098	281,786
Product sales, net	$ 342,291	$ 278,633	$ 918,312	$ 787,516

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 $173.8 million as intangible assets following the FDA approval of DAYBUE, sale of DAYBUE, sale of a Rare Pediatric Disease Priority Review Voucher (PRV) and EC marketing authorization of DAYBU, as disclosed in Note 9. The intangible assets of $138.8 million related to FDA approval of DAYBUE, sale of DAYBUE and sales of a PRV were amortized on a straight-line basis over the estimated useful life of the licensed patents through early 2036. In September 2026, U.S. Patent and Trademark Office (USPTO) issued a notice of allowance for U.S. patent covering weight-banded dosing of trofinetide, extending U.S. patent protections from July 2036 to March 2041. As a result, on a prospective basis the remaining net book value of the intangible assets will be amortized on a straight-line basis through March 2041 starting in October 2026. The intangible asset of $35.0 million related to the EC marketing authorization of DAYBU is amortized on a straight-line basis over the useful life of market exclusivity through the middle of 2038. For the three months ended September 30, 2026 and 2025, the Company recorded amortization expense related to these intangible assets of $3.0 million and $2.7 million, respectively. For the nine months ended September 30, 2026 and 2025, the Company recorded amortization expense related to these intangible assets of $8.4 million and $8.2 million, respectively. As of September 30, 2026, the Company's estimated future amortization expense related to its intangible assets is $2.5 million for the remainder of 2026, and $9.9 million for each of the five succeeding fiscal years.

Royalties incurred in connection with the Company's license agreement with Neuren, as disclosed in Note 9, are expensed to cost of product sales when the related product sales revenue 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. The Company reviews its 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 and nine months ended September 30, 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.

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except per share data)	2026	2025	2026	2025
Net income - basic and diluted	$ 53,524	$ 71,779	$ 88,661	$ 117,432
Weighted average shares outstanding:				
Basic	172,545	168,836	171,563	167,837
Effect of potentially dilutive common shares from:				
Equity awards	2,857	1,709	2,157	1,235
Employee stock purchase plan rights	64	105	50	84
Diluted	175,466	170,650	173,770	169,156
Earnings per share:				
Basic	$ 0.31	$ 0.43	$ 0.52	$ 0.70
Diluted	$ 0.31	$ 0.42	$ 0.51	$ 0.69
Potentially dilutive shares excluded from per share amounts as their effect would have been anti-dilutive	7,623	15,856	12,554	17,990

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 September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Cost of product sales	$ 451	$ 372	$ 1,290	$ 724
Research and development	4,674	4,312	13,562	12,222
Selling, general and administrative	12,325	8,496	34,237	25,954
	$ 17,450	$ 13,180	$ 49,089	$ 38,900

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 relative total shareholder return (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):

	September 30, 2026	December 31, 2025
Finished goods	$ 34,102	$ 25,952
Work in process	11,974	2,638
Raw material	60,768	82,784
	$ 106,844	$ 111,374
Reported as:		
Inventory	$ 40,360	$ 34,670
Long-term inventory	66,484	76,704
Total	$ 106,844	$ 111,374

Amount reported as long-term inventory primarily consists of raw materials as of September 30, 2026 and December 31, 2025.

Accrued liabilities consisted of the following (in thousands):

	September 30, 2026	December 31, 2025
Accrued sales allowances	$ 137,926	$ 140,862
Accrued compensation and benefits	44,385	45,579
Accrued milestone payments	35,000	—
Accrued consulting and professional fees	31,427	29,843
Accrued research and development services	18,021	19,094
Accrued royalties	16,354	13,314
Current portion of lease liabilities	14,532	11,633
Other	18,242	5,886
	$ 315,887	$ 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):

	September 30, 2026			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury notes	$ 443,288	$ 4	$ (2,093)	$ 441,199
Government sponsored enterprise securities	214,717	—	(1,835)	212,882
	$ 658,005	$ 4	$ (3,928)	$ 654,081

	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:

	September 30, 2026	December 31, 2025
One year or less	60%	51%
After one year but within two years	40%	49%
Total	100%	100%

At September 30, 2026 and December 31, 2025, the Company had 75 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 September 30, 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
September 30, 2026						
U.S. Treasury notes	$ 425,193	$ (2,092)	$ —	$ —	$ 425,193	$ (2,092)
Government sponsored enterprise securities	185,935	(1,780)	23,446	(56)	209,381	(1,836)
Total	$ 611,128	$ (3,872)	$ 23,446	$ (56)	$ 634,574	$ (3,928)

	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 September 30, 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 September 30, 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 September 30, 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 September 30, 2026 and December 31, 2025 consisted of the following (in thousands):

		Fair Value Measurements at Reporting Date Using		
	September 30, 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	$ 81,557	$ 81,557	$ —	$ —
U.S. Treasury notes	441,199	441,199	—	—
Government sponsored enterprise securities	212,882	—	212,882	—
Total	$ 735,638	$ 522,756	$ 212,882	$ —

		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. The 2024 Plan was amended on May 29, 2026, and as of the amendment effective date all shares that remained eligible for grant under the Company's 2024 Inducement Plan (Inducement Plan) were transferred to the 2024 Plan. At September 30, 2026, 14,653,541 shares of common stock were available for new grants under the 2024 Plan.

2024 Inducement Plan

The Board adopted the 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. As discussed above, all shares that remained eligible for grant under the Inducement Plan at the time of the most recent amendment of the 2024 Plan were transferred to the 2024 Plan.

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 September 30, 2026, the Company may be required to make milestone payments up to $3.6 billion in the aggregate for candidates in its pipeline, of which, pursuant to the license agreement with Neuren, $35.0 million became payable to Neuren following the first commercial sale of DAYBU in the European Union (EU) in October 2026. As of September 30, 2026, the Company has not paid the $35.0 million milestone payment and will pay it within 60 days after its first commercial sale of DAYBUE in the EU.

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 connection with the EC marketing authorization of DAYBU in August 2026, the Company was required to make a milestone payment of $35.0 million to Neuren following the first commercial sale of DAYBU in the EU pursuant to the license agreement. The Company accrued for and capitalized the $35.0 million milestone payment as an intangible asset as it was deemed probable of occurring as of September 30, 2026 and began amortizing it on a straight-line basis over its estimated useful life.

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 (ercanetide). 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 (ercanetide). 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 (ercanetide) 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, and the oral argument is scheduled for November 9, 2026.

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 (Pimavanserin III Case). The Company entered into an agreement, effective September 29, 2026, with Zydus settling all claims and counterclaims in the Pimavanserin III Case. The agreement allows Zydus to launch its generic pimavanserin 34 mg tablet products on April 1, 2032, subject to certain triggers for earlier launch. The case was dismissed by joint agreement on October 5, 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. The parties exchanged pretrial disclosures on July 10, 2026. The parties lodged the pretrial order with the Court on August 5, 2026. On September 21, 2026, the matter was reassigned to Judge Ruth Bermudez Montenegro. On September 24, 2026, the Court issued an order requiring the parties to submit a joint status report before a Final Pretrial Conference can be scheduled. On September 29, 2026, the parties filed a joint status report.

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. The Court's stay of this suit, previously in effect since January 13, 2025, was lifted on July 8, 2026. The Court set a case management conference for January 12, 2027 to discuss discovery.

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. Plaintiff filed the Motion for Preliminary Approval of Derivative Settlement on July 14, 2026. The Court granted that preliminary motion on August 24, 2026. Pursuant to the proposed settlement, which is still subject to final 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. The Court has scheduled a hearing on the preliminary motion for January 13, 2027.

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 0.3 years to 11.8 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 September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating lease cost	$ 4,935	$ 3,531	$ 14,144	$ 11,439
Operating sublease income	(612)	(594)	(1,830)	(1,777)
Net operating lease cost	$ 4,323	$ 2,937	$ 12,314	$ 9,662

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Cash paid for amounts included in the measurement of lease liabilities:				
Operating cash flows from operating leases	$ 3,695	$ 3,053	$ 9,928	$ 8,921
Right-of-use assets obtained in exchange for operating lease obligations:	653	894	27,133	9,573

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

	September 30, 2026	December 31, 2025
Operating lease liabilities		
Current portion included in accrued liabilities	$ 14,532	$ 11,633
Operating lease liabilities	57,322	40,554
Total operating lease liabilities	$ 71,854	$ 52,187

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

	Operating Leases
Remainder of 2026	$ 3,748
Years ending December 31,	
2027	15,254
2028	15,451
2029	15,002
2030	12,820
Thereafter	28,058
Total lease payments	90,333
Less:	
Imputed interest	(18,479)
Total operating lease liabilities	$ 71,854

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 September 30, 2026, the weighted average remaining lease term was 7.3 years and the weighted average discount rate used to determine the operating lease liability was 6.2%.

In the fourth quarter of 2018, the Company entered into an agreement to lease the 4th and 5th 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 2nd 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 4th and 5th 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 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. The Company's prior Princeton office lease expired in the second quarter of 2026 in accordance with its terms upon commencement of the New

Princeton Lease. The New Princeton Lease commenced in the second quarter of 2026, at which time the Company recognized a right-of-use asset and corresponding operating lease liability of approximately $15.7 million. 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.

11. Income Taxes

For the three months ended September 30, 2026 and 2025, the Company recognized an income tax expense of $26.9 million on a pre-tax income of $80.4 million and income tax benefit of $27.2 million on a pre-tax income of $44.6 million, respectively, resulting in effective tax rates of 33.5% and -61.0%, respectively. The effective tax rate for the three months ended September 30, 2026 varies from the U.S. federal statutory tax rate of 21% mostly due to federal and state income tax expense, offset by a partial valuation allowance, permanent book to tax adjustments including stock based compensation and branded prescription drug fees, and quarterly discrete items. The effective tax rate for the three months ended September 30, 2025 varies from the U.S. federal statutory tax rate of 21% due to the consideration of the One Big Beautiful Bill Act (OBBBA) enacted in the third quarter of 2025 which resulted in a significant reduction to the current taxable income, offset by valuation allowance, and a tax benefit recognized during the third quarter of 2025 to reflect the filing of an accounting method change included in the 2024 federal and state tax return filings. The tax benefit was offset by foreign tax expense.

For the nine months ended September 30, 2026 and 2025, the Company recognized an income tax expense of $42.2 million on a pre-tax income of $130.9 million and income tax benefit of $4.8 million on a pre-tax income of $112.6 million, respectively, resulting in effective tax rates of 32.2% and -4.3%, respectively. The effective tax rate for the nine months ended September 30, 2026 varies from the U.S. federal statutory tax rate of 21% mostly due to federal and state expense, offset by a partial valuation allowance, permanent book to tax adjustments including stock based compensation and branded prescription drug fees, and quarterly discrete items. The effective tax rate for the nine months ended September 30, 2025 varies from the U.S. federal statutory tax rate of 21% due to the consideration of the OBBBA which resulted in a significant reduction to current taxable income, offset by valuation allowance, and a tax benefit recognized during the third quarter of 2025 to reflect the filing of an accounting method change included in the 2024 federal and state tax return filings. The benefit was offset by foreign tax expense.

12. Segment Reporting

Substantially all revenues from the three and nine months ended September 30, 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 September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
NUPLAZID net revenue	$ 202,158	$ 177,530	$ 552,214	$ 505,730
DAYBUE products net revenue	140,133	101,103	366,098	281,786
Total revenues	342,291	278,633	918,312	787,516
Less:				
Cost of product sales	15,705	8,041	40,155	25,636
License fees and royalties	19,385	13,606	48,042	37,137
Research and development expense:				
External research and development	49,283	60,153	153,501	169,457
Internal costs[1]	26,999	24,676	78,703	71,588
Upfront and milestone payments	—	3,000	2,501	3,000
Total research and development expense	76,282	87,829	234,705	244,045
Selling, general and administrative	159,201	133,401	490,472	393,278
Interest income, net	(8,421)	(8,246)	(24,466)	(23,390)
Other income	(300)	(593)	(1,489)	(1,775)
Income tax expense (benefit)	26,915	(27,184)	42,232	(4,847)
Consolidated net income	$ 53,524	$ 71,779	$ 88,661	$ 117,432

(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

Unless the context requires otherwise, we refer to DAYBUE, DAYBUE STIX and DAYBU collectively as DAYBUE products.

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), our unaudited condensed consolidated financial statements and related notes thereto as of and for the quarter ended March 31, 2026 included with our Quarterly Report on Form 10-Q, filed with the SEC on May 7, 2026, and our unaudited condensed consolidated financial statements and related notes thereto as of and for the quarter ended June 30, 2026 included with our Quarterly Report on Form 10-Q, filed with the SEC on August 5, 2026. 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 products 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 DAYBUE products, which are the first and only drug approved for the treatment of Rett syndrome or neurobehavioral symptoms of Rett syndrome. Net product sales from these two commercial products totaled $918.3 million for the nine months ended September 30, 2026, compared with $787.5 million for the nine months ended September 30, 2025.

In August 2026, the EC granted marketing authorization for DAYBU® (trofinetide) for the treatment of the neurobehavioral symptoms of Rett syndrome in adults and pediatric patients aged five years and older. DAYBU® is the first therapy approved for this indication in the EU. We made our first commercial sale of DAYBU in the EU in October 2026.

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 our RADIANT Phase 2 study evaluating the efficacy and safety of remlifanserin for the treatment of hallucinations and delusions associated with ADP. In July 2026, the FDA granted Fast Track designation for remlifanserin for the treatment of hallucinations and delusions associated with ADP. In September 2026, we announced the topline results from our Phase 2 RADIANT study. The study narrowly missed the primary endpoint of the Scale for the Assessment of Positive Symptoms-Hallucinations and Delusions subscales (p=0.0603) with significance (nominal) on the key secondary endpoint of Clinical Global Impression – Severity (p=0.0077). However, the study demonstrated meaningful and consistent efficacy trends across endpoints for the once daily 60 mg dose and a favorable safety and tolerability profile across both once daily 30 mg dose and once daily 60 mg dose. These findings achieved the study's objective of informing dose selection and study design optimization for Phase 3 which we believe supports continuing with Phase 3 development for the once daily 60 mg dose. Therefore, we plan to continue enrolling our two ongoing Phase 3 studies evaluating remlifanserin for the once daily 60 mg dose in ADP while implementing amendments to the Phase 3 program, including removing the once daily 30 mg dosage arm. We initiated an additional Phase 2 study of remlifanserin in LBDP in September 2025 and expect a data readout in the fourth quarter 2027. We received FDA Fast Track designation for remlifanserin in LBDP in August 2026. In the fourth quarter of 2025, we initiated a Phase 2 study of ACP-211 for the treatment of major depressive disorder and expect a data readout in the second half 2027.

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 2027 following the completion of a successful Phase 1 study; 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 September 30, 2026, we had an accumulated deficit of approximately $1.7 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 the second quarter of 2026. In addition, we currently have contracts with multiple distributors outside the United States that distribute DAYBUE for limited named patient/compassionate use. The EC granted marketing authorization for DAYBU for the treatment of neurobehavioral symptoms of Rett syndrome in adults and pediatric patients aged five and older in August 2026. Our first commercial sales of DAYBU took place in October 2026.

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 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 products.

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 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 also 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 nonclinical 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 and nine months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Costs of external service providers:				
NUPLAZID (pimavanserin)	$ —	$ —	$ —	$ 3,706
DAYBUE (trofinetide) products	4,345	8,160	12,396	29,384
ACP-101	(278)	16,119	3,810	39,540
Remlifanserin	27,329	22,847	81,294	58,418
Early-stage programs	17,887	13,027	56,001	38,409
Upfront and milestone payments*	—	3,000	2,501	3,000
Subtotal	49,283	63,153	156,002	172,457
Internal costs	22,325	20,364	65,141	59,366
Stock-based compensation	4,674	4,312	13,562	12,222
Total research and development expenses	$ 76,282	$ 87,829	$ 234,705	$ 244,045

* 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 products, as well as the further development of our 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 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.

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 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 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 September 30, 2026 and 2025

Product Sales, Net

Net product sales, comprised of NUPLAZID and DAYBUE products, were $342.3 million and $278.6 million for the three months ended September 30, 2026 and 2025, respectively.

Net product sales of NUPLAZID were $202.2 million and $177.5 million for the three months ended September 30, 2026 and 2025, respectively. The increase in net product sales of NUPLAZID of $24.7 million was primarily due to the growth in NUPLAZID unit sales in 2026 compared to 2025. Net product sales of DAYBUE products were $140.1 million and $101.1 million for the three months ended September 30, 2026 and 2025, respectively. The increase in net product sales of DAYBUE products of $39.0 million was primarily due to the growth in DAYBUE unit sales in 2026 compared to 2025.

Cost of Product Sales

Cost of product sales was $35.1 million and $21.6 million for the three months ended September 30, 2026 and 2025, respectively, or approximately 10% and 8% of net product sales, respectively. The increase in cost of product sales as a percentage of net product sales during the three months ended September 30, 2026 as compared to the same period of 2025 was primarily due to a higher proportion of DAYBUE sales in the current period as DAYBUE has a higher cost of product sales percentage than NUPLAZID.

Research and Development Expenses

Research and development expenses decreased to $76.3 million for the three months ended September 30, 2026 from $87.8 million for the three months ended September 30, 2025. The decrease in research and development expenses was primarily related to reduced expenditures for ending studies that took place in 2025, offset by increased expenditures for remlifanserin and ACP-211.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased to $159.2 million for the three months ended September 30, 2026 from $133.4 million for the three months ended September 30, 2025. The increase in selling, general and administrative expenses was primarily driven by increased expenditures for DAYBUE products and NUPLAZID in the U.S., including the expansion of the DAYBUE and NUPLAZID teams.

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

Product Sales, Net

Net product sales, comprised of NUPLAZID and DAYBUE products, were $918.3 million and $787.5 million for the nine months ended September 30, 2026 and 2025, respectively.

Net product sales of NUPLAZID were $552.2 million and $505.7 million for the nine months ended September 30, 2026 and 2025, respectively. The increase in net product sales of NUPLAZID of $46.5 million was mainly due to the growth in NUPLAZID unit sales in 2026 compared to 2025. Net product sales of DAYBUE products were $366.1 million and $281.8 million for the nine months ended September 30, 2026 and 2025, respectively. The increase in net product sales of DAYBUE products of $84.3 million was primarily due to the growth in DAYBUE products unit sales.

The following table provides a summary of activity with respect to our sales allowances and accruals for the nine months ended September 30, 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	118,822	3,735	159,657	282,214
Credits/payments for current period sales	(101,827)	(3,997)	(55,387)	(161,211)
Credits/payments for prior period sales	(16,457)	37	(106,955)	(123,375)
Balance as of September 30, 2026	$ 16,995	$ (262)	$ 137,755	$ 154,488

Cost of Product Sales

Cost of product sales was $88.2 million and $62.8 million for the nine months ended September 30, 2026 and 2025, respectively, or approximately 10% and 8% of net product sales, respectively. The increase in cost of product sales as a percentage of net product sales during the nine months ended September 30, 2026 as compared to the same period of 2025 was primarily due to a higher proportion of DAYBUE sales in the current period as DAYBUE has a higher cost of product sales percentage than NUPLAZID, resulting in an unfavorable product mix impact on our overall gross margin.

Research and Development Expenses

Research and development expenses was $234.7 million and $244.0 million for the nine months ended September 30, 2026 and 2025, respectively. The decrease in research and development expenses was primarily related to reduced expenditures for ending studies that took place in 2025, offset by increased expenditures for remlifanserin and ACP-211.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased to $490.5 million for the nine months ended September 30, 2026 from $393.3 million for the nine months ended September 30, 2025. The increase in selling, general and administrative expenses was primarily driven by increased investments to support continued growth of NUPLAZID and DAYBUE products.

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 product sales from our products;
- the costs of preparing applications for regulatory approvals for DAYBUE products 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;
- 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, U.S. treasury notes, 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. In connection with the EC marketing authorization of DAYBU in August 2026, we are required to make a milestone payment of $35.0 million to Neuren following the first commercial sale of DAYBU in the EU during the fourth quarter of 2026.

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, 2025 to September 30, 2026 in June 2027. 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 September 30, 2026, we had $976.4 million in cash, cash equivalents, and investment securities, compared to $819.7 million at December 31, 2025. This $156.7 million increase was due to cash provided by operating activities. Net cash provided by operating activities totaled $146.3 million for the nine months ended September 30, 2026 compared to $158.6 million for the nine months ended September 30, 2025. This decrease in cash provided by operations primarily reflected the timing of working capital movements during the period.

Net cash used in investing activities totaled $28.4 million for the nine months ended September 30, 2026 compared to $246.7 million for the nine months ended September 30, 2025. The decrease in net cash used in investing activities for the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025 was primarily due to increased net sales and maturity of investment securities. Also during the nine months ended September 30, 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 decreased to $26.6 million for the nine months ended September 30, 2026 compared to $27.2 million for the nine months ended September 30, 2025. This decrease in net cash provided by financing activities for the nine months ended September 30, 2026 was attributable primarily to a decrease 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 September 30, 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 September 30, 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 September 30, 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 and product candidates, if approved, may not gain maximal acceptance among physicians, patients, caregivers and the medical community, and our projections regarding the market opportunities for our products and product candidates may not be accurate, 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.
- 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.*

NUPLAZID, DAYBUE and DAYBUE STIX are approved for commercialization in the U.S., DAYBUE is approved for commercialization in Canada and Israel, and DAYBU is approved for commercialization in the EU. 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 or other applicable regulatory authorities' approval of our products, including differences in the scope of approved indications and patient populations across jurisdictions, such as the more limited indication and patient population for which DAYBU is approved in the EU, 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. We face in jurisdictions outside the U.S., such as Canada, the EU and Israel, 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 and product candidates, if approved, may not gain maximal acceptance among physicians, patients, caregivers and the medical community, and our projections regarding the market opportunities for our products and product candidates may not be accurate, 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 product candidates, if approved, 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);
- 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 and product candidates or competing products and treatments; and
- our ability to obtain and maintain sufficient third-party insurance coverage or adequate reimbursement levels.

If a product or product candidate 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 or product candidate will not achieve market acceptance and will not generate sufficient revenues to achieve or maintain profitability. With respect to our approved 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 and DAYBUE STIX are 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, and DAYBU is the first and only product approved in the EU to treat neurobehavioral symptoms of Rett syndrome in adults and pediatric patients aged five years and older. The more limited scope of the approved indication and patient population in the EU compared to the U.S., Canada and Israel may limit the market opportunity for DAYBU in the EU.

Further, our projections regarding the market opportunities for our products and product candidates are subject to several assumptions and estimates. These assumptions and estimates may be derived from, among others, scientific literature, third-party analyses and market research that may prove to be incorrect or inapplicable to the indications our products and product candidates target. For example, there are no approved competitors for our products and certain of our product candidates, making it particularly difficult to estimate the market potential for our products and product candidates and how physicians, patients, caregivers, long-term care facilities and payors will respond to the price of our products or changes to the price of our products. Further, we have developed internal assumptions regarding, for example, 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, and have and will develop similar assumptions for our product candidates, some or all of which may prove to be inaccurate. As a result, one or more of our products or product candidates may fail to meet our or the market's expectations, including our estimates of peak sales, prevalence and incidence, which could adversely affect our business, results of operations, financial condition and prospects.

Estimating the market opportunity of our current products faces unique challenges. 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 products are prescribed for the treatment of Rett syndrome or the neurobehavioral symptoms 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 products, or do not maintain the recommended dosing of DAYBUE products for sufficient periods of time, patients and physicians may believe that DAYBUE products are less effective, and as a result they may discontinue taking it and prescribing it. Additionally, if physicians or patients titrate DAYBUE products below the recommended doses, patients may not experience the desired outcomes, and physicians or patients may develop negative beliefs about the effectiveness of DAYBUE products and/or discontinue their 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 and product candidates, if approved, 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 U.S. and foreign governmental healthcare programs, such as Medicare, Medicaid and EU Member States, as well as 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 our products or 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. 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 our products or 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.

Following the EC's grant of marketing authorization for DAYBU in August 2026, DAYBU is also subject to generally applicable ongoing post-authorization requirements in the EU, including pharmacovigilance and risk management, safety reporting, manufacturing and quality requirements and requirements relating to updates to the marketing authorization and product information. Failure to comply with these requirements could result in regulatory action, including restrictions, suspension, variation or withdrawal of the marketing authorization.

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 or comparable foreign regulatory authorities 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 products 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 products 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.*

Nonclinical testing and clinical trials are long, expensive and unpredictable processes that can be subject to delays. Preliminary, initial, topline 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 nonclinical 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, the unsuccessful Phase 3 COMPASS PWS study of intranasal carbetocin for the treatment of hyperphagia in Prader-Willi Syndrome in September 2025 and the Phase 2 portion of the RADIANT trial of remlifanserin for ADP in September 2026, which narrowly missed the primary endpoint. 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. We plan to continue enrolling our two ongoing Phase 3 studies evaluating remlifanserin in ADP while implementing amendments to the Phase 3 program, including removing the 30 mg dosage arm.

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.

We are currently conducting studies with our product candidates, including remlifanserin. 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.

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), including DAYBUE products. 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 or comparable foreign regulatory authorities 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 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 nonclinical 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 product sales from our products;

- the costs of preparing applications for regulatory approvals for DAYBUE products 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;
- 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 product costs beyond annual patient out-of-pocket thresholds (known as “catastrophic coverage”) 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 nonclinical 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 nonclinical 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 prospects.

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 products 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 nonclinical 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 nonclinical 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 nonclinical 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 nonclinical 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, commercialize, or continue to supply our products or product candidates, if approved.*

We have no manufacturing facilities. 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 products 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 twelve months 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 commercial supply of DAYBUE products.

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, Catalent, 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 the United States, Canada, the EU 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 products. 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 products 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. For example, on June 15, 2026, the FDA approved Colorado's Section 804 Importation Program proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this and Florida's similar program, approved by the FDA in 2024, will be implemented and whether they will overcome potential legal, regulatory, or industry challenges in the United States and/or Canada. 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 our products or 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 artificial intelligence (AI) technologies to perform their work. We continue to increase our use of AI technologies across business functions and have enhanced governance frameworks, policies, and review processes intended to manage associated risks. Despite these efforts, AI technologies may generate inaccurate, biased, incomplete, misleading, or unauthorized outputs, create intellectual property, privacy, security, operational, or regulatory risks, or otherwise adversely affect our business. To the extent our personnel rely upon such outputs in connection with business, operational, scientific, clinical, regulatory, legal, financial, or other decisions, such reliance could result in errors, compliance risks, reputational harm, or other adverse consequences.

AI technologies, and the disclosure and use of personal data in their use, are 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, emerging AI-specific regulatory regimes, including those in the European Union and other jurisdictions, may impose additional compliance obligations, governance requirements, documentation obligations, restrictions on AI use cases, or penalties for non-compliance. 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 nonclinical 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.

On December 11, 2025, the Parliament and the Council of the EU reached a political agreement on a comprehensive overhaul of EU pharmaceutical legislation (the Pharma Package). The reform has been under negotiation since the EC submitted its proposal in April 2023. The Pharma Package, comprised of a new directive and regulation to replace existing legislation, aims to modernize the EU framework. The Council formally adopted its first-reading position on the EU Pharmaceutical Package on September 28, 2026. The legislation is still subject to formal approval by the European Parliament, following which it will be published in the Official Journal of the European Union and enter into force. The Pharma Package encompasses a broad range of measures, including changes to regulatory data and market protection periods, including an eight-year regulatory data protection period and a one-year market protection period, with opportunities for additional periods of market protection subject to specified conditions and a maximum combined regulatory protection period of eleven years; changes to the orphan medicinal product framework, including a reduction in the standard period of orphan market exclusivity from ten to nine years, an eleven-year period of orphan market exclusivity for certain “breakthrough” orphan medicinal products, and changes to the incentives available for additional orphan indications; and an expansion of the “Bolar” exemption to permit certain activities relating to generic and biosimilar medicines while relevant intellectual property rights remain in force, including submissions for procurement tenders. A decrease in market exclusivity opportunities for our products or 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 products or 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 products compete 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;
- nonclinical 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. In addition, we rely, and may increasingly rely, on third-party providers of AI technologies and related infrastructure. Changes in the availability, performance, terms of use, pricing, security posture, or legal permissibility of such technologies could adversely affect our operations, increase costs, or limit our ability to realize anticipated benefits from AI initiatives.

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.

Threat actors increasingly utilize AI technologies to enhance cyberattacks, including phishing, business email compromise, impersonation, deepfake-enabled social engineering, automated reconnaissance, credential theft, and other malicious activities. These capabilities may increase the scale, speed, sophistication, and effectiveness of attacks directed at us and the third parties with whom we work. 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 October 28, 2026, the closing price of our common stock has ranged from a low of $18.62 per share to a high of $30.57 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 dementia-related psychosis, 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, no Company director or officer (as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended (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, except:

- On August 6, 2026, the Rule 10b5-1 trading arrangement, which was intended to satisfy the affirmative defense of Rule 10b5-1(c) and adopted by James Kihara, Senior Vice President, Finance, on December 9, 2025, was terminated. The trading arrangement provided for the sale of up to 41,421 shares of our common stock. Prior to the termination, 11,421 shares were sold under the trading arrangement. The trading arrangement was scheduled to expire on March 9, 2027, or earlier if and when all transactions under the trading arrangement were completed.

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[a]	Joint Venture and License Agreement, dated July 13, 2023, by and between the Registrant and Neuren Pharmaceuticals Limited.
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[b]	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[b]	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 September 30, 2026, filed on November 4, 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] Pursuant to Item 601(b)(10) of Regulation S-K, certain portions of this exhibit have been omitted (indicated by "[…***…]") because the Company has determined that the information is both not material and is the type that the Company treats as private or confidential.

[b] 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: November 4, 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

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY […*…], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.**

Joint Venture and Licence Agreement

Neuren Pharmaceuticals Limited
ABN 72 111 496 130

Acadia Pharmaceuticals Inc

Joint Venture and Licence Agreement

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Joint Venture and Licence Agreement

Details

Date	13 July 2023
Parties	Neuren Pharmaceuticals Limited ABN 72 111 496 130 (Neuren) of Suite 201, 697 Burke Road, Camberwell, Victoria 3124, Australia
	ACADIA Pharmaceuticals Inc (ACADIA) of 12830 El Camino Real, Suite 400, San Diego, California 92130, USA
Background	A Neuren is the owner of the Neuren IP and is entitled to grant ACADIA a licence to use the Neuren IP. B On 6 August 2018, Neuren granted ACADIA an exclusive licence to use the Trofinetide IP to make, use, sell, offer for sale, import, manufacture, market, promote, and distribute the Trofinetide Compound and any Trofinetide Product within the Trofinetide Field within the Initial Territory (Initial Licence). C Subject to the terms and conditions of this Agreement, the parties have agreed to enter into a joint venture for: (a) the global commercialization and development of the Trofinetide IP, Trofinetide Compound and Trofinetide Product within the Trofinetide Field; and (b) the global commercialization and development of NNZ-2591 IP, NNZ-2591 Compound and NNZ 2591 Product within the NNZ 2591 Field. D To enable the JV to be established and operate as intended: (i) the parties have agreed to amend and restate the Initial Licence, including to extend the territory in which the Initial Licence operates to include the New Territory; and (ii) Neuren has agreed to grant to ACADIA an exclusive licence to use the NNZ-2591 IP to make, use, sell, offer for sale, import, manufacture, market, promote, and distribute the NNZ-2591 Compound and any NNZ-2591 Product within the NNZ-2591 Field within the Territory. E This Agreement sets out the terms and conditions which govern the joint venture, the amended and restated terms and conditions of the Initial Licence and the terms and conditions which govern the licence in respect of NNZ-2591 IP.

AGREED TERMS

1 Definitions and interpretation

1.1 Definitions

In this Agreement, unless expressly provided otherwise:

Affiliate	means, with respect to a party to this Agreement, any person, corporation, partnership, or other entity that controls, is controlled by, or is under common control with that party. For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under the common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of 50% or more of the voting stock of such entity, or by contract or otherwise.
Agreement	means this agreement, including the recitals, any schedules and any annexures.
Alliance Manager	has the meaning given to that term in clause 5.5(a)
Business Day	means a day other than a Saturday, Sunday or public holiday in Melbourne, Victoria, or San Diego, California (as appropriate).
Change of Control of any Party	means any of the following: (a) either (i) a Third Party acquires directly or indirectly the beneficial ownership of voting securities of such Party; or (ii) the beneficial ownership by a Third Party of voting securities of such Party is increased through stock redemption, cancellation or other recapitalization, in either case of paragraph (a)(i) or (a)(ii), where (A) such Third Party is, directly or indirectly, the beneficial owner of voting securities representing less than 50% of the total voting power of all of the then-outstanding voting securities of such Party immediately prior to such acquisition or increase; and (B) immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of voting securities representing more than 50% of the total voting power of all of the then-outstanding voting securities of such Party; (b) the consummation of a merger, consolidation, recapitalization, or reorganization of such Party, in which transaction the beneficial owners of outstanding voting securities of such Party immediately prior to such transaction do not beneficially own, directly or indirectly, at least 50% of the total voting power of all of the then-outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction;

	(c) the stockholders or equity holders of such Party approve a plan of complete liquidation of such Party, or an agreement for the sale or disposition by such Party of all or a substantial portion of such Party's assets, other than pursuant to the transaction as described above or to an Affiliate; or (d) the sale or other transfer to a Third Party of all or substantially all of such Party's assets, including those relating to the Compound and Product.
CMC	means chemistry manufacturing and controls.
Commencement Date	means the date of execution of this Agreement by the last party to execute it.
Commercialize and **Commercialization**	means all activities undertaken with respect to or in support of the marketing, promotion, selling, offering for sale, and distribution (including importing, exporting, transporting, customs clearance, warehousing, invoicing, handling and delivering the applicable Product to customers) of any Product, including Manufacturing Product for commercial sale, planning, market research, Pre-Marketing, sales force efforts, detailing, advertising, educating, marketing, the creation and approval of Promotional Materials, promoting, importing, exporting, sales, distributing, pricing, customer and government contracting, and medical affairs, including post-marketing safety surveillance and reporting, medical education, medical information, clinical science liaison activities, health economics and outcomes research, publications and investigator initiated research studies.
Commercially Reasonable Efforts	means, in respect of a party, those efforts and resources consistent with the usual practices of that party in pursuing the Development or Commercialization of its own pharmaceutical products that are of similar market potential as the Compound or the relevant Product, taking into account all relevant factors including product labelling or anticipated labelling, present and future market potential, past performance of the Compound or the relevant Product and such party's other pharmaceutical products that are of similar market potential, financial return, medical and clinical considerations, present and future regulatory environment and competitive market conditions, all as measured by the facts and circumstances at the time such efforts are due, and considering, without limitation, the following factors in assessing the efforts and resources used by such party: (a) prompt assignment of responsibility for the relevant obligation to appropriate personnel who are responsible for monitoring progress on an on-going basis; (b) establishment and measurement of achievement of objectives for carrying out such obligations; and (c) allocation of resources designed to allow progress with respect to such objectives.
Compound	means any Trofinetide Compound or NNZ-2591 Compound.
Confidential Information	means confidential documents, technology, Know-how or other information (whether or not patentable) actually disclosed or made available by one party or its Affiliates to the other party or its Affiliates pursuant to this Agreement or the Prior Confidentiality Agreement,

	including without limitation all confidential information regardless of form that relates to the disclosing party, its Affiliates, and their businesses or affairs, any Methodology and any Know-how transferred from one party to the other party pursuant to clauses 4.8 or 7.2.
Control	means, with respect to any Patent, Know-how, trademark or other intellectual property rights, ownership or possession by a party or any of its Affiliates of the ability (without taking into account any rights granted by one party to the other party under the terms of this Agreement) to grant access, a licence or a sublicence to such Patent, Know-how, trademark or other intellectual property right without violating the terms of any agreement or other arrangement with, or necessitating the consent of, any Third Party, at such time that the party would be first required under this Agreement to grant the other party such access, licence or sublicence.
Development	means all activities described in clause 6.1 for the Trofinetide Compound and clause 7.1 for the NNZ 2591 Compound, and otherwise conducted in pursuit of new and revised Marketing Authorisations.
Development Milestone Fees	means the development milestone fees specified in clause 2 of the Fee Schedule.
EMA Region	means all of the European Union member states as of the Commencement Date.
Encumbrance	means any mortgage, lien, hypothecation, charge (whether fixed or floating), bill of sale, caveat, pledge, claim, trust arrangement, preferential right, right of set-off, title retention or other form of encumbrance.
Exclusivity Period	means, on a country by country basis in the Territory and Product by Product basis, the period commencing on the Commencement Date and ending on the latest to occur of: (a) the date of expiry of the last Valid Claim that would be infringed by an authorised sale of the relevant Product in the relevant country; (b) the date of expiry of the term of any data exclusivity right in such country; and (c) 10 years after the date of the First Commercial Sale of the Product in such country
FDA	means the United States of America Food and Drug Administration or its successor.
FDA Approval	means the approval by the FDA for a New Drug Application made in respect of any Product.
Fees	means the Upfront Fee, the Development Milestone Fees, the Sales Milestone Fees and the Sub-Licensee Fees.
Field	means, in respect of:

	(a) Trofinetide Compound and Trofinetide Product, the Trofinetide Field; and (b) NNZ 2591 Compound and NNZ 2591 Product, the NNZ 2591 Field.
First Commercial Sale	means, for a Product, the first sale or transfer of that Product in a region or other regulatory jurisdiction in the Territory by or on behalf of ACADIA or its Affiliate or its Sub-Licensee to a Third Party, other than for evaluation, research or clinical trial purposes or any not-for-profit or compassionate uses, in exchange for cash or some equivalent to which value can be assigned, and following receipt in that part of the Territory of all Marketing Authorisations and other approvals necessary to sell or transfer that Product in that part of the Territory.
Generic Product	means, on a Product-by-Product and country-by-country basis, any pharmaceutical product sold by a Third Party, other than as a Sub-Licensee to this Agreement that: (a) contains the same active ingredients as the applicable Product, in the same dosage form (e.g., oral) as the applicable Product; (b) is approved by the regulatory authority in such country as a substitutable generic for such Product; or (c) is approved in the applicable field by a regulatory authority pursuant to an NDA (or an equivalent application for regulatory approval filed outside the U.S.), contains the active ingredients in the Product, and relies on the finding of safety and/or effectiveness in the regulatory approval of the Product.
Government Agency	means: (a) a government or government department; (b) a governmental, semi-governmental, regulatory or judicial entity or authority; or (c) a person (whether autonomous or not) who is charged with the administration of a law.
Improvements	means any improvement, modification, adaption, innovation or invention specifically relating to any Compound, any Product, Methodology or the Neuren IP, whether patentable or not, discovered, made, conceived or generated in the course of activities conducted by or on behalf of a party or its Affiliates (or jointly by both parties or their Affiliates) pursuant to this Agreement, including all Know-how in respect of same, and any test results and other data generated by or on behalf of any party or its Affiliates in respect of any Compound or Product or any Marketing Authorisation of any Product.
IND	means an Investigational New Drug Application filed with the FDA in the United States of America or a corresponding application filed with a Government Agency in any other country in the Territory, in each case together with all amendments and supplements thereto.
Infringement	means:

	(a) any actual or alleged infringement by a Third Party of any part of the Neuren IP, including pursuant to a Paragraph IV Patent Certification by a Third Party filing an Abbreviated New Drug Application (i.e., an action under the Hatch-Waxman Act); or (b) any person alleging that use or exploitation of any part of the Neuren IP infringes any rights of that person.
Initial Territory	means, subject to clause 23.2(d), the United States, Canada and Mexico.
Intellectual Property Rights	means all intellectual and industrial property rights of whatever nature (whether or not registered or registrable) including, but not limited to: (a) patents, copyrights, designs, trademarks, trade secrets, Know-how and the right to have Confidential Information kept confidential; and (b) any application or right to apply for registration of any of the rights in paragraph (a) and all renewals and extensions of those rights.
Joint Improvement	means an Improvement made or acquired jointly by Neuren and ACADIA in accordance with clause 19.4.
JSC	means the Joint Steering Committee established and operated in accordance with clause 5.1.
JV	means the joint venture between Neuren and ACADIA as described in clause 3.
Know-how	means any information, ideas, data, inventions, methods, processes, techniques, discoveries, works of authorship, results, trade secrets, technology, or materials, including formulations, molecules, assays, reagents, compounds, compositions, human or animal tissue, samples or specimens, and combinations or components thereof, whether or not proprietary or patentable, or public or confidential, and whether stored or transmitted in oral, documentary, electronic or other form, including all regulatory documentation, but excluding any such information or materials publicly disclosed in Patents.
Manufacture	means all activities related to the manufacture, processing, formulation, filling, finishing, packaging, labelling, shipping, storage and handling of a Product, including manufacturing process development, process qualification and validation, scale-up, process improvements and optimization, product characterization, stability testing, quality assurance and quality control.
Manufacturing Costs	in respect of a Product means the fully allocated and burdened costs and charges incurred in connection with the Manufacture of that Product as determined in accordance with U.S. generally accepted accounting principles, or when referring to Neuren's Manufacturing Cost, the New Zealand equivalent to International Financial Reporting Standards, and as consistently applied by the party selling the Product. Any indirect cost, or a proportion of it, must only be allocated to the relevant Product to the extent and in the proportion that is reasonable and clearly connected to the Manufacture of the Product, based on quantitative evidence (such as time sheets). Any intercompany transfer

	pricing markups, distribution costs and any costs not associated with Manufacturing of the Product will be excluded.
Marketing Authorisations	means the approval of a marketing authorisation application, or any equivalent authorisation, in respect of a Product in a Field that is made by a Government Agency located in the Territory and which, once granted, entitles a party to market and sell that Product in that Field in that part of the Territory and in respect of the United States of America, includes the FDA Approval. Marketing Authorisations do not include INDs.
Methodology	means the methodology developed by a party or its Affiliates, and any information related to such methodology provided to the other party by a party or its Affiliates from time to time (in whatever form), in each case relating to the design, Development, Manufacture, production or distribution of a Product, including any Improvements to such methodology.
NDA	means a New Drug Application filed with the FDA in the United States of America or a corresponding application filed with a Government Agency in any other country in the Territory, in each case together with all amendments and supplements thereto.
Net Revenue	means, with respect to a Product in a country or territory, the gross amount invoiced by ACADIA, ACADIA Affiliates and any Sub-Licensee to Third Parties, excluding any Sub-Licensee, for any sale or disposition of that Product in that country or territory (as applicable), less the following deductions to the extent that they are directly related and applicable to sales of the Product: (a) trade, quantity and cash discounts allowed; (b) commissions, discounts, refunds, rebates (including, but not limited to, wholesaler inventory management fees), chargebacks, retroactive price adjustments, and any other allowances which effectively reduce the net selling price; (c) actual Product returns and allowances; and (d) any tax imposed on the production, sale, delivery or use of that Product, including, without limitation, sales, use, excise or value added taxes provided that such tax is included in the gross invoiced amount and a bona fide deduction from gross invoiced sales in ACADIA's external reporting of sales of that Product under U.S. Generally Accepted Accounting Principles ("US GAAP"). Such amounts shall be determined from the books and records of ACADIA, ACADIA Affiliates and Sub-Licensees, maintained in accordance with US GAAP or, in the case of ACADIA Affiliates and Sub-Licensees, such similar accounting principles, consistently applied. ACADIA further agrees in determining such amounts, it will use ACADIA's then current standard procedures and methodology, including ACADIA's then current standard exchange rate methodology for the translation of foreign currency sales into U.S. Dollars or, in the case of ACADIA Affiliates and Sub-Licensees, such similar methodology, consistently applied.

	For the purposes of calculating Net Revenues, sales or dispositions of Products among ACADIA, ACADIA Affiliates and Sub-Licensees intended for resale shall be excluded from the calculation of Net Revenues, but rather the sale of such Products by ACADIA, ACADIA Affiliates and Sub-Licensees to Third Parties that are not Sub-Licensees shall be included in the calculation of Net Revenues. Net Revenues shall exclude sale or distribution of Products, at or below the Manufacturing Cost, for use for marketing, regulatory, development or charitable purposes, such as clinical trials, compassionate use, named patient use, or indigent patient programs. For Products which comprise a Compound and at least one other active ingredient, whether packaged together or in the same therapeutic formulation and in any dosage ("Combination Products"), the Net Revenues for such Combination Products shall be adjusted by multiplying the actual Net Revenues by the fraction A/(A+B) where A is the actual average of the invoice price (on a per unit basis) of the Product that is part of the Combination Product in the relevant country, if sold separately, and B is the sum of the actual average of the invoice price (on a per unit basis) of the other active component that is part of the Combination Product in the relevant country, if such other active component is sold separately. If the other component is not sold separately, then the actual Net Revenues shall be adjusted by multiplying the actual Net Revenues by the fraction A/C where A is the actual average of the invoice price (on a per unit basis) of the Product that is part of the Combination Product in the relevant country, if sold separately, and C is the actual average of the invoice prices (on a per unit basis) of the Combination Product in the relevant country. If neither of the foregoing applies, then ACADIA shall determine the Net Revenues of the Combination Product in good faith based on the respective values of the components of such Combination Product.
Neuren IP	means the Trofinetide IP and the NNZ-2591 IP.
New Indication	means an indication classified as a New Indication in accordance with clause 6.2(d), which has not ceased to be a New Indication in accordance with clause 6.2(e).
New Territory	means, subject to clause 23.2(d), the whole of the world excluding the Initial Territory.
NNZ-2591 Compound	means: (a) NNZ-2591, having the structure set forth in Part B of Exhibit A, including all salts, esters, mixtures, hydrates, isomers, solvates, complexes, isotopologs, polymorphs, resinates, metabolites, impurities, or degradation products of NNZ 2591; and (b) Each of the other compounds that fall within the scope of the formulae set forth in the specifications of the NNZ-2591 Patents, but excludes any Trofinetide Compound.
NNZ-2591 Field	means uses of the NNZ-2591 Compound or any NNZ-2591 Product solely in and for Rett Syndrome and Fragile X Syndrome and excludes any and all uses in and for any other indication.

NNZ-2591 IP	means all of the Intellectual Property Rights in or relating to the NNZ-2591 Compound or any NNZ-2591 Product owned or Controlled by Neuren or its Affiliates, including: (a) the Patents, (b) the Methodology, (c) the Know-how; and (d) any Improvements solely made or acquired by Neuren or its Affiliates during the Term, in or relating to the NNZ-2591 Compound or any NNZ-2591 Product.
NNZ-2591 Patents	means: (a) all patents, certificates of invention, applications for certificates of invention, priority patent filings and patent applications that are: (i) set out in Part B of the Schedule of Patents and Patent Applications; or (ii) that are filed in accordance with clause 20.3 (which will be added to such schedule) or otherwise added to such schedule by agreement in writing between the parties; and (b) any renewals, divisions, continuations (in whole or in part), or requests for continued examination of any of such patents, certificates of invention and patent applications, and any all patents or certificates of invention issuing thereon, and any and all reissues, reexaminations, extensions, divisions, renewals, substitutions, confirmations, registrations, revalidations, revisions, and additions of or to any of the foregoing.
NNZ-2591 Product	means any product developed by or on behalf of Neuren or ACADIA containing a NNZ-2591 Compound as an active ingredient, alone or in combination with one or more other active pharmaceutical ingredient(s), in any dosage form or formulation.
Patents	means the Trofinetide Patents and the NNZ-2591 Patents.
Phase II Clinical Study	means a clinical study for a Product in humans conducted to evaluate the efficacy of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug, as described in 21 C.F.R. §312.21(b) or the equivalent regulation outside the United States (and any amended or successor regulations).
Phase III Clinical Study	means a human clinical trial for a Product, the principal purpose of which is to gather safety and efficacy data of one or more particular doses in patients being studied that is needed to evaluate the overall benefit and risk relationship of the Product, as more fully defined in 21 C.F.R. §312.21(c) or the equivalent regulation outside the United States (and any amended or successor regulations), and is intended to support approval of an NDA and labeling (or marketing authorisation application).

Pre-Marketing	means all sales and marketing activities undertaken prior to and in preparation for the launch of a Product in the Territory. Pre-Marketing will include market research, key opinion leader development, advisory boards, medical education, disease-related public relations, health care economic studies, sales force training and other pre-launch activities prior to the First Commercial Sale of that Product in a given country or other regulatory jurisdiction in the Territory.
Prior Confidentiality Agreement	means the Confidentiality Deed between Neuren and ACADIA dated […***…].
Product	means any Trofinetide Product or NNZ 2591 Product.
Promotional Materials	means all written, printed, video or graphic advertising, promotional, educational and communication materials (other than any Product labels and package inserts) for marketing, advertising and promoting of the Compound or any Product.
Proposal	has the meaning given in clause 6.2(a).
Primary Party	has the meaning given in clause 20.1.
Quarter	means each period of three consecutive months ending on 31 March, 30 June, 30 September or 31 December in any year.
Region	means any of the Initial Territory or Region A, Region B or Region C as defined in the Fee Schedule.
Regulatory	means all activities regarding filing for, obtaining and maintaining any IND, NDA or Marketing Authorisation, including those described in clause 9, in support of Development and Commercialization activities.
Regulatory Authority	means the federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the testing, Manufacture, use, storage, import, promotion, marketing or sale of a Product in a country or jurisdiction, including, by way of example the FDA, the European Medicines Agency (EMA) and Japan's Pharmaceuticals and Medical Devices Agency (PMDA).
Royalty	means the royalty payable by ACADIA to Neuren in respect of Products sold by ACADIA, ACADIA's Affiliates and all Sub-Licensees as set forth in clause 15.3 and specified in clause 4 of the Fee Schedule.
Sales Milestone Fees	means the sales milestone fees specified in clause 3 of the Fee Schedule.
Secondary Party	has the meaning given in clause 20.1.
Sub-Licensee	means: (a) any Third Party that has received a sublicence from ACADIA or its Affiliates under the Neuren IP to use, sell, offer for sale or import any Product in the Field in the Territory pursuant to clause 14,

	beyond the mere right to purchase Products from or to provide services on behalf of ACADIA and its Affiliates; and (b) any Third Party appointed by ACADIA or its Affiliates to Manufacture any Compound or Product for ACADIA or its Affiliates.
Sub-Licensee Fee	means the fee specified in clause 5 of the Fee Schedule
Tax	means any tax, levy, impost, duty, charge, deduction, or withholding of whatever kind (together with any related interest, penalty, fine or expense) that is imposed by law or any Government Agency.
Term	has the meaning given to that term in clause 2.
Territory	means the Initial Territory and the New Territory. For clarity, the Territory with respect to Trofinetide Compounds and Trofinetide Products may be separate and distinct from the Territory with respect to NNZ-2591 Compounds and NNZ-2591 Products (i.e. in the event that a given territory is terminated only with respect to a Trofinetide Compound and Trofinetide Product, on the one hand, or a NNZ-2591 Compound and NNZ-2591 Product, on the other hand, and removed from such Territory as a result pursuant to clause 23.2(d)).
Third Party	means any person or entity other than ACADIA, Neuren or their respective Affiliates.
Trofinetide Compound	means: (a) Trofinetide, also known as NNZ-2566, having the structure set forth in Part A of Exhibit A, including all salts, esters, mixtures, hydrates, isomers, solvates, complexes, isotopologs, polymorphs, resinates, metabolites, impurities, or degradation products of trofinetide; and (b) Each of the other compounds that fall within the scope of the formulae set forth in the specifications of the Trofinetide Patents, excluding compounds within the scope of the claims of US patent numbers […***…].
Trofinetide Field	means any and all uses of the Trofinetide Compound or any Trofinetide Product, including in Rett Syndrome and Fragile X Syndrome
Trofinetide IP	means all of the Intellectual Property Rights in or relating to the Trofinetide Compound or any Trofinetide Product owned or Controlled by Neuren or its Affiliates, including: (a) the Patents, (b) the Methodology, (c) the Know-how; and (d) any Improvements solely made or acquired by Neuren or its Affiliates during the Term, in or relating to the Trofinetide Compound or any Trofinetide Product.

Trofinetide Patents	means: (a) all patents, certificates of invention, applications for certificates of invention, priority patent filings and patent applications that are: (i) set out in the Part A of the Schedule of Patents and Patent Applications; or (ii) that are filed in accordance with clause 20.3 (which will be added to such schedule) or otherwise added to such schedule by agreement in writing between the parties; and (b) any renewals, divisions, continuations (in whole or in part), or requests for continued examination of any of such patents, certificates of invention and patent applications, and any all patents or certificates of invention issuing thereon, and any and all reissues, reexaminations, extensions, divisions, renewals, substitutions, confirmations, registrations, revalidations, revisions, and additions of or to any of the foregoing.
Trofinetide Product	means any product developed by or on behalf of Neuren or ACADIA containing a Trofinetide Compound as an active ingredient, alone or in combination with one or more other active pharmaceutical ingredient(s), in any dosage form or formulation.
Upfront Fee	means the fee specified in clause 1 of the Fee Schedule.
U.S. or United States	means the United States of America and its territories and possessions.
Valid Claim	means a claim of an issued and unexpired Patent, to the extent such claim has not been revoked, held invalid or unenforceable by a patent office, court or other governmental agency of competent jurisdiction in a final order, from which no further appeal can be taken, and which claim has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer.

1.2 Words and expressions

In this Agreement, unless the context requires otherwise:

(a) the singular includes the plural and vice versa;

(b) words denoting any gender include all genders;

(c) where a word or phrase is defined, its other grammatical forms have a corresponding meaning;

(d) a reference to a party, clause, paragraph, schedule, or annexure is a reference to a party, clause or paragraph, schedule, or annexure to or of, this Agreement;

(e) a reference to this Agreement includes any schedules or annexures to it;

(f) headings are for convenience and do not affect interpretation;

(g) the background or recitals to this Agreement are adopted as and for part of this Agreement;

(h) a reference to any document or agreement includes a reference to that document or agreement as amended, novated, supplemented, varied or replaced from time to time;

(i) a reference to “$”, “US$”, “USD” or “dollar” is a reference to the currency of the United States;

(j) a reference to a party includes its executors, administrators, successors, substitutes (including persons taking by novation) and permitted assigns;

(k) a reference to writing includes any method of representing words, figures or symbols in a permanent and visible form;

(l) words and expressions denoting natural persons include bodies corporate, partnerships, associations, firms, governments and governmental authorities and agencies and vice versa;

(m) a reference to any legislation or to any provision of any legislation includes

(i) any modification or re-enactment of the legislation;

(ii) any legislative provision substituted for, and all legislation statutory instruments and regulations, issued under the legislation or provision; and

(iii) where relevant, corresponding legislation in any Australian State or Territory;

(n) no rule of construction applies to the disadvantage of a party because that party was responsible for the preparation of this Agreement or any part of it;

(o) the word “or” means “and/or” unless the context dictates otherwise because the subject of the conjunction are mutually exclusive; and

(p) the words “including”, “for example”, “such as” or other similar expressions (in any form) are not words of limitation.

2 Term

This Agreement will commence on the Commencement Date and will continue until terminated under clause 22 (or any other clause of this Agreement that gives a party a right to terminate) (“**Term**”).

3 Joint Venture

3.1 Establishment of JV

The parties agree to conduct a joint venture, as and from the Commencement Date:

(a) to commercialize and develop the Trofinetide Compound and Trofinetide Product within the Trofinetide Field and within the Territory; and

(b) to commercialize and develop the NNZ-2591 Compound and NNZ-2591 Product within the NNZ-2591 Field and within the Territory,

on the terms and conditions set out in this Agreement.

3.2 Contributions to JV

The parties acknowledge and agree that their respective contributions to the JV will be:

(a) in the case of Neuren, the grant of the licences to ACADIA in accordance with this Agreement for the purposes of the JV and the performance of its other obligations as set out in this Agreement; and

(b) in the case of ACADIA, the provision and application of its expertise and resources within the Territory in relation to the marketing of pharmaceutical products and the performance of its other obligations as set out in this Agreement.

3.3 Sharing of proceeds of JV

(a) In consideration for its participation in the JV and the grant of the licences to ACADIA in accordance with this Agreement, Neuren will be entitled to the Upfront Fee, Development Milestone Fees, Sales Milestone Fees, Sub-Licensee Fee and Royalty in accordance with this Agreement and any other exercise of its rights under this Agreement including by way of example proceeds relating to Manufacturing.

(b) In consideration for its participation in the JV, ACADIA will be entitled to the proceeds of Commercialization of any Compound or Product in the applicable Field in the Territory and any other exercise of its rights under this Agreement, including by way of example proceeds relating to Manufacturing and sublicensing activities.

4 Licences

4.1 Amendment and restatement of Trofinetide Licence

Neuren and its Affiliates hereby confirm and, to the extent not previously granted, grant to ACADIA, for the Term:

(a) an exclusive (even as to Neuren and its Affiliates) licence under the:

(i) Trofinetide IP; and

(ii) Neuren's rights (including any Intellectual Property Rights) in any Joint Improvements in so far as they relate to the Trofinetide Compound, Trofinetide Product or Trofinetide IP or Methodology in respect thereof,

solely to make or have made (both, for the avoidance of doubt, subject to Neuren's rights upon termination as set forth in clause 4.5), use, develop, sell, offer for sale, import, export and otherwise Commercialize, and including the right to Manufacture, have Manufactured, market, promote, advertise, and distribute, any Trofinetide Compound and any Trofinetide Product within the Trofinetide Field and within the Territory; and

(b) the right to grant sub-licences under the Neuren IP to Affiliates and Sub-Licensees in accordance with clause 14,

in accordance with the terms and conditions of this Agreement.

4.2 Grant of NNZ-2591 Licence

Neuren and its Affiliates hereby grant to ACADIA for the Term:

(a) an exclusive (even as to Neuren and its Affiliates) licence under the:

(i) NNZ-2591 IP; and

(ii) Neuren's rights (including any Intellectual Property Rights) in any Joint Improvements in so far as they relate to the NNZ-2591 Compound, NNZ-2591 Product or NNZ-2591 IP or Methodology in respect thereof,

solely to make or have made (both, for the avoidance of doubt, subject to Neuren's reserved rights and/or rights upon termination as set forth in clause 4.5), use, develop, sell, offer for sale, import, export and otherwise Commercialize, and including the right to Manufacture or have Manufactured (both subject to clause 7.2), market, promote, advertise, and distribute, any NNZ-2591 Compound and any NNZ-2591 Product within the NNZ-2591 Field and within the Territory; and

(b) the right to grant sub-licences under the Neuren IP to Affiliates and Sub-Licensees in accordance with clause 14,

in accordance with the terms and conditions of this Agreement.

4.3 Rights personal to ACADIA

Subject to clauses 14 and 29.5, the rights given by this Agreement are personal to ACADIA and are not saleable or transferable in any manner whatsoever except in accordance with this Agreement and ACADIA must not in any way encumber, mortgage or grant rights under this Agreement to any other person except in accordance with this Agreement, and any attempt to do so that is not in accordance with this Agreement will be void.

4.4 Section 365(n) of the Bankruptcy Code

All rights and licences granted under or pursuant to any clause of this Agreement, including the licences granted under this clause 4 are and will otherwise be deemed to be for purposes of Section 365(n) of the United States Bankruptcy Code (Title 11, U.S. Code), as amended (the "**Bankruptcy Code**"), licences of rights to "intellectual property" as defined in Section 101(35A) of the Bankruptcy Code. ACADIA will retain and may fully exercise all of its respective rights and elections under the Bankruptcy Code. Neuren agrees that ACADIA, as licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the Bankruptcy Code or any other provisions of applicable law outside the United States that provide similar protection for "intellectual property." Any agreements supplemental hereto will be deemed to be "agreements supplementary to" this Agreement for purposes of Section 365(n) of the Bankruptcy Code. Notwithstanding clause 29.14, intellectual property rights as set out in this clause 4.4 shall be dealt with in bankruptcy in accordance with US bankruptcy law.

4.5 Manufacturing rights

(a) Neuren reserves the non-exclusive right under the Neuren IP to Manufacture (or have Manufactured) any NNZ-2591 Compound or NNZ-2591 Product inside the Territory (and, to the extent applicable, to import, export, transport, obtain customs clearance, warehouse, invoice, handle and deliver), but solely where such NNZ-2591 Compound or NNZ-2591 Product is not sold, transferred, otherwise disposed of, used or supplied for use within the NNZ-2591 Field; provided that in the event of termination of this Agreement in a given territory with respect to a given NNZ-2591 Compound or NNZ-2591 Product, then upon such termination, Neuren may Manufacture (or have Manufactured) (and, to the extent applicable, to import, export, transport, obtain customs clearance, warehouse, invoice, handle and deliver) such NNZ-2591 Compound or NNZ-2591 Product inside the Territory only for use or sale within or outside of the NNZ-2591 Field in such terminated territory.

(b) With respect to a given Trofinetide Compound or Trofinetide Product, upon termination of this Agreement in a given territory with respect to such Trofinetide Compound or Trofinetide Product, Neuren shall have the right to Manufacture (or have Manufactured) such Trofinetide Compound or Trofinetide Product inside the Territory (and, to the extent applicable, to import, export, transport, obtain customs clearance, warehouse, invoice, handle and deliver), only for use or sale of such Trofinetide Compound or Trofinetide Product in such terminated territory.

4.6 No Implied Licence

No right or licence under any intellectual property rights of a party is granted or shall be granted by implication to the other party. All such rights or licences are or shall be granted only as expressly provided in the terms of this Agreement.

4.7 Failure to Develop or Commercialize

(a) If, in any Region, ACADIA ceases, for a period of at least […***…] at any time after the Relevant Date, all activities, in each case in relation to the Trofinetide Product in Rett Syndrome, and provided that such cessation was not:

(i) directly attributable to circumstances outside the reasonable control of ACADIA (including delays due to regulatory or legal reasons); or

(ii) due to ACADIA's determination not to conduct activities in the applicable Region during that […***…] period for a commercially reasonable reason (after giving effect to all applicable factors such as commercially reasonable sequencing of activities across Regions, issues affecting pricing and reimbursement, and having clearly communicated these reasons to Neuren),

Neuren may give notice in writing to ACADIA requiring ACADIA to provide a written report within […***…] of receipt of such notice detailing the steps and activities currently being undertaken and that ACADIA plans to undertake within the following […***…]. The Relevant Date will be:

(iii) with respect to the Initial Territory, following receipt of Marketing Authorisation and applicable regulatory approvals, the date on which any of the following events occurs:

(A) a Change of Control of ACADIA;

(B) ACADIA publicly discloses that it has abandoned Development and Commercialization of Trofinetide Compound or Trofinetide Product; or

(C) ACADIA reports holding "cash and cash equivalents" and "investment securities available for sale" of less than US$[…***…] in the aggregate in its most recent consolidated balance sheet filed with the U.S. Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended;

(iv) with respect to […***…], the […***…];

(v) with respect to […***…], the […***…]; and

(vi) for any territory in […***…], […***…].

(b) If ACADIA:

(i) fails to provide the required report in the applicable timeframe; or

(ii) does not use Commercially Reasonable Efforts to undertake the steps or activities set forth in the report during the subsequent […***…] period,

then

(iii) if the cessation of activities occurs with respect to the Initial Territory, Neuren may terminate this Agreement in accordance with clause 22.1, or

(iv) if the cessation of activities occurs with respect to any part of the New Territory, at the request of Neuren, ACADIA will discuss with Neuren in good faith the circumstances affecting commercially reasonable development and Commercialization of the Trofinetide Product in Rett Syndrome in the applicable Region, including the possibility of seeking Sub-Licensees for the applicable Region. For the avoidance of doubt, except in relation to the Initial Territory, nothing in this clause 4.7 will create any diligence obligation beyond the obligations to use Commercially Reasonable Efforts in the applicable Region as required by this Agreement.

4.8 Technology Transfer and Cooperation for NNZ-2591 (Non-Manufacturing)

Within […***…] from the Commencement Date, Neuren will complete transfer of all Know-how, Methodology, materials, regulatory filings and associated documentation and other correspondence with Regulatory Authorities and other Intellectual Property Rights to ACADIA necessary or reasonably useful to enable ACADIA to practice the licences and rights granted to it under this Agreement with respect to NNZ-2591 other than with respect to Manufacturing or any in-progress Intellectual Property Rights. Any in-progress Intellectual Property Rights will only be transferred once they have been completed. From time to time thereafter, or upon ACADIA's

reasonable request during the Term, Neuren shall provide reasonable cooperation to ACADIA with respect to the conduct of the activities pursuant to this Agreement.

5 Joint Steering Committee

5.1 Establishment and function

(a) The parties confirm that the Joint Steering Committee established under the Initial Licence will be and become the Joint Steering Committee under this Agreement ("**JSC**").

(b) Each party will retain the rights, powers and discretion granted to it under this Agreement and no such rights, powers or discretion will be delegated or vested in the JSC unless such delegation or vesting of rights is expressly provided for in this Agreement or the parties expressly agree to such delegation or vesting of rights in writing.

(c) The JSC will only have the powers expressly assigned to the JSC by this Agreement, and will not have any power to amend, modify or waive compliance with this Agreement.

(d) Without limiting clause 5.1(c), and except as otherwise provided in clause 5.1(e)(iii) and clause 5.6, the JSC's powers in respect of NNZ-2591 Compound or NNZ-2591 Product will only be in respect of any activities related solely to NNZ-2591 Compound or NNZ-2591 Product in the NNZ-2591 Field in the applicable Territory and the JSC will not have any power over any activities in respect of NNZ-2591 Compound or NNZ-2591 Product which do not relate solely to the NNZ-2591 Field in the applicable Territory.

(e) The JSC will perform the following functions:

(i) acting as the governing body of the JV;

(ii) remaining informed of the development and contents of all material regulatory submissions to Government Agencies for any Compound or Product in the applicable Field and Territory for Marketing Authorisations and all necessary filing and registration activities related to Marketing Authorisations for any Compound or Product in the applicable Field and applicable Territory;

(iii) subject to the information-sharing obligations set forth in clause 5.6, serve as a forum for consideration of and exchanging data and results generated by each party relating to any NNZ-2591 Compound or NNZ-2591 Product in and outside the applicable Field and applicable Territory;

(iv) review the development plans prepared by ACADIA in accordance with clause 6.1(b) and any updates to them;

(v) review and approve (if appropriate) any Proposal to develop the Trofinetide Compound for use in an indication other than Rett Syndrome and Fragile X Syndrome in accordance with clause 6.2;

(vi) subject to the information-sharing obligations set forth in clause 5.6 and clause 7.2, responsibility for monitoring and reviewing each party's Regulatory, manufacturing, CMC, Development or Commercialization activities in respect of any NNZ-2591 Compound or NNZ-2591 Product to the extent they relate to the NNZ-2591 Field in the applicable Territory;

(vii) subject to the information-sharing obligations set forth in clause 5.6 and clause 7.2, provide development, review and oversight of each party's CMC and non-indication specific clinical and non-clinical studies for NNZ-2591 Compound or NNZ-2591 Product to the extent they relate to the NNZ-2591 Field in the applicable Territory;

(viii) inform and raise for discussion and consideration all material activities or decisions with respect to any Compound or Product in the applicable Field (e.g.,

initiation or termination of any study and material filings with regulatory authorities);

(ix) review, comment on and approve any proposed scientific or academic publication by either party pursuant to the procedures in clause 18.11(a); and

(x) such other responsibilities as may be assigned to the JSC pursuant to this Agreement or as may be mutually agreed upon in writing by the parties from time to time.

5.2 Membership

(a) Neuren and ACADIA will each designate […***…] representatives (or any other number agreed in writing between the parties) of appropriate seniority, expertise and experience to serve on the JSC by written notice to the other party, such representatives to include individuals who have clinical trial and regulatory experience and expertise in pharmaceutical drug Development. The representatives of the JSC as at the Commencement Date will continue as the designated representatives for the parties, subject to clause 5.2(b).

(b) Either party may designate in writing substitutes for its representatives if one or more of such party's designated representatives are unable to be present at a meeting, provided such substitutes have the appropriate seniority and experience. From time to time each party may replace its representatives by written notice to the other party specifying the prior representative(s) and their replacement(s), provided such replacements have the appropriate seniority and experience.

5.3 Meetings

(a) Meetings of the JSC will commence at a time to be mutually agreed upon by the parties but in any event the JSC will meet at least once every Quarter during such time as Development of a Compound or Product is ongoing, and in any case more or less frequently as ACADIA and Neuren deem appropriate or as reasonably requested by either such party, by means of teleconference, video conference, or in person as deemed necessary or appropriate. Upon completion or termination of all Development activities in respect of the Compounds and Products, as mutually agreed upon by the parties, the JSC shall meet on an ad hoc or as reasonably requested by a party basis, but in any event […***…] every calendar year.

(b) ACADIA and Neuren may each, on advance notice to the other party, invite non-member employees of such party or third party contractors of either of the parties to attend meetings of the JSC, provided that such non-member employees and third party contractors cannot take part in the decision making process and shall be subject to confidentiality obligations consistent with those set forth in clause 18.

5.4 Decision making process

(a) The JSC may make decisions with respect to any subject matter that is subject to the JSC's decision-making authority and functions as set out in this clause 5.4.

(b) All decisions of the JSC will be made by unanimous vote or written consent, with ACADIA and Neuren each having collectively, among its respective members, one vote in all decisions.

(c) The JSC will use Commercially Reasonable Efforts to resolve the matters within its roles and functions or otherwise referred to it.

(d) If the JSC cannot reach consensus on a matter within […***…] Business Days after such matter has been brought to the JSC's attention, then such matter shall be first referred to the chief executive officers of the parties ("**CEOs**").

(e) The CEOs will use Commercially Reasonable Efforts to reach mutually acceptable resolutions on all such disputed matters.

(f) If the CEOs are unable to resolve such dispute within […***…] Business Days after the dispute is first referred to them, the matter will be resolved as follows:

(i) if the dispute relates to any Regulatory, Manufacturing, CMC, Development, or Commercialisation activities for any Trofinetide Compound or Trofinetide Product in the Territory, including the approval of a Proposal for a New Indication pursuant to clause 6.2, then ACADIA will have the final decision-making authority;

(ii) except for matters subject to clause 7.2(a)(ii), which will be governed by the process set forth therein, if the dispute relates to any Regulatory, Manufacturing (subject to clause 7.2(a)(ii)), CMC (subject to clause 7.2(a)(ii)), Development, or Commercialisation activities for any NNZ-2591 Compound or NNZ-2591 Product in the Territory:

(A) ACADIA will have the final decision-making authority with respect to matters that solely relate to uses of NNZ-2591 Compound or NNZ 2591 Product in the NNZ-2591 Field in the Territory; provided that ACADIA uses Commercially Reasonable Efforts to refrain from any activities that would be reasonably likely to materially adversely impact the Development and Commercialization of NNZ-2591 Compounds or NNZ-2591 Products outside of the NNZ-2591 Field; and

(B) Neuren will have the final decision-making authority with respect to all other uses of NNZ-2591 Compound or NNZ-2591 Product including uses of NNZ-2591 Compound or NNZ-2591 Product outside of the NNZ-2591 Field or that relate to uses of NNZ-2591 Compound or NNZ-2591 Product both within and without the NNZ-2591 Field,

except for matters subject to clause 7.2(a)(ii), which will be governed by the process set forth therein.

(iii) if the dispute relates to:

(A) approval of a publication or presentation pursuant to clause 18.11; or

(B) any other decision assigned to the JSC pursuant to this Agreement or as agreed upon in writing by the parties that specifically provides for dispute resolution pursuant to this clause 5.4(f)(iii), the dispute resolution procedure set out in clause 28.4 will apply.

(g) For clarity, matters relating to the conduct of Development activities relating to the Manufacture of NNZ-2591 Compound or NNZ-2591 Product or non-indication specific clinical or non-clinical studies for NNZ-2591 Compound or NNZ-2591 Product shall be governed by clause 7.2(a)(ii) and not at the JSC.

(h) Notwithstanding clause 5.4(f), neither party will exercise its right to finally resolve a dispute under this Agreement in a manner that excuses such party from any of its obligations specifically enumerated under this Agreement or in a manner that negates any consent rights or other rights specifically allocated to the other party under this Agreement. In addition, in resolving a dispute under this Agreement, each party agrees to act in good faith.

5.5 Alliance Managers

(a) Promptly following the Commencement Date, each party must designate an individual to serve as the main point of contact for each party to exchange information, facilitate communication and coordinate the parties' Development, Regulatory, Manufacturing and CMC activities relating to any Compound and Product and to provide day-to-day support to the JSC (each, an "**Alliance Manager**").

(b) Each Alliance Manager must be experienced in project management and have appropriate experience in the pharmaceutical industry.

(c) The Alliance Managers may attend all meetings between the parties, including all JSC meetings, and, if applicable, must work together to resolve any deadlock between the parties in accordance with the procedures set out in this Agreement.

(d) Each party may change its designated Alliance Manager from time to time upon written notice to the other party, provided that such replacement has the appropriate expertise and experience.

5.6 Exchange of Information

(a) Subject to clause 5.6(b), each party shall keep the other party informed as to its material progress and activities relating to the Development of any Compound and Product, including by promptly sharing data and results generated or related to any Compound and Product, inside and outside the applicable Field, and information with respect to Regulatory matters and meetings with Government Agencies (collectively "**Program Information**"), by way of updates to the JSC at its meetings or to the other party if the JSC is disbanded and as otherwise specified in this Agreement, or as reasonably requested from time to time by the other party.

(b) Notwithstanding any other provision of this Agreement (including clause 5.6(a)), but without limiting the scope of the licences granted to ACADIA pursuant to this Agreement, the Program Information required to be provided by either party (**Sharing Party**) to the other party (**Receiving Party**):

(i) in the case of ACADIA as the Sharing Party, with respect to a Compound or Product; and

(ii) in the case of Neuren as the Sharing Party, with respect to a NNZ-2591 Compound or NNZ-2591 Product,

will be limited to information:

(iii) relating to safety or toxicity data or results, including, without limitation, clinical and non-clinical safety or toxicity data, CMC information related to safety, or otherwise;

(iv) that has been publicly disclosed by the Sharing Party;

(v) that is non-indication specific or related to CMC, as provided in clause 7.2;

(vi) that is necessary or reasonably useful for any Regulatory filing, Regulatory approvals or any Regulatory communications to be made or applied for by the Receiving Party and either:

(A) relates to activities completed by the Sharing Party, including, without limitation, pre-clinical and clinical data; or

(B) is included in any Regulatory filings, Regulatory approvals or any Regulatory communications by the Sharing Party with Regulatory Authorities;

(vii) relating to any matter expressly provided elsewhere in this Agreement, including clauses 8, 9, 20 and 23, which is not expressly stated to be subject to this clause 5.6; and

neither party will be required to disclose, and the party may redact from any information provided, any information with respect to a Compound or Product:

(viii) that is incomplete or relates to any incomplete study or trial; provided, that this limit shall not apply to any information described in clause 5.6(b)(iii), and provided further, that if a study progressed but was halted, and the incomplete

information could still provide interpretable conclusions, this shall not be limited by this clause; or

(ix) relating to prospective or proposed activities to be undertaken by or on behalf of the party.

(c) If a Receiving Party reasonably believes that the other party has failed to disclose information of the kind referred to in clauses 5.6(b)(iii), 5.6(b)(iv), 5.6(b)(v), 5.6(b)(vi) or 5.6(b)(vii), the Receiving Party may request the Sharing Party provide the relevant information by providing a description of the information and, in the case of clause 5.6(b)(vi) details of why the information is necessary or reasonably useful for that Regulatory filing, Regulatory approval or Regulatory documentation. The Sharing Party will consider such request in good faith and respond within […***…] Business Days of the request either by providing the information requested or providing details of the reasons for not doing so. If a dispute remains as to the provision of the information requested, it will be referred to the CEOs of the parties who will use Commercially Reasonable Efforts to reach mutually acceptable resolution on all such disputed matters within […***…] Business Days after the dispute is first resolved to them. If the CEOs are unable to resolve such dispute within […***…] Business Days after the dispute is first referred to them, the matter may be referred to arbitration for final resolution in accordance with clause 28.4.

5.7 CMC

Neuren and ACADIA acknowledge and agree that:

(a) ACADIA shall conduct and be responsible for all Manufacturing and CMC activities for any Trofinetide Compound and Trofinetide Product in the Trofinetide Field in the Territory and the day-to-day operations and decision-making for such manufacturing and CMC activities;

(b) subject to clause 7.2, Neuren and ACADIA shall coordinate with respect to the conduct of all Manufacturing and CMC activities for any NNZ-2591 Compound and NNZ-2591 Product, whether for use inside or outside the NNZ-2591 Field in the Territory; and

(c) as requested by the JSC, each party shall from time to time update the JSC with its progress in such Manufacturing and CMC activities for any Compound or Product for which it is responsible.

6 Trofinetide

6.1 Development Activities

(a) Following the Commencement Date, ACADIA shall be responsible for and conduct all development activities with respect to any Trofinetide Compound and any Trofinetide Product.

(b) Within […***…] of the Commencement Date, ACADIA will provide Neuren, through the JSC, with ACADIA's high-level non-binding development plans for the Trofinetide Product in Rett Syndrome in each of:

(i) Japan;

(ii) Australia; and

(iii) the United Kingdom, France, Italy, Germany and Spain.

ACADIA will update the plans, through the JSC, from time to time and when any material amendments occur.

(c) ACADIA will use Commercially Reasonable Efforts to achieve Marketing Authorisations for the Trofinetide Product in Rett Syndrome in those parts of the Territory referred to in clause 6.1(b).

(d) ACADIA will be responsible, at its sole cost and expense, for the day-to day operations and decision making for all development activities under the development plans or otherwise with respect to the Trofinetide Compound and Trofinetide Product in the Trofinetide Field in the Territory.

(e) ACADIA will be the sponsor and owner of all Marketing Authorisations for the Trofinetide Product in the Trofinetide Field in the Territory.

(f) ACADIA will conduct, and be responsible for all costs associated with, any clinical and non-clinical development and registration of any Trofinetide Compound or Trofinetide Product in the Trofinetide Field in the Territory, including securing the necessary Trofinetide Compound and Trofinetide Product.

6.2 New Indication

(a) ACADIA must inform and seek the approval of the JSC for any proposal to undertake development or Commercialization activities in the Territory with respect to any Trofinetide Compound or Trofinetide Product in an indication other than Rett Syndrome or Fragile X Syndrome (**Proposal**).

(b) The JSC will review the Proposal in detail and assess the potential studies and development activities in respect of the use of a Trofinetide Compound or Trofinetide Product in that new indication to identify a basis for proceeding, taking into consideration the commercial, scientific and clinical potential for such proposed development activities in relation to that new indication.

(c) If the JSC approves the Proposal, ACADIA may commence the activities in accordance with the Proposal and must keep the JSC informed of the progress of the development activities.

(d) On receipt by JSC of evidence of the commencement in the Initial Territory of clinical development, of which ACADIA is the sponsor, of the Trofinetide Compound in accordance with the Proposal, the relevant new indication, if it is not:

(i) Phelan-McDermid Syndrome, Pitt Hopkins Syndrome, Angelman Syndrome or Prader-Willi Syndrome, or

(ii) an indication for which NNZ -2591 Compound or NNZ-2591 Product has already received Marketing Authorisation in the Initial Territory,

will be classified as a **New Indication** for Trofinetide in the Initial Territory.

(e) If ACADIA ceases clinical development, of which ACADIA is the sponsor, of the Trofinetide Compound for the New Indication in the Initial Territory, ACADIA must notify the JSC and the relevant indication will cease to be a New Indication. If ACADIA has ceased that clinical development in the Initial Territory but fails to notify the JSC, Neuren may notify the JSC and unless ACADIA provides reasonable evidence to the JSC that it is still continuing that clinical development in the Initial Territory, the relevant indication will cease to be a New Indication.

7 NNZ-2591

7.1 Development Activities – NNZ-2591

(a) Following the Commencement Date, Neuren and ACADIA will work together in good faith to facilitate efficient and timely development of NNZ-2591 Compound and NNZ-2591 Product, in the case of ACADIA, in the NNZ 2591 Field and in the Territory and in the case of Neuren, outside the NNZ-2591 Field in the Territory (**Neuren's Indications**),

including Manufacturing activities and non-indication specific clinical and non-clinical studies.

(b) Any meetings and exchange of information shall be conducted through the JSC or if required more frequently than the JSC meets, through the parties' respective development teams.

(c) ACADIA will be responsible, at its sole cost and expense, for the Development and Commercialization of the NNZ-2591 Compound and NNZ-2591 Product in the NNZ-2591 Field in the Territory.

(d) ACADIA will be the sponsor and owner of all Marketing Authorisations for the NNZ-2591 Product in the NNZ-2591 Field in the Territory.

(e) Without limiting clause 7.1(c), ACADIA will conduct, and be responsible for all costs associated with, any clinical and non-clinical development and registration of any NNZ-2591 Compound or NNZ-2591 Product in the NNZ-2591 Field in the Territory, including securing the necessary NNZ-2591 Compound and NNZ-2591 Product.

(f) Subject to clause 7.2, ACADIA will have the right to Manufacture, or have Manufactured, NNZ-2591 for use in the NNZ 2591 Field in the Territory.

7.2 Manufacturing and non-indication specific studies – NNZ-2591

(a) While either party is conducting Development activities in respect of NNZ-2591 Compound or NNZ-2591 Product:

(i) ACADIA's rights in relation to NNZ-2591 Compound and NNZ-2591 Product are subject to an obligation to not materially adversely impact Neuren's ongoing Development activities, including activities in respect of Manufacture and non-indication specific clinical and non-clinical studies for NNZ-2591 Compound and NNZ-2591 Product;

(ii) In the event that ACADIA desires to conduct any Development activities relating to the Manufacture of NNZ-2591 Compound or NNZ-2591 Product or non-indication specific clinical or non-clinical studies for NNZ-2591 Compound or NNZ-2591 Product, it will notify Neuren of such proposed activities and provide reasonable details of the proposed activities. In the event that Neuren is actively conducting Development of NNZ-2591 Compound or NNZ-2591 Product, Acadia must seek and obtain Neuren's consent before carrying out any development work on Manufacturing and non-indication specific clinical and non-clinical studies of NNZ-2591 Compound or NNZ-2591 Product. Neuren's consent may only be withheld in the event that Neuren has a reasonable basis to believe that such proposed Development activities of Acadia would have a material adverse impact on Neuren's ongoing Development (an "**Adverse Impact**"). In the event Neuren withholds consent, it will promptly provide a reasonably detailed explanation to ACADIA as to the basis for its belief that ACADIA's proposed work would have an Adverse Impact.

(iii) Prior to filing for any patent in respect of the Manufacturing of NNZ-2591, ACADIA must notify Neuren and provide to Neuren a copy of the proposed application at least […***…] days prior to the application being filed. If Neuren reasonably believes that the patent application will have an Adverse Impact, Neuren may object to the proposed patent application by notice to ACADIA. If Neuren objects to the proposed patent application prior to the end of the […***…] day period, it will promptly provide a reasonably detailed explanation as to how it believes Acadia's proposed application would have an Adverse Impact on Neuren's Development activities, and the parties will meet to discuss the proposed patent application and effect on Neuren's Development activities. If the parties cannot agree a way in which to overcome Neuren's reasonable concerns (such as an amendment to the proposed application or a deferral in lodging the

application), the matter will be dealt with by the JSC under clause 5.4 and ACADIA will not file the proposed patent application until the dispute is resolved.

(b) If, at any time after the Commencement Date, ACADIA elects to use Neuren as a supplier, ACADIA may present a Development plan to the JSC in respect of NNZ-2591, including the quantities of NNZ-2591 Compound and NNZ-2591 Product required for that Development plan and the desired timing for receipt of those quantities. Within […***…] days after a request by ACADIA, Neuren will provide ACADIA with a quote to supply the NNZ-2591 Compound or NNZ-2591 Product to meet the requirement of the Development plan. The transfer price for all NNZ-2591 Compound or NNZ-2591 Product supplied by Neuren to ACADIA will be equal to Neuren's Manufacturing Cost. If ACADIA accepts the quote, the quote will become irrevocable and ACADIA will pay to Neuren the full amount of the quote, which will be non-refundable. Promptly after receiving ACADIA's payment of the full amount of the quote, Neuren will place an order with its suppliers for the quantities of NNZ-2591 Compound or NNZ-2591 Product as requested by ACADIA. If the requested quantity or timing cannot be achieved by Neuren's suppliers, the parties will discuss in good faith the optimum alternative.

(c) After ACADIA's IND application (or its foreign equivalent) for NNZ-2591 in Rett Syndrome or Fragile X Syndrome has been accepted by the applicable Regulatory Authority (including by expiration of any applicable waiting period), the parties will discuss whether ACADIA will use the same manufacturer as Neuren then uses for the Manufacture of NNZ-2591 Compound or NNZ-2591 Product.

(d) If ACADIA elects to use the same manufacturer, the allocation of supply will prioritise Neuren's Development and Commercialization of NNZ-2591 Compound or NNZ-2591 Product outside the NNZ-2591 Field.

(e) If ACADIA elects to use a different manufacturer to Neuren for the Manufacture of NNZ-2591 Compound or NNZ-2591 Product:

(i) ACADIA may request that Neuren transfers all Know-how, Methodology, materials and other Intellectual Property Rights to ACADIA necessary or reasonably useful to enable ACADIA to commence the Manufacture of NNZ-2591 Compound or NNZ-2591 Product. Neuren will complete the technology transfer promptly following such request. Any in-progress Improvements will only be transferred once they have been completed. ACADIA will reimburse to Neuren all reasonable costs and expenses incurred by or on behalf of Neuren in completing the technology transfer;

(ii) Acadia will have the right and licence to have Manufactured NNZ-2591 Compound or NNZ-2591 Product prior to such technology transfer as needed to support Development activities for its indications, subject to conditions described herein including Neuren's consent pursuant to clause 7.2(a)(ii); and

(iii) Neuren may and has the right to, but is not required to, use the same manufacturer to Manufacture NNZ-2591 Compound or NNZ-2591 Product and if it does so, the allocation of supply from that manufacturer will prioritise ACADIA's Development and Commercialization of NNZ-2591 Compound or NNZ-2591 Product in the NNZ-2591 Field.

(f) In addition to the JSC meetings relating to NNZ-2591 Compound or NNZ-2591 Product, at least once per Quarter, the parties agree, subject to clause 5.6, to share and discuss CMC related matters in connection with NNZ-2591 Compound or NNZ-2591 Product inside and outside of the NNZ-2591 Field.

(g) If ACADIA has developed a different Manufacturing process for NNZ-2591 Compound or NNZ-2591 Product, Neuren may:

(i) request that ACADIA transfer all Know-how, Methodology, materials and other Intellectual Property Rights to Neuren necessary or reasonably useful to enable

Neuren to commence the Manufacture of NNZ-2591 Compound or NNZ-2591 Product using that different process. ACADIA will complete the technology transfer promptly following such request. Neuren will reimburse to ACADIA all reasonable costs and expenses incurred by or on behalf of ACADIA in completing the technology transfer; or

(ii) source NNZ-2591 Compound or NNZ-2591 Product from ACADIA at ACADIA's Manufacturing Cost.

(h) In relation to the Manufacturing of NNZ-2591 Compound and NNZ-2591 Product:

(i) the parties will discuss in good faith alternatives for the optimum specifications, including specifications relating to impurities and excipients;

(ii) ACADIA will use Commercially Reasonable Efforts to Manufacture NNZ-2591 Compound API to the same specifications as Neuren and not deviate materially from those specifications without Neuren's prior consent, not to be unreasonably withheld; and

(iii) each party will comply with all applicable laws, including applicable cGMP requirements.

(i) Upon the other party's reasonable request during the Term, each party shall provide reasonable cooperation to the other party with respect to the conduct of the Manufacturing activities in respect of NNZ-2591 Compound or NNZ-2591 Product, including:

(i) the transfer of any additional Know-how, Methodology, materials and other Intellectual Property Rights that are Controlled by such party to the other party to the extent necessary or reasonably useful to enable such other party to practice the licences and rights granted to such other party under this Agreement; and

(ii) providing the other party with technical assistance through personnel familiar with the NNZ-2591 Compound or NNZ-2591 Product to enable the Development and Commercialization of the NNZ-2591 Compound and NNZ-2591 Product, including any CMC and Methodology expertise in connection therewith, at the requesting party's cost.

The parties will agree in good faith and undertake the actions reasonably required to ensure that those ongoing Development or CMC activities may continue after the Commencement Date without interruption.

8 FDA and other Approvals

8.1 Regulatory Approvals

(a) ACADIA will be responsible for all costs associated with any clinical and non-clinical development of any Compound or Product in the applicable Field in the Territory, including any Phase II Clinical Studies, Phase III Clinical Studies and post-marketing studies that are required by the Regulatory Authority as a condition of granting the Marketing Authorisation or that are otherwise required by ACADIA. ACADIA will be responsible for conducting, at its own cost, any additional studies required to gain approval outside of the United States but in the Territory as determined solely at ACADIA's discretion.

(b) ACADIA will be responsible for obtaining all necessary approvals to Commercialize any Product in the applicable Field from the Regulatory Authority. With respect to NNZ-2591 Product:

(i) ACADIA will procure that, unless the urgency of the matter reasonably precludes it from providing Neuren with an opportunity to review and/or comment on

responses and submissions made or to be made to a Regulatory Authority, ACADIA will not respond to a Regulatory Authority or otherwise make any submissions to a Regulatory Authority without giving Neuren a reasonable opportunity (not exceeding […***…] Business Days) to review and comment on the response and/or submission; and

(ii) Neuren will procure that, ACADIA will be provided copies or parts of any such response and/or submission to the extent they relate solely to the NNZ-2591 Field or are non-indication specific or relate to CMC.

For the avoidance of doubt, ACADIA will have final decision-making authority with respect to such submissions in the NNZ-2591 Field and Neuren will have final decision-making authority with respect to such submissions outside of the NNZ-2591 Field.

(c) Neuren representatives shall be entitled to attend all meetings with the Regulatory Authority with respect to obtaining necessary approvals from the Regulatory Authority to Commercialize any NNZ-2591 Product in the NNZ-2591 Field. The JSC will endorse attendee number and type based on meeting objective needs.

(d) All Third Party charges for obtaining any necessary Marketing Authorisation for any NNZ-2591 Product in the NNZ-2591 Field will be paid by ACADIA. All Third Party charges for obtaining any necessary Marketing Authorisation for any NNZ-2591 Product outside the NNZ-2591 Field will be paid by Neuren.

(e) For countries in the Territory:

(i) ACADIA will be responsible for the preparation and filing of, all required applications for Marketing Authorisations for any NNZ-2591 Product in the NNZ-2591 Field; and

(ii) Neuren will be responsible for the preparation and filing of, all required applications for Marketing Authorisations for any NNZ-2591 Product outside the NNZ-2591 Field.

(f) ACADIA will be the holder and own all right, title and interest in and to all the Marketing Authorisations for any NNZ-2591 Product in the NNZ-2591 Field, subject to clause 23.3(a)(i). Neuren will be the holder and own all right, title and interest in and to all the Marketing Authorisations for any NNZ-2591 Product outside the NNZ-2591 Field.

8.2 Rights to Data

Each party grants to the other party a royalty free, fully paid-up, irrevocable and non-exclusive licence to the data generated from the Development of any Compound and any Product for Rett Syndrome, Fragile X Syndrome or any other application to the extent required by the other party for the Development or commercial exploitation (including sub-licensing) of any Compound or Product by ACADIA in the applicable Field in the applicable Territory or by Neuren outside the applicable Field or outside the applicable Territory; provided that with respect to such rights granted to Neuren with respect to Trofinetide Compounds or Trofinetide Products, such rights shall only be effective upon termination of this Agreement in a given territory with respect to a given Trofinetide Compound or Trofinetide Product, and upon such termination, for use of such Trofinetide Compound or Trofinetide Product in or for use in such terminated territory. In the case of the licence granted by Neuren to ACADIA, the licence will continue for the Term and in the case of the licence granted by ACADIA to Neuren, the licence will be perpetual with respect to the Compound and Product outside the applicable Field or outside the Territory.

9 Regulatory Compliance

(a) ACADIA must not market, distribute or sell any Product in any part of the Territory unless ACADIA has a Marketing Authorisation (if required by a Government Agency) for that Product in the applicable Field in that part of the Territory.

(b) ACADIA will be responsible for keeping itself informed about and complying with any relevant regulations and laws or agreements applying to the Manufacturing, labelling, storage, distribution, marketing, promotion and sale of any Compound or any Product in all parts of the applicable Field and Territory.

(c) ACADIA agrees, at its sole cost and expense, to use Commercially Reasonable Efforts to maintain all Marketing Authorisations (following receipt) throughout the Term in the Initial Territory and each of the countries set out in clause 6.1(b), including all supplemental applications, annual reports, variations or renewals thereof.

(d) ACADIA shall, at its sole cost and expense, be responsible for all post-Marketing Authorisation approval reporting of Adverse Drug Events (ADEs) and post-marketing Product surveillance in the applicable Field in the Territory, if and as required by Government Agencies in the Territory. The parties acknowledge that Neuren has provided ACADIA with a listing of all safety reports obtained by Neuren prior to the Commencement Date in respect of the Trofinetide Compound from clinical development and serious adverse event (SAE) reports including narrative (e.g. CIOMS II with narrative) from clinical development as well as source documentation and proof of where each case was submitted.

(e) The parties confirm that the global pharmacovigilance agreement previously entered into by them, setting forth details with respect to the management of safety information including adverse events reports related to the Development and the Commercialization of the Trofinetide Products as well as a Safety Governance Structure and provisions ensuring Neuren has full rights of access to all such information and data, will continue in full force and effect after the Commencement Date.

(f) ACADIA shall continue to maintain a global safety database for the Trofinetide Products.

(g) The parties will enter into a global pharmacovigilance agreement setting forth details with respect to the management of safety information including adverse events reports related to the Development and the Commercialization of the NNZ-2591 Products as well as a Safety Governance Structure and provisions ensuring that each party has full rights of access to all such information and data.

(h) ACADIA will have the right to maintain the global PV database for NNZ-2591 Products in the NNZ-2591 Field and Neuren will have the right to maintain the global PV database with respect to all other uses of NNZ-2591 Products.

(i) Neuren hereby grants to ACADIA, solely for the purposes set out in this Agreement, a right of reference or use to that part of any and all Regulatory documentation Controlled by Neuren or any of its Affiliates relating to any Compound or Product in the applicable Field that is existing as of the Commencement Date or generated from any clinical trial commenced by Neuren or any of its Affiliates after the Commencement Date, and Neuren agrees to sign, and cause its Affiliates to sign, any instruments reasonably requested by ACADIA in order to effect such grant.

(j) ACADIA hereby grants to Neuren, solely for the purposes set out in this Agreement, a right of reference or use to that part of any and all Regulatory documentation Controlled by ACADIA or any of its Affiliates relating to any Compound or Product that is existing as of the Commencement Date or generated from any clinical trial commenced by ACADIA or any of its Affiliates after the Commencement Date, and ACADIA agrees to sign, and cause its Affiliates to sign, any instruments reasonably requested by Neuren in order to effect such grant; provided that:

    (i) with respect to NNZ-2591 Compounds and NNZ-2591 Products, such right shall only be for use outside of the NNZ-2591 Field, or following termination of this Agreement in a given territory with respect to a given NNZ-2591 Compound or NNZ-2591 Product, for use of such NNZ-2591 Compound or NNZ-2591 Product in such terminated territory; and

(ii) with respect to Trofinetide Compounds or Trofinetide Products, such right shall only be effective upon termination of this Agreement in a given territory with respect to a given Trofinetide Compound or Trofinetide Product, and upon such termination, for use of such Trofinetide Compound or Trofinetide Product in or for use in such terminated territory.

10 Commercialization

10.1 Commercial launch

ACADIA will be responsible for planning, forecasting and Manufacturing or having Manufactured all quantities of any Product required for launch of that Product in the applicable Field in the Territory.

10.2 Commercialization in the Field in the Territory

During the Term, ACADIA shall be solely responsible for Commercializing any Product in the Territory for use in the applicable Field, which Commercialization shall be in accordance with this Agreement. ACADIA shall be responsible for 100% of the expenses (including Pre-Marketing and other Commercialization expenses) incurred by or on behalf of ACADIA (including any expenses incurred by Neuren at the written request of ACADIA) in connection with the Commercialization of any Product in the Territory for use in the applicable Field.

10.3 Commercialization of Trofinetide Product

Without limiting clause 10.2, ACADIA shall use its Commercially Reasonable Efforts to launch and Commercialize the Trofinetide Product for use in Rett Syndrome in each of the countries set out in clause 6.1(b) after the Marketing Authorisation (if applicable) and all other applicable regulatory approvals for that Trofinetide Product have been obtained in that country (including pricing and reimbursement approvals). ACADIA shall book all sales of Trofinetide Products on a worldwide basis.

10.4 Actions

In developing strategies, making decisions and exercising its rights under this Agreement (including acting through its representatives on the JSC and its Alliance Managers), each party shall act in good faith and use its Commercially Reasonable Efforts to further the interests of the JV in accordance with this Agreement. For clarity, ACADIA shall be responsible for the day-to-day operations and decision-making for all Commercialization activities with respect to any Compound or any Product in the applicable Field in the Territory.

10.5 Commercialization Obligations

(a) Without limiting any other provision of this Agreement ACADIA (or its Affiliate or Sub-Licensee, as applicable) shall be solely responsible for:

(i) receiving, accepting and filling orders for any Product in the applicable Field in the Territory;

(ii) handling all returns of any Product in the applicable Field in the Territory;

(iii) controlling invoicing, order processing and collection of accounts receivable for the sales of any Product in the applicable Field in the Territory; and

(iv) distributing and managing inventory of any Product in the applicable Field in the Territory.

(b) ACADIA shall use Commercially Reasonable Efforts to carry out the Commercialization activities for the Products:

(i) as set forth in clause 10.3 with respect to Trofinetide Product, and

(ii) with respect to NNZ-2591 in the NNZ-2591 Field, in the Initial Territory and each of the countries set out in clause 6.1(b) following approval of the Marketing Authorisation and receipt of any other approvals of Governmental Agencies required to conduct such Commercialization activities in the applicable country of the Territory. ACADIA shall book all sales of NNZ-2591 Products in the NNZ-2591 Field on a worldwide basis, and Neuren shall book all sales of NNZ-2591 Products outside of the NNZ-2591 Field in the Territory on a worldwide basis (for clarity the booking of sales does not limit the obligation to pay Gross Profits to the other party as described in clause 11.1, as applicable).

10.6 Marketing and sale

ACADIA will, and will cause its officers, agents and contractors to, conduct all details with respect to each Product and the performance of ACADIA's Commercialization activities under this Agreement in the applicable Field and in the Territory in adherence with the applicable Marketing Authorisation, the Product package inserts, labelling and packaging, and any professional requirements, including those relating to promotion of pharmaceutical products, consumer protection, fraud and abuse and false claims.

10.7 Promotional Materials

(a) ACADIA will create and develop Promotional Materials for the Products in the applicable Field in the Territory in accordance with the Marketing Authorisations and applicable laws. ACADIA shall own all right, title and interest in and to any Promotional Materials created by ACADIA under this Agreement relating to any Product in the applicable Field in the Territory and any website (including without limitation Daybue.com) relating to the Product.

(b) With respect to any NNZ-2591 Product, ACADIA and Neuren will disclose to each other any and all Promotional Materials created by the respective parties, and co-operate with each other in relation to Promotional Materials to promote a reasonable level of consistency with respect to the Products; provided that ACADIA retains the right to modify any Promotional Materials in the NNZ-2591 Field in the Territory, at its sole discretion and Neuren retains the right to modify any Promotional Materials outside the NNZ-2591 Field, at its sole discretion.

(c) Neither party shall use any of the other party's Promotional Materials without the prior written consent of the other party, not to be unreasonably withheld.

11 JV Obligations of loyalty and exclusivity

11.1 Commercialization through JV

(a) The parties acknowledge and agree that it is their intention that all their activities:

(i) for the Commercialization of the Trofinetide Compound and Trofinetide Product in the Trofinetide Field in the Territory; and

(ii) for the development or Commercialization of the NNZ-2591 Compound and NNZ-2591 Product in the NNZ-2591 Field in the Territory,

will be conducted through the JV.

(b) In order to protect the parties' respective investment and resultant goodwill in the JV, Neuren and its Affiliates will not develop or Commercialize any other compound or product (including NNZ-2591 Compound or NNZ-2591 Product) other than through the JV on terms to be agreed between the parties on a product by product basis for the periods, parts of the Territory and indications set out in the following table:

Period	Part of Territory	Indication
During any period in which the Exclusivity Period for a Trofinetide Product for use in Rett Syndrome continues in any part of the Territory	All of the Territory	Rett Syndrome
During any period in which the Exclusivity Period for a Trofinetide Product for use in Fragile X continues in any part of the Territory	All of the Territory	Fragile X Syndrome
During any period in which the Exclusivity Period for a Trofinetide Product for use in the New Indication continues	Anywhere in the Initial Territory	New Indication

(c) If Neuren has commenced clinical development in the Initial Territory of a product for an indication and that indication subsequently becomes a New Indication in the Initial Territory, Neuren must halt clinical development for the New Indication in the Initial Territory, and may only reinitiate clinical development for that indication in the Initial Territory on the first to occur of:

(i) Neuren and ACADIA agreeing on the terms on which that product and New Indication can be included in the JV; and

(ii) the indication ceases to be classified as a New Indication pursuant to clause 6.2(e).

This clause 11.1(c) will not prevent, and Neuren will be entitled at all times, to develop and Commercialize the product for the New Indication outside the Initial Territory.

(d) For the avoidance of doubt, if Neuren wishes to pursue, in part of the Territory, a product for an indication that it is prevented from developing or Commercializing in accordance with clause 11.1(b) and ACADIA does not wish to pursue that product for that indication in that part of the Territory, or the parties do not agree the terms on which that product and indication can be included in the JV, Neuren must not pursue that product for that indication in that part of the Territory during the period in which it is prevented from doing so under clause 11.1(b).

(e) For the avoidance of doubt, the parties acknowledge and agree, that:

(i) nothing in this Agreement requires Neuren to develop or Commercialize any other compound or product (including NNZ-2591) for use in the Field;

(ii) notwithstanding any other provision of this Agreement, Neuren retains the right to develop or Commercialize any compound or product (including NNZ-2591) anywhere in the Territory for the treatment of Phelan-McDermid Syndrome, Pitt Hopkins Syndrome, Angelman Syndrome and Prader-Willi Syndrome.

(f) Neuren and ACADIA will work together in good faith to minimize, to the extent possible, the potential for off-label sales of NNZ-2591 Product Commercialized by ACADIA in Neuren's Indications and off-label sales of NNZ-2591 Product Commercialized by Neuren in the NNZ-2591 Field in the Territory. The parties will not directly or indirectly promote off-label use of NNZ-2591 Product and will use Commercially Reasonable Efforts to prevent any off-label use of NNZ-2591 Product.

(g) If Neuren generates any Commercial Sales of an NNZ-2591 Product in:

(i) the NNZ-2591 Field inside the Territory; or

(ii) the Initial Territory in a New Indication,

Neuren will pay to ACADIA the Gross Profits generated from those sales of that Product.

(h) If Acadia generates any Commercial Sales of a NNZ-2591 Product outside the NNZ-2591 Field or outside the Territory, ACADIA will pay to Neuren the Gross Profits generated from those sales of that Product.

(i) For the purposes of clauses 11.1(g) and 11.1(h):

(i) **Commercial Sale** means the sale or transfer of that Product in a region or other regulatory jurisdiction in the Territory by or on behalf of a party or its sub-licensees to a Third Party, other than for evaluation, research or clinical trial purposes or any not-for-profit or compassionate uses, in exchange for cash or some equivalent to which value can be assigned; and

(ii) **Gross Profits** means Net Revenue from the sales of the relevant Product less the Manufacturing Costs of the relevant Products sold.

(j) The parties acknowledge that the payments referred to in clause 11.1(g) and 11.1(h) do not limit the parties' rights to seek equitable remedies for breach of any applicable obligations under this Agreement.

11.2 Limit on party's rights to sell, supply or export Product

(a) ACADIA and its Affiliates will not, and must procure that Sub-Licensees do not, use, develop, Commercialize, sell, supply or export any NNZ-2591 Compound or NNZ-2591 Product, directly or indirectly, for use, outside the NNZ-2591 Field or in any terminated territory with respect to such NNZ-2591 Compound or NNZ-2591 Product.

(b) ACADIA and its Affiliates will not, and must procure that Sub-Licensees do not, use, develop, Commercialize, sell, supply or export any Trofinetide Compound or Trofinetide Product, directly or indirectly, for use in any terminated territory with respect to such Trofinetide Compound or Trofinetide Product.

(c) Subject to clause 4.5, Neuren and its Affiliates will not, and must procure that any licensees or sublicensees do not, use, develop, Commercialize, sell, supply or export any NNZ-2591 Compound or NNZ-2591 Product, directly or indirectly, for use, within the NNZ-2591 Field in the Territory.

(d) Subject to clause 4.5, Neuren and its Affiliates will not, and must procure that any licensees or sublicensees do not, use, develop, Commercialize, sell, supply or export any Trofinetide Compound or Trofinetide Product, directly or indirectly, for use, in the Territory.

Without limiting the foregoing, each party undertakes, and must procure that its Sub-Licensees, licensees or sublicensees (as applicable) undertake, except as expressly permitted by this Agreement:

(i) not to sell, supply or export any Compound or Product directly or indirectly for use in contravention of the foregoing covenants; and

(ii) in the case of ACADIA, not to:

(A) engage in promotional activities for any NNZ-2591 Compound or NNZ-2591 Product directed outside the NNZ-2591 Field or in or to any terminated territory with respect to such NNZ-2591 Compound or NNZ-2591 Product;

(B) engage in promotional activities for any Trofinetide Compound or Trofinetide Product directed outside the Trofinetide Field or in or to any terminated territory with respect to such Trofinetide Compound or Trofinetide Product;

(C) sell or fill any orders for any NNZ-2591 Compound or NNZ-2591 Product to customers directed outside the NNZ-2591 Field or in any terminated

territory with respect to such NNZ-2591 Compound or NNZ-2591 Product; or

(D) sell or fill any orders for any Trofinetide Compound or Trofinetide Product to customers directed outside the Trofinetide Field or in any terminated territory with respect to such Trofinetide Compound or Trofinetide Product; and

(iii) in the case of Neuren, not to:

(A) engage in promotional activities for any NNZ-2591 Compound or NNZ-2591 Product directed inside the NNZ-2591 Field in or to the Territory;

(B) engage in promotional activities for any Trofinetide Compound or Trofinetide Product directed in or to the Territory;

(C) sell or fill any orders for any NNZ-2591 Compound or NNZ-2591 Product to customers directed inside the NNZ-2591 Field in the Territory; or

(D) sell or fill any orders for any Trofinetide Compound or Trofinetide Product to customers directed in the Territory.

12 Warranties by ACADIA

12.1 ACADIA representations

ACADIA represents, warrants and covenants to Neuren that:

(a) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof,

(b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action,

(c) this Agreement is legally binding upon it, enforceable in accordance with its terms, and the execution, delivery and performance of this Agreement by ACADIA does not conflict with, or breach any agreement to which ACADIA is a party, or any of ACADIA's articles of incorporation or bylaws;

(d) it has:

(i) or will have, access to suitably qualified technical staff to carry out the manufacture of each Product in the Territory to be performed by or on behalf of ACADIA, subject to Neuren's compliance with the terms of this Agreement or any other written agreement between the parties; and

(ii) access to the necessary staff and facilities to carry out the marketing, promotion, distribution and sale of each Product in the Territory to be performed by or on behalf of ACADIA;

(e) it will exercise Commercially Reasonable Efforts in connection with the Manufacture, distribution, marketing, promotion and sale of each Product in the applicable Field in the Territory;

(f) in the Manufacture, distribution, marketing, promotion and sale of each Product, it will comply in all material respects with the provisions of all acts, regulations, by-laws, orders, directions, notices and instructions made or given by any Governmental Agency or other Regulatory Authority acting under any act, regulation or by-law in the Territory and with the applicable Marketing Authorisation;

(g) it will comply fully with all relevant safety standards in connection with the storage, transportation and distribution of each Product in the Territory; and

(h) it is not debarred or disqualified under the U.S. Federal Food, Drug and Cosmetic Act, as may be amended, or comparable laws in any country or jurisdiction other than the U.S., and it does not, and will not during the Term, employ or use the services of any person who is debarred or disqualified, in connection with activities relating to any Compound or Product, and in the event that either party becomes aware of the debarment or disqualification or threatened debarment or disqualification of any person providing services to such party, including the party itself or its Affiliates or licensees or sublicensees, which directly or indirectly relate to activities contemplated by this Agreement, such party shall immediately notify the other party in writing and such party shall cease employing, contracting with, or retaining any such person to perform any such services.

12.2 Exclusion

Except as expressly set forth in this Agreement, ACADIA expressly disclaims any and all warranties of any kind, express or implied, including the warranties of design, merchantability, fitness for a particular purpose, noninfringement of the intellectual property rights of third parties, or arising from a course of dealing, usage or trade practices, in all cases with respect thereto. Without limiting the generality of the foregoing, ACADIA does not represent or warrant:

(a) that the activities contemplated in any Development plan or Commercialization plan shall achieve any of the objectives contemplated therein; or

(b) the success of any study or test conducted by ACADIA pursuant to this Agreement.

13 Warranties by Neuren

13.1 Neuren representations

Neuren represents, warrants and covenants to ACADIA that:

(a) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof,

(b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action,

(c) this Agreement is legally binding upon it, enforceable in accordance with its terms, and the execution, delivery and performance of this Agreement by Neuren does not conflict with, or breach any agreement to which Neuren is a party, or any of Neuren's articles of incorporation or bylaws;

(d) Neuren has the right to grant to ACADIA the licences and rights granted to ACADIA by Neuren under this Agreement;

(e) it has not as of the Commencement Date, and will not during the Term, grant any right to any Third Party under the Neuren IP or Methodology that would conflict with the rights granted to ACADIA hereunder;

(f) it has or will have, access to suitably qualified technical staff to carry out the activities to be performed by or on behalf of Neuren as contemplated by this Agreement, subject to ACADIA's compliance with the terms of this Agreement or any other written agreement between the parties;

(g) it will exercise Commercially Reasonable Efforts in connection with the activities to be conducted by or on behalf of Neuren with respect to Products pursuant to this Agreement;

(h) in connection with the activities to be conducted by or on behalf of Neuren with respect to Products pursuant to this Agreement, it will comply in all material respects with the provisions of all acts, regulations, by-laws, orders, directions, notices and instructions made or given by any Governmental Agency or other Regulatory Authority acting under any act, regulation or by-law in the Territory and with the applicable Marketing Authorisation;

(i) Neuren has not received notice from any Third Party alleging, and is not aware of any facts or circumstances that would result in, any infringement of the rights of any Third Party in the Development, Manufacture, use or Commercialization of any Compound or Product or practice of the Methodology as contemplated by this Agreement, and, to the best of Neuren's knowledge, use of the Neuren IP in accordance with the terms of this Agreement will not infringe on the rights of any Third Party (including any Third Party's Intellectual Property Rights);

(j) as of the Commencement Date, it has received no notice and is not aware of any claim or demand or of any threatened or pending litigation regarding the Neuren IP or the Methodology, including any action or litigation alleging that the practice or use of any Neuren IP or the Methodology would infringe any patent rights or other Intellectual Property Right of any Third Party;

(k) no Third Party has any rights to or interest in the Neuren IP in the Territory in respect of the applicable Field;

(l) Neuren has not given any notice to any Third Party asserting infringement by such Third Party of any of the Neuren IP and, to Neuren's knowledge, there is no unauthorized use, infringement or misappropriation of any of the Neuren IP;

(m) the Neuren IP is valid, subsisting and in full force and effect and, to Neuren's knowledge, is enforceable and Neuren has not misappropriated any rights of Third Parties with respect to the Neuren IP;

(n) Neuren or its Affiliates own all right, title and interest in and to the Neuren IP in the Field free and clear of all encumbrances, security interests, options and licences; and

(o) it is not debarred or disqualified under the U.S. Federal Food, Drug and Cosmetic Act, as may be amended, or comparable laws in any country or jurisdiction other than the U.S., and it does not, and will not during the Term, employ or use the services of any person who is debarred or disqualified, in connection with activities relating to any Compound or Product, and in the event that either party becomes aware of the debarment or disqualification or threatened debarment or disqualification of any person providing services to such party, including the party itself or its Affiliates or licensees or sublicensees, which directly or indirectly relate to activities contemplated by this Agreement, such party shall immediately notify the other party in writing and such party shall cease employing, contracting with, or retaining any such person to perform any such services.

13.2 Exclusion

Except as expressly set forth in this Agreement, Neuren expressly disclaims any and all warranties of any kind, express or implied, including the warranties of design, merchantability, fitness for a particular purpose, noninfringement of the intellectual property rights of third parties or arising from a course of dealing, usage or trade practices, in all cases with respect thereto. Without limiting the generality of the foregoing, Neuren does not represent or warrant:

(a) that the activities contemplated in any Development plan or Commercialization plan shall achieve any of the objectives contemplated therein; or

(b) the success of any study or test conducted by Neuren pursuant to this Agreement.

14 Sub-Licences

14.1 Appointment

(a) Subject to this clause 14, ACADIA may appoint Sub-Licensees.

(b) ACADIA must notify Neuren of the appointment and identity of each Sub-Licensee and must enter into a binding agreement with each Sub-Licensee (as may be amended, a "**Sub-Licence Agreement**").

(c) If requested by Neuren, ACADIA must promptly share any Sub-Licence Agreement with Neuren; provided that ACADIA may redact competitively sensitive information that is not necessary for Neuren to determine compliance with this Agreement or the amount of payments due to Neuren hereunder.

(d) The Sub-Licence Agreement and the terms and conditions of appointment of any Sub-Licensee must be consistent with the terms of this Agreement.

(e) Without the prior written consent of Neuren, which consent shall not be unreasonably withheld, ACADIA must not, prior to the commencement by ACADIA of a Phase II Clinical Study anywhere in the world with respect to NNZ-2591 Compound or NNZ-2591 Product in the NNZ-2591 Field, appoint a Sub-Licensee to acquire, assume or otherwise take on all or substantially all of ACADIA's rights or obligations under this Agreement with respect to NNZ-2591 Compound or NNZ-2591 Product or in circumstances which would, in effect, constitute an assignment, transfer or other disposal by ACADIA of, all or substantially all of ACADIA's rights or obligations under this Agreement with respect to NNZ-2591 Compound or NNZ-2591 Product if that assignment, transfer or other disposal would not be permitted under clause 29.5.

14.2 Compliance with sub-licence

ACADIA will cause any Sub-Licensee to comply with the terms and conditions of its Sub-Licence Agreement, including compliance with any of the terms and conditions required for ACADIA to comply with this Agreement.

14.3 Responsibility of ACADIA

The performance of any obligation by a Sub-Licensee of ACADIA does not relieve ACADIA of responsibility for any obligation of ACADIA under this Agreement.

14.4 Sublicence to Affiliates

ACADIA may also grant sublicences under the Neuren IP to any of its Affiliates, will cause any Affiliate to comply with any of the terms and conditions required for ACADIA to comply with this Agreement, and will remain responsible for performance by any Affiliate of ACADIA of any obligation of ACADIA under this Agreement. Any such sublicence will terminate immediately upon the relevant party ceasing to be an Affiliate of ACADIA.

14.5 Sub-Licensee royalties

ACADIA will cause all Sub-Licensees to have the same obligations to keep accounts and records as ACADIA has under clause 15.3(b).

14.6 Sublicences by Neuren

The provisions of clauses 14.1 through 14.4 shall apply with respect to Neuren and any sublicence granted by it under any Intellectual Property Rights of ACADIA licensed to Neuren pursuant to this Agreement.

15 Fees and Royalties

15.1 Payment of the Fees

(a) ACADIA shall pay or procure its nominated Affiliate to pay (as applicable) Neuren:

(i) the Upfront Fee in accordance with the payment terms set out in clause 1 of the Fee Schedule;

(ii) each Development Milestone Fee in accordance with the payment terms set out in clause 2 of the Fee Schedule;

(iii) each Sales Milestone Fee in accordance with the payment terms set out in clause 3 of the Fee Schedule; and

(iv) each Sub-Licensee Fee in accordance with the payment terms set out in clause 5 of the Fee Schedule.

(b) For the avoidance of doubt, none of the Fees are refundable under any circumstances; provided, however, that ACADIA retains the right to claim any excess payments as damages in any court or arbitration proceeding.

(c) Upon the achievement of each Development Milestone Fee and Sales Milestone Fee, Neuren shall invoice ACADIA, and ACADIA shall pay such Fee within […***…] days of delivery of the invoice.

15.2 Priority review voucher

(a) If ACADIA receives or has already received a Rare Paediatric Disease Priority Review Voucher from the FDA on approval of a NDA for any Product for any indication, ACADIA will pay to Neuren one third of the proceeds after applicable taxes from the sale of such voucher or the value if not sold but used by ACADIA in connection with filing an NDA with the FDA for a product other than a Product within […***…] days of delivery of the invoice with respect to such payment.

(b) For the purposes of this clause 15.2, if:

(i) a Priority Review Voucher is sold to an independent Third Party, the sale value will be the amount paid or to be paid by that Third Party or, if any part of the consideration for the sale is not in cash, the market value of such non-cash consideration less applicable taxes on such sale or transfer (but in any event, excluding tax on the income of ACADIA resulting from such sale); and

(ii) a Priority Review Voucher is not sold at all or is not sold to an independent Third Party and ACADIA submits it to the FDA with the corresponding NDA for any product other than a Product, the sale value will be the average price paid by purchasers of Rare Paediatric Disease Priority Review Vouchers in the last 3 publicly announced sales of such vouchers by any holders to independent third parties immediately preceding the issuance of the priority review voucher to ACADIA.

15.3 Royalties

(a) Royalties are payable by ACADIA to Neuren within […***…] days after the last day of each Quarter for all Net Revenues during such Quarter, in accordance with the royalty calculations set forth in clause 4 of the Fee Schedule.

(b) ACADIA (including its Affiliates) and Sub-Licensees shall keep complete and accurate books and records which may be necessary to ascertain properly and to verify the payments owed hereunder and retain those books and records for at least […***…] years. ACADIA shall furnish Neuren with quarterly reports on sales of the Product within […***…] days after the end of each Quarter; provided that such report shall be due

[…***…] days after the end of the fourth Quarter of each calendar year, together with the payment of Royalties for such Quarter. Each quarterly report must include:

(i) the gross amounts invoiced for each Product by ACADIA (including its Affiliates) and Sub-Licensees in each country and Region in the Territory;

(ii) each category of the allowable deductions (as set forth in the definition of Net Revenue) that result in the Net Revenue for those countries and Regions;

(iii) a calculation of the Royalties due on such sales;

(iv) the number of units and price of Products sold; and

(v) the application of any reductions, in accordance with clauses 4.3 and 4.6 of the Fee Schedule.

15.4 Translation of Foreign Currency Sales

ACADIA's then current standard exchange rate methodology will be employed for the translation of foreign currency sales into United States dollars. This methodology is used by ACADIA in the translation of its foreign currency operating results, is consistent with generally accepted accounting principles, is audited by ACADIA's independent certified public accountants in connection with the audit of the consolidated financial statements of ACADIA, and is used for external reporting of foreign currency operating results.

15.5 Payment

All payments to Neuren under this Agreement must be made:

(a) to the account that Neuren nominates in writing from time to time during the Term;

(b) electronically; and

(c) in US$.

If an amount specified in this Agreement is expressed in currency other than US$, that amount will be converted into US$ using the exchange rate methodology set out in clause 15.4.

15.6 Tax

If any withholding taxes are levied by any taxing authority in connection with the payment to Neuren of Fees, Royalties or other amounts under this Agreement and are required to be paid or deducted by ACADIA, ACADIA will withhold and pay such taxes from the applicable payment to Neuren to such taxing authority on behalf of Neuren and will promptly provide written evidence of such payment and such other related documentation as Neuren may reasonably require.

15.7 Fully Paid Licences

Unless the Agreement has been terminated under clause 22, upon expiration of the Exclusivity Period for a Product in a given country in the Territory, the licence granted to ACADIA in the applicable Field in such country in respect of that Product only (and not for any other indication, country or Product or Compound) shall survive any termination of this Agreement on a fully-paid, royalty-free, irrevocable, perpetual and non-exclusive basis.

16 Default interest

16.1 ACADIA to pay interest

If ACADIA fails to pay any undisputed amount payable under this Agreement on the due date for payment, ACADIA must pay interest on the amount unpaid at the rate of […***…]% per annum above the current Citibank N.A. published prime rate. This interest must be paid on demand.

16.2 Calculation of interest

The interest payable under clause 16.1 accrues daily from and including the due date for payment up to but excluding the actual date of payment.

16.3 Other remedies unaffected

Neuren's right to require payment of interest under this clause 16 does not affect any other rights and remedies it may have in relation to any failure to pay an amount due under this Agreement.

17 ACADIA to keep accounts and records

(a) Within the Term of this Agreement, Neuren may not more than […***…] each calendar year have an independent Third Party certified public accountant, proposed by Neuren and agreed to by ACADIA (such agreement not to be unreasonably withheld or delayed) (an "**Independent Auditor**"), inspect ACADIA's records for […***…] years preceding the period to which the applicable Royalties pertain for the purpose of determining the accuracy of royalty payments in accordance with the procedure set out in this clause 17. Upon Neuren's reasonable request, ACADIA shall exercise its right to appoint an Independent Auditor to audit each Sub-Licensee's records in accordance with this clause 17 and shall share the results of such audit with respect to amounts payable to Neuren under this Agreement.

(b) Neuren must submit an audit plan, including audit scope, to ACADIA for ACADIA's approval, which shall not be unreasonably withheld, prior to audit implementation. Such audits may be exercised during normal business hours upon reasonable prior written notice to ACADIA.

(c) Each Independent Auditor must be instructed to keep confidential any information obtained during such inspection and to report to Neuren and ACADIA only the amounts of Net Revenues and Royalties that have been or are due and payable.

(d) If determined that additional Royalties are owed, or that Royalties were overpaid, during such period, ACADIA will pay Neuren the additional Royalties, or Neuren will pay ACADIA the overpaid Royalties within […***…] days of the date the Independent Auditor's written report is received by the parties.

(e) The fees charged by an Independent Auditor will be paid by Neuren unless any additional Royalties owed to Neuren exceed […***…]% of the Royalties paid for the period subject to the audit, in which case ACADIA will pay the fees of the accounting firm.

18 Confidential Information

18.1 Confidential Information to be kept confidential

Subject to this clause 18, the receiving party must keep all Confidential Information (which shall include the Methodology) received either prior to the Commencement Date or during the Term, strictly confidential.

18.2 Prior consent

Subject to clauses 18.3, 18.8 and 18.9, neither party will directly or indirectly disclose, disseminate, distribute, divulge, sell or communicate to or use for any purpose except as expressly permitted by this Agreement or any other written agreement between the parties, any of the Confidential Information of the other party, unless and until the receiving party has first obtained the written consent of the other party.

18.3 Disclosure to employees and contractors

Subject to clauses 18.8 and 18.9, the receiving party will not directly or indirectly disclose Confidential Information of the other party to its employees, contractors or any other persons

unless such persons necessarily require access to such Confidential Information in order to assist the receiving party to exercise its rights or perform its obligations under this Agreement.

18.4 Compliance by employees and contractors

(a) Each party will direct any of its employees, contractors or other persons to whom Confidential Information of the other party is disclosed to comply with the terms of this Agreement relating to confidentiality.

(b) Each party will be responsible for compliance by its officers, employees, agents, contractors, advisers or any other persons to whom Confidential Information of the disclosing party has been disclosed by or on behalf of the receiving party (including as permitted under clause 18.9(b)) with the receiving party's obligations under this clause 18.

18.5 Reasonable steps and precautions

Each party will take all reasonable steps to eliminate the risk of unauthorised disclosure of any Confidential Information that it has received from the other party or its Affiliates and the burden will be on the receiving party to show that all such precautions and care were used.

18.6 Uncertainty as to confidentiality

In the event of any uncertainty as to whether or not any part of the Confidential Information is confidential, the receiving party will treat that part of the Confidential Information, as the case may be, as confidential and will not disclose that part of the Confidential Information until the receiving party is advised by disclosing party in writing that that part of the Confidential Information is not part of the disclosing party's Confidential Information.

18.7 Unauthorised disclosure

If the receiving party becomes aware of any unauthorised disclosure or misuse of any Confidential Information of the disclosing party, it will immediately notify the disclosing party in writing of the full particulars of the unauthorised disclosure or misuse.

18.8 Exceptions to obligations

The restrictions contained in clause 18 shall not apply to information that the receiving party can prove by competent written evidence:

(a) is already in the public domain or becomes available to the public other than through breach of this Agreement by the receiving party;

(b) was lawfully in the receiving party's possession prior to the Commencement Date, other than as provided to the receiving party by the disclosing party or any of its Affiliates under the terms of the Prior Confidentiality Agreement or Initial Licence;

(c) was received by the receiving party independently from a Third Party free to disclose such information to receiving party without obligation of confidentiality; or

(d) was developed by the receiving party independent of any Confidential Information of the disclosing party.

18.9 Authorized disclosures

The receiving party may disclose Confidential Information of the disclosing party as expressly permitted by this Agreement or if and to the extent such disclosure is reasonably necessary in the following instances:

(a) submission by a receiving party to a Government Agency including, for the avoidance of doubt, any Regulatory Authorities, to facilitate the issuance of registrations for the Product, provided that reasonable measures shall be taken by the receiving party to assure confidential treatment of such Confidential Information (if possible);

(b) disclosure by the receiving party to Affiliates and Third Parties, including Sub-Licensees and potential Sub-Licensees, under confidentiality agreements having provisions at least as stringent as those in this Agreement, to facilitate the receiving party's exercise of its rights or performance of its obligations pursuant to this Agreement or in connection with due diligence investigations or financing transactions of the receiving party or its Affiliates; or

(c) is otherwise required to be disclosed in compliance with applicable laws or regulations (including, without limitation and for the avoidance of doubt, the requirements of the U.S. Securities and Exchange Commission (the "**SEC**") or any stock exchange on which securities issued by a party are traded) or order by a court or other regulatory body having competent jurisdiction, including prosecuting or defending litigation, provided that, if a party is required to make any such disclosure of the other party's Confidential Information, such party will give reasonable advance written notice to the disclosing party of such disclosure requirement and, except to the extent inappropriate in the case of patent applications, will use reasonable measures to secure confidential treatment of such Confidential Information required to be disclosed; or

18.10 Survival of obligations

The parties' confidentiality obligations under this Agreement will survive during the Term of this Agreement and for […***…] years thereafter.

18.11 Publications

(a) Each party and its Affiliates may propose for disclosure through academic or scientific publication or presentation any results of and other information regarding such party's Development activities with respect to any Compound or Product, whether by oral presentation, manuscript or abstract, with the prior review and approval of the JSC in accordance with the procedures set forth in this clause 18.11. The other party may consent in writing to such publication or presentation if the JSC is not scheduled to meet at a time that would allow for review on the timelines contemplated in this clause 18.11, in which case, references to the JSC review, comment and approval shall be deemed to refer to the party other than the party proposing to make such publication or presentation. Before any such information is submitted for publication or presentation of any such information is made, the party proposing to make such publication or presentation shall deliver a complete copy to the JSC at least […***…] days prior to submitting the material to a publisher or initiating any other disclosure. The JSC shall review any such material and give its comments to the publishing Party within […***…] days of receipt of such information. With respect to oral presentation materials and abstracts, the parties, through the JSC, will use reasonable efforts to expedite review of such materials and abstracts, and shall return such items as soon as practicable to the publishing party with comments, if any, but in no event later than […***…] days from receipt. The publishing party shall comply with the JSC's request to delete references to Confidential Information in any such publication or presentation and agrees to delay any submission for publication or other public disclosure for a period of up to an additional […***…] days for the purpose of preparing and filing appropriate patent applications. Notwithstanding the foregoing:

(i) after First Commercial Sale in the Territory of a Trofinetide Compound or Trofinetide Product:

(A) ACADIA may publish, present or disclose any information relating to any Trofinetide Compound or Trofinetide Product in the applicable Field, without JSC review or approval; and

(B) Neuren may publish, present or disclose any information that ACADIA has made publicly available relating to any Trofinetide Compound or Trofinetide Product in the applicable Field, without JSC review or approval; and

(ii) after first commercial sale outside the NNZ-2591 Field of a NNZ-2591 Compound or NNZ-2591 Product:

(A) ACADIA may publish, present or disclose any information relating to any NNZ-2591 Compound or NNZ-2591 Product in the NNZ-2591 Field, without JSC review or approval; and

(B) Neuren may publish, present or disclose any information relating to any NNZ-2591 Compound or NNZ-2591 Product outside the NNZ-2591 Field or any information that ACADIA has made publicly available within the NNZ-2591 Field, without JSC review or approval.

(b) Each party will be permitted to disclose information with respect to Development of any Compound or Product in the applicable Field on clinicaltrials.gov (or comparable website for any jurisdiction outside the United States) in accordance with normal business practices, without the need to obtain the consent of the other party or the JSC.

18.12 Prior agreements

As of the Effective Date, the terms of this clause 18 shall supersede any prior non-disclosure, secrecy or confidentiality agreement between the parties (or their Affiliates) dealing with the subject of this Agreement, including the Prior Confidentiality Agreement and Initial Licence. Any information disclosed pursuant to any such prior agreements shall be deemed Confidential Information for purposes of this Agreement.

18.13 Equitable Relief

Given the nature of the Confidential Information and the competitive damage that a party would suffer upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the parties agree that monetary damages would not be a sufficient remedy for any breach of this clause 18. In addition to all other remedies, a party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this clause 18.

19 Improvements

19.1 Improvements

If Neuren or ACADIA makes any Improvement, Neuren or ACADIA (as applicable) will forthwith disclose the same to the other party.

19.2 Improvements solely made by Neuren

If the Improvement is solely made by or on behalf of Neuren or any of its Affiliates (a "**Neuren Improvement**"), it will automatically form part of the Neuren IP upon the creation or acquisition of such Neuren Improvement by or on behalf of Neuren or its Affiliate (and test results and data within any such Neuren Improvement shall be subject to clause 8.2).

19.3 Improvements solely made by ACADIA

(a) If the Improvement is made by or on behalf of ACADIA or any of its Affiliates ("**ACADIA Improvement**"), such ACADIA Improvement shall be solely owned by ACADIA.

(b) ACADIA shall grant and hereby grants to Neuren during the Term an exclusive (other than with respect to ACADIA), royalty-free, fully-paid license, with rights to grant sublicences (subject to clause 14.6), under any ACADIA Improvement that is necessary or reasonably useful to make, have made, use, sell, and import a Product outside the applicable Field or outside the applicable Territory; provided that with respect to Trofinetide Compounds or Trofinetide Products, such licence shall only be effective upon termination of this Agreement in a given territory with respect to a given Trofinetide Compound or Trofinetide Product, and upon such termination, for use of such Trofinetide Compound or Trofinetide Product in such terminated territory.

19.4 Improvements made jointly by Neuren and ACADIA

If the Improvement is made jointly by or on behalf of Neuren and ACADIA or their respective Affiliates ("**Joint Improvement**"), each party shall own an equal undivided interest in such Joint Improvement. Each party shall have the unrestricted right to practice and use any Joint Improvement to make, have made, use, sell, offer for sale and import products; provided that with respect to Products, in the case of ACADIA, such rights shall be exclusive in the applicable Field, and in the case of Neuren, exclusive outside of the applicable Field, and rights to Joint Improvements shall be subject to any rights and licences granted by one party to the other party hereunder. Neither party shall have an obligation to obtain the other party's consent or account to the other with respect to the exploitation of such Joint Improvement or the grant of any right or licence to any other person to use or practice any Joint Improvement.

19.5 Execution of further documents

Each party agrees to do all things, take all reasonable actions and execute all documents necessary or desirable, at the requesting party's cost as and when reasonably required by a party, to give effect to this clause 19.

20 Prosecution and maintenance of Patents

20.1 Intention

The parties acknowledge that it is their intention that:

(a) ACADIA will be primarily responsible for and control the enforcement, prosecution and maintenance of the Trofinetide Patents and Trofinetide IP;

(b) ACADIA will be primarily responsible for and control the enforcement, prosecution and maintenance of the NNZ-2591 Patents and NNZ-2591 IP to the extent that they relate solely to the NNZ-2591 Field in the Territory; and

(c) Neuren will be primarily responsible for and control the enforcement, prosecution and maintenance of the NNZ-2591 Patents and NNZ-2591 IP in all other cases.

on and subject to the terms of this Agreement. Accordingly, for the purposes of this clause 20 and clause 21:

(d) for the Trofinetide Patents, Trofinetide IP, Trofinetide Compound and Trofinetide Product, ACADIA will be the Primary Party, the Trofinetide Patents will be ACADIA's Primary Patents and Neuren will be the Secondary Party; and

(e) for the NNZ-2591 Patents, NNZ-2591 IP, NNZ-2591 Compound and NNZ-2591 Product, Neuren will be the Primary Party, the NNZ-2591 Patents will be Neuren's Primary Patents and ACADIA will be the Secondary Party, except to the extent they solely relate to the NNZ 2591 Field in the Territory, in which case, ACADIA will be the Primary Party, they will be ACADIA's Primary Patents and Neuren will be the Secondary Party.

20.2 Patents applied for as of the Commencement Date

The Primary Party will take, or will procure that an Affiliate of the Primary Party takes, all actions necessary to achieve registration in a timely manner of any of its Primary Patents that either party or an Affiliate of either party has applied to have registered anywhere in the Territory as of the Commencement Date, and to maintain any of its Primary Patents when issued, at that Primary Party's expense.

20.3 Patents applied for after the Commencement Date

(a) If a Secondary Party requires any of the Primary Party's Improvements or Joint Improvements patents to be applied for in any country in the Territory, the Secondary Party will notify the Primary Party of this, and the Primary Party must notify the Secondary Party within […***…] days of such a request whether or not the Primary Party

will file the patent application in some or all of the requested countries. If the Primary Party elects to file the patent application, the Primary Party will promptly file the patent application in those countries that the Secondary Party requests, and take all actions necessary to achieve registration of those patents in a timely manner, provided however that:

(i) all costs in applying for, prosecuting and registering such patent applications and maintaining any patents that issue thereon must be borne by the Primary Party; and

(ii) all such patent applications in respect of Neuren Improvements or Joint Improvements will be made in the name of Neuren or an Affiliate of Neuren; and

(iii) all such patent applications in respect of ACADIA improvements will be made in the name of ACADIA or an Affiliate of ACADIA.

(b) Once such patent applications have been filed, they will automatically form part of the Patents licensed to ACADIA by Neuren under this Agreement.

(c) If the Primary Party elects not to file for such patent application in any country in the Territory, the Primary Party shall promptly assign its interest in the Primary Party's Improvement or Joint Improvement and any rights to file for such patent applications to the Secondary Party and the Secondary Party may itself apply for, prosecute and register those patent applications and maintain any patents that issue thereon in such country in the Territory at its own cost and in its own name and the Secondary Party will own any and all rights therein in the applicable Field (and the foregoing shall no longer be included in the Primary Party's Improvements or Joint Improvements, as applicable).

20.4 Obligations in respect of Patents

Subject to clause 20.5(b), unless otherwise agreed between the parties, the Primary Party will procure that none of the Primary Party's Patents in respect of a Compound or Product or Joint Improvement patents are abandoned or allowed to lapse during the Term.

20.5 Cooperation; Secondary Party Step In Rights

(a) The Primary Party shall keep the Secondary Party informed of progress with regard to the preparation, filing, prosecution and maintenance of its Primary Patents in the Territory, including content, timing and jurisdiction of the filing of such Patents, and shall consult with, and follow the good faith requests and suggestions of, the Secondary Party with respect to filing and prosecuting the Primary Party's Primary Patents in the Territory.

(b) In the event that a Primary Party desires to abandon or cease prosecution or maintenance of any Primary Patent in the Territory, the Primary Party shall provide reasonable prior written notice to the Secondary Party of such intention to abandon (which notice shall, to the extent possible, be given no fewer than […***…] days prior to the next deadline for any action that must be taken with respect to any such Patent in the relevant patent office). In such case, at the Secondary Party's sole discretion, upon written notice from the Secondary Party to the Primary Party, the Secondary Party may elect to continue prosecution or maintenance of any such Patent at its own expense, and the Primary Party shall execute such documents and perform such acts, at the Primary Party's expense, as may be reasonably necessary to effect an assignment of the Primary Party's entire right, title, and interest in and to such Patent in the Territory in the Field to the Secondary Party. Any such assignment shall be completed in a timely manner to allow the Secondary Party to continue prosecution and maintenance of any such Patent in the Territory and any such Patent so assigned shall cease to be a Patent of the Primary Party and shall no longer be subject to any rights granted by the Secondary Party to the Primary Party under this Agreement.

(c) Each party agrees to cooperate fully in the preparation, filing, prosecution and maintenance of patent applications and patents as contemplated in this clause 20 and in

the obtaining and maintenance of any patent term extensions, supplementary protection certificates and their equivalent with respect thereto. Such cooperation includes:

(i) executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, so as enable the other party to prepare, file for, prosecute and maintain patent applications and patents as contemplated in this clause 20; and

(ii) promptly informing the other party of any matters coming to such party's attention that may affect the preparation, filing, prosecution or maintenance of any such patent applications or patents.

Without limiting the foregoing, ACADIA shall have the sole authority and discretion to maintain with the applicable Governmental Agencies in the Territory during the Term listings of applicable Patents for any Product then being commercialized by ACADIA in the applicable Field in the Territory, including all Orange Book listings required under the Hatch-Waxman Act.

(d) Subject to clause 5.6, Neuren shall update ACADIA through the JSC (or pursuant to clause 7.2(a)(iii), as applicable) of material events with regard to the preparation, filing, prosecution and maintenance of patent applications and patents relating to any Compound or Product outside the applicable Field in the Territory.

21 Infringement of IP and Proceedings

21.1 Reporting infringement of Neuren IP

Upon either party becoming aware of any use by any other person of a method of Manufacture of any Product, a product, mode of advertising or design which might reasonably amount to infringement of any of the Neuren IP or to unfair competition or passing off or any other equivalent or similar breach of any applicable law within the Territory, that party will promptly report to the other party particulars.

21.2 Allegations of invalidity of Neuren IP

If it comes to the notice of either party that any person alleges that any part of the Neuren IP is invalid, infringes any rights of that person, or is open to any other form of attack, that party will not make any admission but will promptly report the matter in full detail to the other party.

21.3 Conduct of proceedings with respect to Neuren IP

(a) Subject to clause 21.3(c), if within […***…] days after reporting under clause 21.1, the parties fail to agree on a joint course of action with respect to an Infringement claim that specifically relates to any Product in the Field in the Territory ("**Infringement Claim**"), the Primary Party for that Product will have the first right to undertake the defence or prosecution of the Infringement Claim ("**Infringement Defence**").

(b) Should the Primary Party undertake any Infringement Defence, the Secondary Party will fully co-operate with the Primary Party in relation to such Infringement Defence, including, if required to bring such action, the furnishing of a power of attorney or being named as a party, and the costs and expenses of any such Infringement Defence will be borne by the Primary Party, unless the Secondary Party chooses to participate in such Infringement Defence in which case all parties will bear their own costs of the action. For the avoidance of doubt and subject to clause 21.3(c), the conduct of any Infringement Defence that the Primary Party undertakes in accordance with this clause 21.3 shall be controlled by the Primary Party. Unless otherwise agreed in writing as part of any cost-sharing arrangement, any recoveries resulting from such Infringement Defence shall be applied as follows:

(i) first, to reimburse each party for all out-of-pocket costs incurred by such party in connection with such Infringement Defence (on a pro rata basis, based on each

party's respective litigation costs, to the extent the recovery was less than all such litigation costs); and

(ii) second, any remainder shall be retained by the Primary Party, except that, in the case where ACADIA is the Primary Party such amounts shall be regarded as Net Revenues and any applicable Royalty thereon paid to Neuren.

(c) Should the defence or prosecution of any Infringement Defence undertaken by the Primary Party also involve an Invalidity Claim ("**Infringement and Invalidity Defence**"):

(i) the Secondary Party and/or its Affiliates and any of the Secondary Party's or its Affiliates' Third Party licensees of any of the Neuren IP at issue outside the Field or outside the Territory ("**Third Party Licensees**") shall have the right, at their own expense, to be involved in such Infringement and Invalidity Defence as it relates to invalidity issues and the Primary Party will make no admissions which would materially prejudice the Secondary Party's or its Affiliates' or any Third Party Licensees' rights in such Neuren IP without the written consent of the Secondary Party, not to be unreasonably withheld;

(ii) any amounts recovered under an Infringement and Invalidity Defence that the Secondary Party and/or its Affiliates or Third Party Licensees participate in, will be shared in the same manner as set out in clause 21.3(b); and

(iii) other than for matters involving admissions which would materially prejudice the Secondary Party's or its Affiliates' or any Third Party Licensee's rights in such Neuren IP, the conduct of any Infringement and Invalidity Defence that the Primary Party undertakes in accordance with this clause 21.3 shall be controlled by the Primary Party in the same manner as an Infringement Defence.

(d) If within […***…] days after reporting under clause 21.2, the parties fail to agree on a joint course of action with respect to a claim or allegation challenging the validity, scope or enforceability of any Patent in the Territory or opposition proceeding against any Patent in the Territory, including *inter partes review* proceedings before PTAB or a similar tribunal in the Territory ("**Invalidity Claim**"), other than an Invalidity Claim that is part of any Infringement and Invalidity Defence pursuant to clause 21.3(c), the Primary Party will have the first right to undertake the defence or prosecution of the Invalidity Claim ("**Invalidity Defence**"), provided that the Secondary Party and its Affiliates and any Third Party Licensees shall have the right to participate in such action on the same conditions as an Infringement and Invalidity Defence as specified in clause 21.3(c), and the Invalidity Defence shall be conducted on the same conditions as an Infringement and Invalidity Defence as specified in clause 21.3(c). Any amounts recovered under an Invalidity Defence that the Secondary Party, or its Affiliates or Third Party Licensees participate in will be shared in the same manner as set out in clause 21.3(b).

(e) In the event of the Primary Party choosing not to undertake any Infringement Defence or Invalidity Defence, the Secondary Party and/or any of its Affiliates may do so on its own behalf and in that event, the Primary Party will fully co-operate with the Secondary Party or any of its Affiliates in relation to such action, and the costs and expenses of any such action, including any costs or expenses normally incurred by or on behalf of the Primary Party will be borne by the Secondary Party, except as otherwise stated in this Agreement, and the proceeds of any such action will belong to the Secondary Party or any of its Affiliates; provided, however, that with respect to the Trofinetide Patents in the Territory, Neuren shall not have the right to undertake any Infringement Defence or Invalidity Defence without the prior written consent of Acadia (not to be unreasonably withheld). To establish whether the Primary Party has chosen to undertake any Infringement Defence or Invalidity Defence, the Secondary Party may at any time after becoming aware of such claim serve a notice on the Primary Party requesting the Primary Party to specify whether it will undertake the Infringement Defence or Invalidity

Defence. The Primary Party will have […***…] Business Days from the date of receipt of such notice, or if later until the date that is:

(i) […***…] days following the notice in clause 21.1 or 21.2; or

(ii) […***…] days before the time limit, if any, set forth in the appropriate laws and regulations for the filing or defence of such actions,

whichever of clause 21.3(e)(i) or (ii) comes first, to respond to the Secondary Party in writing. If the Primary Party does not respond to the Secondary Party in writing within the specified time period, the Primary Party will be deemed to have undertaken not to undertake the Infringement Defence or Invalidity Defence. Neither the Secondary Party nor its Affiliate shall settle or compromise any such action or proceeding in any manner that would negatively affect the Primary Party's rights under the Patents in the Territory under this Agreement without the prior written consent of the Primary Party, which shall not be unreasonably withheld.

21.4 Infringement of Third Party rights

(a) Each party shall promptly notify the other party in writing of any allegation by a Third Party that the activity of either party, or any of their respective Affiliates or Third Party licensees or sub-licensees (or Sub-Licensees), as applicable, pursuant to this Agreement infringes or may infringe the Intellectual Property Rights of a Third Party. Subject to Neuren's indemnification obligations, ACADIA shall have the sole right to control any defence of any such claim involving alleged infringement of Third Party rights by activities of ACADIA or its Affiliates or Sub-Licensees at its own expense and by counsel of its own choice, and Neuren shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. Subject to ACADIA's indemnification obligations, Neuren shall have the sole right to control any defence of any such claim involving alleged infringement of Third Party rights by activities of Neuren or its Affiliates or Third Party licensees or sub-licensees at its own expense and by counsel of its own choice, and ACADIA shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.

(b) Neither Party shall enter into any settlement of any claim described in this clause 21.4 that negatively affects the other party's rights or interests without such other party's written consent, which consent shall not be unreasonably withheld, conditioned or delayed. Each party shall have the right to decline to defend or to tender defence of any such claim to the other party upon reasonable notice, including if the other party fails to agree to a settlement that such party proposes.

22 Termination

22.1 Termination by Neuren

Neuren may immediately terminate this Agreement with respect to a given Product with immediate effect by giving 10 Business Days' notice in writing to ACADIA if, with respect to such Product:

(a) ACADIA challenges the validity of any of the Patents within the Neuren IP that is registered or opposes the grant to Neuren of registration of any of the Patents with the Neuren IP that is not registered; or

(b) it is permitted to do so under clause 4.7.

22.2 Termination by ACADIA

ACADIA may elect to terminate this Agreement at any time in its entirety or on a Product-by-Product basis, by providing 90 Business Days' prior written notice to Neuren, provided that at any time after such notice by ACADIA, Neuren may accelerate the commencement date of such termination by providing 30 Business Days' prior written notice to ACADIA of such accelerated commencement date.

22.3 Termination by either party for breach

Either party may terminate this Agreement with immediate effect, solely with respect to a given Product or country, by giving notice to the other party ("**Defaulting Party**") if, with respect to such Product or country:

(a) the Defaulting Party breaches any provision of this Agreement requiring the payment of a monetary amount and fails to remedy the breach within 30 Business Days after receiving notice requiring it to do so with respect to any undisputed payment amounts; or

(b) the Defaulting Party breaches any material provision of this Agreement (other than any provision requiring the payment of a monetary amount) and fails to remedy the breach within 60 Business Days after receiving notice requiring it to do so.

If the Defaulting Party has a dispute as to whether such breach occurred or has been cured, it will so notify the non-Defaulting Party, and the expiration of the applicable cure period shall be suspended until such dispute is resolved pursuant to clause 28. Upon a determination of breach or failure to cure, the Defaulting Party may have the remainder of the applicable cure period to cure such breach. If such breach is not cured within the applicable cure period, then absent withdrawal of the non-Defaulting Party's request for termination, this Agreement shall terminate with respect to the applicable Product or country as of the expiration of the applicable cure period.

For clarity, if a party has a right to terminate this Agreement due to an uncured material breach of the other party, and such breach relates solely to a particular Product or country, then the non-breaching party may terminate this Agreement solely with respect to such Product or country, and not this Agreement in its entirety.

23 Rights on Termination

23.1 Termination without prejudice to rights or obligations of parties

Any termination of this Agreement will be without prejudice to the rights, and without relief of obligations, of either party accruing prior to such termination or in respect of any sums or other claims outstanding at the time of termination.

23.2 Effect of any termination

Upon any termination of this Agreement under clause 22.1, 22.2 or 22.3 with respect to a given Product or country, then, solely with respect to such terminated Product or country:

(a) ACADIA will immediately pay any sums payable to Neuren including without limitation all Royalties which are then due and payable;

(b) except to the extent of any surviving licences as provided under clause 15.7, ACADIA will immediately cease to use the Neuren IP in any connection whatsoever;

(c) except to the extent of any surviving licences as provided under clause 15.7 or to the extent that Neuren is entitled to information from ACADIA pursuant to clause 23.3, each party shall promptly return to the other party, or delete or destroy, all relevant records and materials in such party's possession or control containing Confidential Information of the other party; provided that such party may keep one copy of such information for archival purposes only subject to continuing confidentiality obligations; and

(d) in the case of termination in respect of a given country and subject to clause 23.3, that country will be excluded from the definition of Initial Territory, New Territory and Territory (as applicable) for the applicable Compound and Product.

23.3 Additional effect of termination under clause 22.2 or by Neuren under clause 22.1 or 22.3

Upon any termination of this Agreement by Neuren under clause 22.1 or 22.3 or by ACADIA under clause 22.2 with respect to a given Product or country, then, solely with respect to such terminated Product or terminated country:

(a) subject to clause 23.3(a)(v), ACADIA will do the following, except in any country in which there is a surviving licence as provided under clause 15.7:

(i) at Neuren's expense, arrange for the transfer of all of the Marketing Authorisations and any IND with respect to such terminated Product in such terminated country held by ACADIA or its Affiliate to Neuren or its nominated representative and to take all actions reasonably necessary to ensure the transfer of those Marketing Authorisations and any IND to Neuren or its nominated representative occurs in a timely manner;

(ii) at Neuren's expense, arrange for the transfer of sponsorship of any clinical or non-clinical studies of such terminated Product in such terminated country of which ACADIA or its Affiliate is the sponsor that are in progress to enable Neuren to continue such studies if it elects to do so by written notice to ACADIA provided on or before the effective date of termination;

(iii) at ACADIA's expense:

(A) transfer to Neuren electronic copies of all data, reports, Methodology and Know-how solely relating to such terminated Product (or relevant Compound contained therein) that are Controlled by ACADIA or its Affiliates, to the extent necessary or reasonably useful for use or sale of such terminated Product in such terminated country;

(B) following termination of all rights in the Territory with respect to such terminated Product, deliver up all physical copies of the Methodology and Neuren and its Affiliates' Confidential Information and Know-how relating to such terminated Product; and

(C) following termination of all rights in the Territory with respect to such terminated Product, permanently delete all electronic copies of the Methodology, Neuren and its Affiliates' Confidential Information and Know-how relating to such terminated Product (or relevant Compound contained therein), including any notes, reports and documents which contain or refer to the Methodology, Neuren and its Affiliates' Confidential Information and Know-how relating to such terminated Product in ACADIA's possession, power or control; provided, however, that ACADIA retain one copy of such Confidential Information and Know-how for legal archival purposes only; provided, however, if there is a surviving licence in any country as provided under clause 15.7, ACADIA will share copies of the foregoing with Neuren for use in all countries excluding any country in which ACADIA retains a license, and ACADIA shall retain all of the foregoing for use pursuant to any country in which ACADIA retains a license;

(iv) ACADIA must not, at any time, use any trademarks previously used by it that solely relate to such terminated Product (or relevant Compound contained therein) in such terminated country or use any trademarks, names, labels or logos deceptively or confusingly similar to those trademarks; for clarity, in no event shall the foregoing apply to any trademark, name, label or logo with respect to the name ACADIA or Acadia Pharmaceuticals Inc.; and

(v) ACADIA will be entitled to sell off and distribute (but not Manufacture or produce except for completion of any work-in-progress, at the election of ACADIA) such terminated Products in such terminated country existing at the date of termination for a period of […***…] from such date on the same terms and conditions amended as necessary as are contained in this Agreement.

(b) ACADIA shall, and hereby does effective upon such termination, grant to Neuren an exclusive, royalty-free, fully-paid license, with rights to grant sublicences, under any

ACADIA Improvement or Joint Improvement that is necessary or reasonably useful to make, have made, use, sell, or import such terminated Product in the Field in or for use in such terminated country (excluding any country in which there is a surviving licence as provided under clause 15.7), to make, have made, use, sell, and import such terminated Product in the Field in or for use in such terminated country (excluding any country in which there is a surviving licence as provided under clause 15.7).

(c) ACADIA shall grant Neuren a right to source such terminated Product (or the relevant Compound contained therein) from ACADIA at ACADIA's Manufacturing Cost for a period of […***…] from the effective date of such termination; provided that the allocation of supply will prioritise ACADIA's continuing Development and Commercialization (in non-terminated territories, if any) of any such terminated Product (or the relevant Compound contained therein).

(d) following termination of all rights in the Territory with respect to such terminated Product, at the expiry of the […***…] period referred to in clause 23.3(a)(v), in any country in the Territory (excluding any country in which there is a surviving licence as provided under clause 15.7):

(i) ACADIA will cease to sell such terminated Product and will supply to Neuren an inventory of ACADIA's stocks of the Product at that date verified by an independent accountant ("**Inventory**");

(ii) Neuren will be entitled to purchase from ACADIA all or part of the Inventory at prices agreed between Neuren and ACADIA;

(iii) ACADIA will comply with all of the provisions of clause 23.3(a) and (b) that it has not already complied with; and

(iv) Neuren will be required to relabel and repackage materials to remove any ACADIA trademarks, trade dress or other indications of ACADIA origin from such terminated Product, but will be entitled to continue to use the content of the Promotional Materials.

(e) In such terminated Territory (excluding any country in which there is a surviving licence as provided under clause 15.7) and if Neuren so requests, any sublicence granted by ACADIA to any Sub-Licensee shall remain in effect and become a direct licence from Neuren, so long as actions or omissions by the applicable Sub-Licensee did not cause or contribute to such termination and is not then in material breach of its Sub-Licence Agreement and such Sub-Licensee provides to Neuren within […***…] days after such termination of this Agreement a written agreement to be bound as licensee under the terms and conditions of this Agreement as to the field and territory in which such Sub-Licensee has been granted rights under its Sub-Licence Agreement.

(f) Notwithstanding the foregoing and anything else in this Agreement (including without limitation clauses 4.5 and 9(j)(i)), Neuren's exclusivity obligations with respect to Rett Syndrome and Fragile X Syndrome as set forth in clause 11.1(b) shall survive any termination of this Agreement (including any partial termination of this Agreement or termination of this Agreement in relation to a given territory) with respect to NNZ-2591 Compound or NNZ-Product for the period described in clause 11.1(b).

23.4 Survival

Clauses 1, 8.2, 10.7(c), 12.2, 13.2, 15.7, 17, 18 (for the period specified therein), 19.2, 19.3(a), 19.4, 19.5, 23, 24, 25, 27, 28, 29 and any other right, obligation, or required performance of the parties in this Agreement which, by its express terms or nature and context is intended to survive termination or expiration of this Agreement, shall survive any such termination or expiration.

24 Liability, Indemnity and Insurance

24.1 ACADIA and Neuren liability

Subject to the terms and conditions of this Agreement, including clauses 24.2 and 24.3, each party shall be solely responsible for any acts or omissions with respect to the activities or failures to act of such party or its Affiliates, including as follows:

(a) ACADIA will be responsible for the Development, Manufacture, advertising, marketing, distribution or sale of the Compound and each Product in the applicable Field in the Territory and will bear all risk and liability, loss and damage arising from such Development, Manufacture, advertising, marketing, distribution and sale in the applicable Field in the Territory.

(b) Neuren will be responsible for the Development, Manufacture, advertising, marketing, distribution or sale of the Compound and each Product outside the applicable Field or outside the applicable Territory, and will bear all risk and liability, loss and damage arising from such Development, Manufacture, advertising, marketing, distribution and sale outside the applicable Field or outside the applicable Territory.

24.2 Indemnity by ACADIA

ACADIA agrees to indemnify and hold harmless Neuren, each of Neuren's Affiliates, and each of Neuren's and Neuren's Affiliates' directors, officers, employees, contractors and agents ("**Neuren Indemnified Parties**") against all liability, expenses, losses, damages and costs (including reasonable attorneys' fees and expenses) ("**Losses**") incurred by or awarded against any Neuren Indemnified Party as a result of any claim, demand, action, or other proceeding by any Third Party ("**Claim**"), to the extent arising out of or in connection with:

(a) Claims made in connection with the Compound or any Product Manufactured by ACADIA or any contract manufacturer appointed by ACADIA or in connection with the Development, advertising, marketing, distribution or sale of the Compound or any Product in the applicable Field in the Territory by ACADIA or its Affiliates or any Sub-Licensee;

(b) Claims made in connection with any clinical trials conducted by ACADIA in relation to any Product in the applicable Field in the Territory;

(c) a breach by ACADIA, its officers, employees, contractors or agents of this Agreement or the Initial Licence;

(d) a breach by ACADIA of any of its warranties or representations contained within this Agreement or the Initial Licence; and

(e) the negligence or wilful misconduct of ACADIA or its officers, employees, contractors or agents in connection with this Agreement or the Initial Licence;

in each case except to the extent caused or contributed to by Neuren's fraud, negligence or wilful misconduct, and excluding Claims that the possession or use of any Compound, Product or Neuren IP in the applicable Field infringes any Third Party's Intellectual Property Rights.

24.3 Indemnity by Neuren

Neuren agrees to indemnify and hold harmless ACADIA, each of ACADIA's Affiliates, and each of ACADIA's and ACADIA's Affiliates directors, officers, employees, contractors and agents ("**ACADIA Indemnified Parties**") against all Losses incurred by or awarded against any ACADIA Indemnified Party as a result of any Claim, to the extent arising out of or in connection with:

(a) Claims made in connection with the Compound or any Product Manufactured by Neuren or any contract manufacturer appointed by Neuren or in connection with the Development, advertising, marketing, distribution or sale of the Compound or any

Product by Neuren or its Affiliates, licensees or sub-licensees outside the applicable Field or pursuant to any rights granted under clause 23.3;

(b) a breach by Neuren, its officers, employees, contractors or agents of this Agreement or the Initial Licence;

(c) a breach by Neuren of any of its warranties or representations contained within this Agreement or the Initial Licence;

(d) the negligence or wilful misconduct of Neuren or its officers, employees, contractors or agents in connection with this Agreement or the Initial Licence; and

(e) any Claims made in connection with the Product to the extent that such claim arises solely from conduct of Neuren which occurred prior to the Commencement Date,

except to the extent caused or contributed to by ACADIA's fraud, negligence or wilful misconduct.

24.4 Indemnification Procedures

Any entity entitled to indemnification under clause 24.2 or 24.3 shall give notice to the indemnifying party of any Losses or Claims that may be subject to indemnification, promptly after learning of such Losses or Claims, and the indemnifying party shall assume the defence of such Claims with counsel reasonably satisfactory to the indemnified party. If such defence is assumed by the indemnifying party with counsel so selected, the indemnifying party will not be subject to any liability for any settlement of such Losses or Claims made by the indemnified party without its consent (but such consent will not be unreasonably withheld or delayed), and will not be obligated to pay the fees and expenses of any separate counsel retained by the indemnified party with respect to such Losses or Claims.

24.5 No liability for consequential loss

Notwithstanding anything else in this Agreement, both parties expressly exclude liability for:

(a) indirect, special, incidental, or consequential loss or damage which may arise in respect of this Agreement; and

(b) loss of profit, business, revenue, goodwill or anticipated savings;

provided, however, that this clause 24.5 shall not be construed to limit either party's liability for breach of clause 18. For the avoidance of doubt, if a party is required to pay or compensate a Third Party for a loss or damage referred to in clause 24.5(a) or (b) as part of a Claim and that party is entitled to an indemnity from the other party in respect of that claim under clause 24.2 or 24.3, the indemnity shall extend to such loss or damage paid to the Third Party and this clause 24.5 shall not be construed to limit either party's indemnification obligations in respect of the amounts paid to that Third Party.

24.6 Product recall

(a) In the event of a recall of any Product in the Territory, which shall be done by:

(i) ACADIA with respect to a Trofinetide Product,

(ii) ACADIA with respect to an NNZ-2591 Product in the NNZ-2591 Field; and

(iii) Neuren with respect to an NNZ-2591 Product outside of the NNZ-2591 Field

(such recalling Party, the "**Recalling Party**") in the sole discretion of the Recalling Party but in compliance with all applicable laws, rules and regulations, the Recalling Party must pay all costs in association with such recall, including reimbursement for the cost of any faulty Product supplied by such Recalling Party, subject to the parties' indemnification obligations under this clause 24.

(b) In any case where a party believes that a change in the risk-benefit-ratio of any Product becomes evident or safety actions due to adverse drug reactions seem to be necessary (for example, change of label, product information, special information/warnings to the

medical profession, patients or authorities or a Product recall), such party will inform the other party of material details in a timely fashion.

25 Publicity

(a) The parties agree to jointly develop the first public announcements by the parties of the execution of this Agreement on the Commencement Date.

(b) ACADIA may issue subsequent public announcements with respect to its Development and Commercialization of Compounds and Products in the applicable Field in the Territory; subject to clause 18 and clauses 25(d) and 25(e).

(c) In subsequent public announcements, Neuren shall not include information regarding the Development and Commercialization of Product in the applicable Field in the Territory that is not already in the public domain without the prior written approval of ACADIA, not to be unreasonably withheld.

(d) The parties agree to consult with each other reasonably and in good faith with respect to the text and timing of public announcements or press releases regarding activities with respect to any Product contemplated by this Agreement prior to the issuance of any such announcement or press releases to the extent not previously disclosed in accordance with this clause 25, provided that a party may not unreasonably withhold, condition or delay consent to such announcements or releases, and that either party may issue such press releases or make such disclosures to the SEC pursuant to Form 8-K or pursuant to local fiscal reporting laws, filing regulations and stock exchange disclosure rules or otherwise as it determines, based on advice of counsel, are reasonably necessary to comply with applicable laws, rules or regulations or for appropriate market disclosure.

(e) The parties will consult with each other on the provisions of this Agreement to be redacted in any filings made by a party with the SEC or as otherwise required by applicable laws, rules or regulations. In addition, following the initial press releases by the parties announcing this Agreement, either party shall be free to disclose, without the other party's prior written consent, the existence of this Agreement, the identity of the other party and those terms of the Agreement which have already been publicly disclosed in accordance herewith.

26 Force majeure

(a) Any delay in the performance of any of the duties or obligations of either party hereto shall not be considered a breach of this Agreement, and the time required for performance shall be extended for a period equal to the period of such delay, if such delay has been caused by or is the result of acts of God; acts of public enemy; insurrections; riots; injunctions; embargoes; labour disputes, including strikes, lockouts, job actions, or boycotts; fires; explosions; earthquakes; floods; shortages of energy; governmental prohibition or restriction; or other unforeseeable causes beyond the reasonable control and without the fault or negligence of the party so affected. The party so affected shall give prompt notice to the other party of such cause, and shall take whatever reasonable steps are necessary to relieve the effect of such cause as rapidly as reasonably possible.

(b) This clause 26 does not apply to any obligations to pay money.

27 Notices

27.1 Method

All notices, requests, demands, consents, approvals, offers, agreements or other communications given by a party under or in connection with this Agreement must be:

(a) in writing;

(b) signed by a person duly authorised by the sender or, where transmitted by e-mail, sent by a person duly authorised by the sender;

(c) directed to the intended recipient's address (as specified in clause 27.3 or as varied by any notice); and

(d) hand delivered, sent by prepaid post or transmitted by e-mail to that address.

27.2 Receipt

A Notice given in accordance with this clause is taken as having been given and received:

(a) if hand delivered, on delivery;

(b) if sent by prepaid post:

(i) within Australia or within the United States, on the third Business Day after the date of posting;

(ii) except as provided in clause 27.2(b)(i), on the seventh Business Day after the date of posting; or

(c) if transmitted by e-mail, on transmission, subject to confirmation of receipt;

but if the delivery or transmission is not on a Business Day or is after 5.00pm (recipient's time) on a Business Day, the notice is taken to be received at 9.00am (recipient's time) on the next Business Day.

27.3 Address of parties

Unless varied by notice in accordance with this clause 27, the parties' addresses and other details are:

Party: Neuren
Attention: […***…]
Address: Suite 201, 697 Burke Road, Camberwell, Victoria, 3124, Australia
E-mail: […***…]

Party: ACADIA
Attention: Liz Carter, VP, Business Development, Head of Strategic Transactions & Partnering
Address: 12830 El Camino Real, Suite 400, San Diego, California 92130, USA
E-mail: […***…]

28 Disputes

28.1 No arbitration or court proceedings

If a dispute arises out of or in relation to this Agreement ("**Dispute**") no party to the Dispute ("**Disputant**") will start arbitration or court proceedings (except proceedings seeking interlocutory relief) unless it has complied with this clause 28. Notwithstanding the foregoing, Disputes within the authority of the JSC as described in clause 5.4(f)(i) or clause 5.4(f)(ii) shall be resolved in the manner provided in clause 5.4(f)(i) or clause 5.4(f)(ii), respectively.

28.2 Notice

A party claiming that a Dispute has arisen must notify each other Disputant in writing giving details of the Dispute and its proposal for a resolution.

28.3 Initial Period

For a […***…] day period after a notice is given, each Disputant must use all reasonable endeavours to resolve the Dispute and the CEO of each Disputant, or their designee, will meet

within the first […***…] days of that period with that aim. Such resolution, if any, of a Dispute shall be final and binding on the parties. All negotiations pursuant to this clause 28 are confidential and shall be treated as compromise and settlement negotiations for purposes of applicable rules of evidence.

28.4 Final Resolution

(a) If the CEOs are unable to settle the dispute within the period described in clause 28.3, the matter will be referred to arbitration for final resolution.

(b) The arbitration will be conducted under the ICC Rules of Arbitration of the International Chamber of Commerce as modified by any other instructions that the parties may agree upon at the time.

(c) There shall be three arbitrators, unless the parties are able to agree on a single arbitrator. In the absence of such agreement within […***…] days after the initiation of an arbitration proceeding, Neuren shall select one arbitrator and ACADIA shall select one arbitrator, and those two arbitrators shall then select, within […***…] days, a third arbitrator. If those two arbitrators are unable to select a third arbitrator within such […***…] day period, a third arbitrator shall be appointed by the ICC International Court of Arbitration. Within […***…] days of the appointment of such third arbitrator, the arbitrators shall issue a decision. The decision in writing of at least two of the three arbitrators shall be final and binding upon the parties.

(d) The governing law for the arbitration will be the law of the State of New York and, unless the parties otherwise agree, the forum for the arbitration will be New York City, New York.

(e) The arbitrators' decision shall be in writing and shall provide a reasoned basis for the resolution of each dispute and for any award.

(f) Each party shall bear its own fees and expenses with respect to the arbitration and any proceeding related thereto and the parties shall share equally the fees and expenses of the ICC International Court of Arbitration and the arbitrators.

(g) The arbitrators shall have power and authority to award any remedy or judgment that could be awarded by a court of law in the State of New York. The award rendered by arbitration shall be final and binding upon the parties, and judgment upon the award may be entered in any court of competent jurisdiction in the United States or in Australia to the extent required for enforcement purposes.

28.5 Costs

Each Disputant must bear its own costs of complying with this clause 28.

29 General

29.1 Entire agreement

Other than the Prior Confidentiality Agreement, this Agreement constitutes the entire agreement between the parties in relation to its subject matter from and after the Commencement Date. All prior discussions, undertakings, agreements, representations, warranties and indemnities in relation to that subject matter other than the Prior Confidentiality Agreement are replaced by this Agreement and have no further effect from and after the Commencement Date.

29.2 Paramountcy of Agreement

If this Agreement conflicts with any other document, agreement or arrangement between the parties, this Agreement prevails to the extent of the inconsistency.

29.3 No merger

The provisions of this Agreement will not merge on completion of any transaction contemplated in this Agreement and, to the extent any provision has not been fulfilled, will remain in force.

29.4 Amendment

This Agreement may not be amended or varied unless the amendment or variation is in writing signed by all parties.

29.5 Assignment; Change of Control

Neither party may assign its rights and obligations under this Agreement without the prior written consent of the other party, except that:

(a) either party may make such assignment without the prior written consent of the other party to an Affiliate (so long as such party shall remain jointly and severally liable with such Affiliate with respect to all obligations so assigned); and

(b) either party may, without the prior written consent of the other party, assign its rights and transfer its duties hereunder to any acquirer of all or substantially all of its business or in the event of such party's merger, consolidation or involvement in a similar transaction.

If Neuren determines to initiate a Change of Control process or transaction, then prior to initiating any discussions or negotiations with a Third Party, but in any event not later than engaging an advisor or investment banker to advise on a Change of Control, Neuren shall notify ACADIA of its initiation of the process or transaction and allow ACADIA to participate in such process or negotiations on the same terms as applicable to all other participants in such process or transaction.

No assignment will release either party from responsibility for the performance of any accrued obligation of such party hereunder. Any purported assignment in contravention of this clause 29.5 will, at the option of the non-assigning party, be null and void and of no effect. This Agreement shall be binding upon and enforceable against the successor to or any permitted assignee from either of the parties.

29.6 Severability

Part or all of any provision of this Agreement that is illegal or unenforceable will be severed from this Agreement and will not affect the continued operation of the remaining provisions of this Agreement.

29.7 Waiver

Waiver of any power or right under this Agreement:

(a) must be in writing signed by the party entitled to the benefit of that power or right; and

(b) is effective only to the extent set out in that written waiver.

29.8 Rights, remedies additional

Any rights and remedies that a person may have under this Agreement are in addition to and do not replace or limit any other rights or remedies that the person may have.

29.9 Further assurances

Each party must use Commercially Reasonable Efforts to do or cause to be done all things necessary or reasonably desirable to give full effect to this Agreement and the transactions contemplated by it (including, but not limited to, the execution of documents).

29.10 Costs

Each party must bear its own legal, accounting and other costs for the preparation and execution of this Agreement.

29.11 Electronic execution and delivery of Agreement

(a) This Agreement may be electronically executed and each person signing this Agreement may sign a separate counterpart of this Agreement.

(b) A company may execute this Agreement by its authorised representative signing electronically or in wet ink. If execution is under common seal, the fixing of the seal may be observed by electronic means.

(c) A party may deliver its executed counterpart or any other document executed in connection with it by electronic means and the delivery will be deemed to be an effective delivery of an originally executed counterpart.

29.12 Counterparts

This Agreement may be executed in any number of counterparts and all counterparts taken together will constitute one document.

29.13 Initial Licence

The parties agree that upon the Commencement Date, the Initial Licence will be amended and restated as set out in this Agreement. The amendment and restatement will not adversely affect any act or thing that was validly done under the Initial Licence prior to the Commencement Date.

29.14 Governing law and jurisdiction

This Agreement will be governed by and construed in accordance with the laws in force in the State of New York, without reference to its conflicts of law principles with the exception of sections 5-1401 and 5-1402 of New York General Obligations Law, and each party submits to the exclusive jurisdiction of the courts of the State of New York.

Schedule 1 Fee Schedule

In this Schedule:

Region A	means the EMA Region plus the United Kingdom, Iceland, Norway, Switzerland and Liechtenstein
Region B	means Japan
Region C	means the New Territory other than Region A and Region B

1 Upfront Fee

The Upfront Fee is US$100 million and will be payable by ACADIA to Neuren within 10 Business Days after signing of this Agreement.

For the avoidance of doubt, this Upfront Fee is in addition to the US$10 million Phase II Reimbursement Fee already paid by ACADIA pursuant to the Initial Licence prior to the Commencement Date.

2 Development Milestone Fee

2.1 Trofinetide Compound and Trofinetide Product

Subject to clauses 2.3(c) and 2.3(e) of this Fee Schedule, the Development Milestone Fees in respect of the Trofinetide Compound and Trofinetide Product are as set out in the following table:

Development Milestone – Initial Territory		**Development Milestone Fee**
1	FDA accepts for review ACADIA's first Rett Syndrome NDA for a Trofinetide Product in the US	US$10 million
2	ACADIA's First Commercial Sale of a Trofinetide Product for Rett Syndrome in the US	US$40 million
3	[…***…]	US$[…***…]
4	[…***…]	US$[…***…]
5	[…***…]	US$[…***…]
Development Milestone – New Territory		**Development Milestone Fee**
1	ACADIA's First Commercial Sale of a Trofinetide Product for Rett Syndrome in the […***…] European Markets (being […***…] Germany […***…])	US$35 million

2	ACADIA's First Commercial Sale of a Trofinetide Product for Rett Syndrome in Japan	US$15 million
3	ACADIA's First Commercial Sale of a Trofinetide Product for a second indication in the […***…] European Markets ([…***…])	US$10 million
4	ACADIA's First Commercial Sale of a Trofinetide Product for a second indication in Japan	US$3.75 million

2.2 NNZ-2591 Compound and NNZ-2591 Product

Subject to clauses 2.3(c) and 2.3(e) of this Fee Schedule, the Development Milestone Fees in respect of the NNZ-2591 Compound and NNZ-2591 Product are as set out in the following table:

Development Milestone – Initial Territory		**Development Milestone Fee**
1	[…***…]	US$[…***…]
2	[…***…]	US$[…***…]
3	[…***…]	US$[…***…]
Development Milestone – New Territory		**Development Milestone Fee**
1	ACADIA's First Commercial Sale of a NNZ-2591 Product for Rett Syndrome in the […***…] European Markets ([…***…])	US$35 million
2	ACADIA's First Commercial Sale of a NNZ-2591 Product for Rett Syndrome in Japan	US$15 million
3	ACADIA's First Commercial Sale of a NNZ-2591 Product for a second indication in the […***…] European Markets ([…***…])	US$10 million
4	ACADIA's First Commercial Sale of a NNZ-2591 Product for a second indication in Japan	US$3.75 million

2.3 Payment of Development Milestone Fees

(a) The Development Milestone Fee will be payable within […***…] days of the achievement of the relevant Development Milestone.

(b) Subject to clause 2.3(c) of this Schedule, and for the avoidance of doubt, if more than one Development Milestone is reached in any year, the relevant Development Milestone Fee for each of those Development Milestones will be payable in accordance with this Agreement.

(c) If ACADIA develops both a Trofinetide Compound and a NNZ-2591 Compound for the same indication in a given territory, each Development Milestone in respect of that indication in the relevant territory will be payable only once, and not payable for each of a Trofinetide Compound and a NNZ-2591 Compound.

(d) Each Development Milestone Fee will be payable only once, upon first achievement regardless of the number of times such Development Milestone is achieved.

(e) The parties acknowledge that Development Milestones 1 and 2 for the Trofinetide Product in the Initial Territory were achieved prior to the Commencement Date and the relevant Development Milestone Fees in respect of those Development Milestones have been paid.

3 Sales Milestone Fees

3.1 Trofinetide Product

The Sales Milestone Fees in respect of Trofinetide Products are as set out in the following table:

Sales Milestone – Initial Territory		**Sales Milestone Fee**
1	The end of the first calendar year in which the aggregate Net Revenue from all Trofinetide Product in the Initial Territory in that calendar year equals or exceeds US$250 million	US$50 million
2	The end of the first calendar year in which the aggregate Net Revenue from all Trofinetide Product in the Initial Territory in that calendar year equals or exceeds US$500 million	US$50 million
3	The end of the first calendar year in which the aggregate Net Revenue from all Trofinetide Product in the Initial Territory in that calendar year equals or exceeds US$750 million	US$100 million
4	The end of the first calendar year in which the aggregate Net Revenue from all Trofinetide Product in the Initial Territory in that calendar year equals or exceeds US$1,000 million	US$150 million
Sales Milestone – Region A		**Sales Milestone Fee**
1	The end of the first calendar year in which the aggregate Net Revenue from all Trofinetide Product in Region A in that calendar year equals or exceeds US$120 million	US$15 million
2	The end of the first calendar year in which the aggregate Net Revenue from all Trofinetide Product in Region A in that calendar year equals or exceeds US$240 million	US$30 million
3	The end of the first calendar year in which the aggregate Net Revenue from all Trofinetide Product in Region A in that calendar year equals or exceeds US$400 million	US$50 million
4	The end of the first calendar year in which the aggregate Net Revenue from all Trofinetide Product in Region A in that calendar year equals or exceeds US$600 million	US$75 million

Sales Milestone – Region B		Sales Milestone Fee
	The end of the first calendar year in which the aggregate Net Revenue from all Trofinetide Product in Region B in that calendar year equals or exceeds US$[…***…]	US$[…***…]
	The end of the first calendar year in which the aggregate Net Revenue from all Trofinetide Product in Region B in that calendar year equals or exceeds US$[…***…]	US$[…***…]
	The end of the first calendar year in which the aggregate Net Revenue from all Trofinetide Product in Region B in that calendar year equals or exceeds US$[…***…]	US$[…***…]
	The end of the first calendar year in which the aggregate Net Revenue from all Trofinetide Product in Region B in that calendar year equals or exceeds US$[…***…]	US$[…***…]
Sales Milestone – Region C		**Sales Milestone Fee**
	The end of the first calendar year in which the aggregate Net Revenue from all Trofinetide Product in Region C in that calendar year equals or exceeds US$[…***…]	US$[…***…]
	The end of the first calendar year in which the aggregate Net Revenue from all Trofinetide Product in Region C in that calendar year equals or exceeds US$[…***…]	US$[…***…]
	The end of the first calendar year in which the aggregate Net Revenue from all Trofinetide Product in Region C in that calendar year equals or exceeds US$[…***…]	US$[…***…]
	The end of the first calendar year in which the aggregate Net Revenue from all Trofinetide Product in Region C in that calendar year equals or exceeds US$[…***…]	US$[…***…]

3.2 NNZ-2591 Product

The Sales Milestone Fees in respect of NNZ-2591 Products are as set out in the following table:

Sales Milestone – Initial Territory		Sales Milestone Fee
1	The end of the first calendar year in which the aggregate Net Revenue from all NNZ-2591 Product in the Initial Territory in that calendar year equals or exceeds US$250 million	US$50 million
2	The end of the first calendar year in which the aggregate Net Revenue from all NNZ-2591 Product in the Initial Territory in that calendar year equals or exceeds US$500 million	US$50 million

3	The end of the first calendar year in which the aggregate Net Revenue from all NNZ-2591 Product in the Initial Territory in that calendar year equals or exceeds US$750 million	US$100 million
4	The end of the first calendar year in which the aggregate Net Revenue from all NNZ-2591 Product in the Initial Territory in that calendar year equals or exceeds US$1,000 million	US$150 million
Sales Milestone – Region A		**Sales Milestone Fee**
1	The end of the first calendar year in which the aggregate Net Revenue from all NNZ-2591 Product in Region A in that calendar year equals or exceeds US$[…***…]	US$[…***…]
2	The end of the first calendar year in which the aggregate Net Revenue from all NNZ-2591 Product in Region A in that calendar year equals or exceeds US$[…***…]	US$[…***…]
3	The end of the first calendar year in which the aggregate Net Revenue from all NNZ-2591 Product in Region A in that calendar year equals or exceeds US$[…***…]	US$[…***…]
4	The end of the first calendar year in which the aggregate Net Revenue from all NNZ-2591 Product in Region A in that calendar year equals or exceeds US$[…***…]	US$[…***…]
Sales Milestone – Region B		**Sales Milestone Fee**
	The end of the first calendar year in which the aggregate Net Revenue from all NNZ-2591 Product in Region B in that calendar year equals or exceeds US$[…***…]	US$[…***…]
	The end of the first calendar year in which the aggregate Net Revenue from all NNZ-2591 Product in Region B in that calendar year equals or exceeds US$[…***…]	US$[…***…]
	The end of the first calendar year in which the aggregate Net Revenue from all NNZ-2591 Product in Region B in that calendar year equals or exceeds US$[…***…]	US$[…***…]

	The end of the first calendar year in which the aggregate Net Revenue from all NNZ-2591 Product in Region B in that calendar year equals or exceeds US$[…***…]	US$[…***…]
Sales Milestone – Region C		**Sales Milestone Fee**
	The end of the first calendar year in which the aggregate Net Revenue from all NNZ-2591 Product in Region C in that calendar year equals or exceeds US$[…***…]	US$[…***…]
	The end of the first calendar year in which the aggregate Net Revenue from all NNZ-2591 Product in Region C in that calendar year equals or exceeds US$[…***…]	US$[…***…]
	The end of the first calendar year in which the aggregate Net Revenue from all NNZ-2591 Product in Region C in that calendar year equals or exceeds US$[…***…]	US$[…***…]
	The end of the first calendar year in which the aggregate Net Revenue from all NNZ-2591 Product in Region C in that calendar year equals or exceeds US$[…***…]	US$[…***…]

3.3 Payment of Sales Milestone Fees

(a) The Sales Milestone Fee will be payable within […***…] days of the achievement of the relevant Sales Milestone.

(b) Each Sales Milestone Fee will be payable only once, upon first achievement of that Sales Milestone, regardless of the number of times that Sales Milestone is achieved or the number of Products that achieves it.

(c) For the avoidance of doubt:

(i) if more than one Sales Milestone is reached in any year, the relevant Sales Milestone Fee for each of those Sales Milestones will be payable in accordance with this Agreement; and

(ii) if a Sales Milestone is reached for both Trofinetide Product and NNZ-2591 Product in any year, the relevant Sales Milestone Fee for each of those Products will be payable in accordance with this Agreement.

4 Royalties

4.1 Royalty Payments – Trofinetide Product, Initial Territory

Subject to the royalty reductions set forth in clause 4.3 of this Fee Schedule, and during the applicable Exclusivity Period, ACADIA shall pay to Neuren, on a Quarterly basis, a running royalty on aggregate Net Revenues of all countries in the Initial Territory at the following incremental royalty rates calculated on a country-by-country basis on total Net Revenue of all Trofinetide Product in the Initial Territory in the applicable Quarter:

Aggregate Annual Net Revenue – Initial Territory	Royalty Rate
For the portion of aggregate annual Net Revenue of all Trofinetide Product in the Initial Territory less than or equal to Two Hundred and Fifty Million Dollars (US$250,000,000) (i.e. ≤ US$250,000,000)	Ten Percent (10%)
For the portion of aggregate annual Net Revenue of all Trofinetide Product in the Initial Territory greater than Two Hundred and Fifty Million Dollars (US$250,000,000) but less than or equal to Five Hundred Million Dollars (US$500,000,000) (i.e. > US$250,000,000 but ≤ US$500,000,000)	Twelve Percent (12%)
For the portion of aggregate annual Net Revenue of all Trofinetide Product in the Initial Territory greater than Five Hundred Million Dollars (US$500,000,000) but less than or equal to Seven Hundred and Fifty Million Dollars (US$750,000,000) (i.e. > US$500,000,000 and ≤ US$750,000,000)	Fourteen Percent (14%)
For the portion of aggregate annual Net Revenue of all Trofinetide Product in the Initial Territory greater than Seven Hundred and Fifty Million Dollars (US$750,000,000) (i.e. > US$750,000,000)	Fifteen Percent (15%)

For example, if the Annual Net Revenue for all Trofinetide Product in the Initial Territory is US$3,000,000, comprised of Annual Net Revenue in the United States of US$2,500,000 and US$500,000 in Mexico. If a Generic Product in respect of that Trofinetide Product is sold in Mexico during such Quarter, then the royalty payable pursuant to this clause 4.1 in Mexico would be subject to the 50% royalty reduction set forth in clause 4.3(a). Total royalties payable on total Annual Net Revenues would be US$275,000 calculated as:

(Annual Net Revenue in the United States (US$2,500,000) multiplied by the applicable royalty rate (10%)) plus

(Annual Net Revenue in Mexico (US$500,000) multiplied by the reduced applicable royalty rate (5%) for such country).

4.2 Royalty Payments – Trofinetide Product, New Territory

During the applicable Exclusivity Period, ACADIA shall pay to Neuren, on a Quarterly basis, a running royalty on aggregate Net Revenues for a given Trofinetide Product in each of Region A, Region B and Region C in the Territory at the following incremental royalty rates calculated on a Region-by-Region basis on total Net Revenue of all Trofinetide Product in that Region in the applicable Quarter:

Aggregate Annual Net Revenue – Region A, Region B and Region C in the New Territory	Royalty Rate
For the portion of aggregate annual Net Revenue of all Trofinetide Product in the relevant Region less than or equal to One Hundred and Fifty Million Dollars (US$150,000,000) (i.e. ≤ US$150,000,000)	Region A: Seventeen Percent (17%) Region B: […***…] Percent ([…***…]%) Region C: […***…] Percent ([…***…]%)

Aggregate Annual Net Revenue – Region A, Region B and Region C in the New Territory	Royalty Rate
For the portion of aggregate annual Net Revenue of all Trofinetide Product in the relevant Region greater than One Hundred and Fifty Million Dollars ($150,000,000) but less than or equal to Three Hundred Million Dollars ($300,000,000) (i.e. > US$150,000,000 but ≤ US$300,000,000)	Region A: Twenty Percent (20%) Region B: […***…] Percent ([…***…]%) Region C: […***…] Percent ([…***…]%)
For the portion of aggregate annual Net Revenue of all Trofinetide Product in the relevant Region greater than Three Hundred Million Dollars (US$300,000,000) (i.e. > US$300,000,000)	Region A: Twenty-Three Percent (23%) Region B: […***…] Percent ([…***…]%) Region C: […***…] Percent ([…***…]%)

4.3 Royalty Reduction – Trofinetide Product

(a) Generic Entry. The royalty rates set forth in clauses 4.1 of this Fee Schedule that are applied to the Net Revenue of Trofinetide Product in a country shall be reduced by 50% if a Generic Product in respect of that Trofinetide Product is sold in such country, beginning in the first Quarter during which such Generic Product is sold in such country.

(b) Third Party Licences. ACADIA shall be responsible for paying the licence fees, royalties, and milestones with respect to Third Party licences for intellectual property that ACADIA reasonably believes are necessary or reasonably useful for the Development, Manufacturing or Commercialization of the Trofinetide Product in the Territory. For such Third Party licences, ACADIA will be entitled to deduct up to 33% of all such amounts due to such Third Party from Royalties payable to Neuren pursuant to clauses 4.1 of this Fee Schedule.

4.4 Royalty Payments – NNZ-2591 Product, Initial Territory

Subject to the royalty reductions set forth in clause 4.6 of this Fee Schedule, and during the applicable Exclusivity Period, ACADIA shall pay to Neuren, on a Quarterly basis, a running royalty on aggregate Net Revenues of all countries in the Initial Territory at the following incremental royalty rates calculated on a country-by-country basis on total Net Revenue of all NNZ-2591 Product in the Initial Territory in the applicable Quarter:

Aggregate Annual Net Revenue – Initial Territory	Royalty Rate
For the portion of aggregate annual Net Revenue of all NNZ-2591 Product in the Initial Territory less than or equal to Two Hundred and Fifty Million Dollars (US$250,000,000) (i.e. ≤ US$250,000,000)	Ten Percent (10%)

Aggregate Annual Net Revenue – Initial Territory	Royalty Rate
For the portion of aggregate annual Net Revenue of all NNZ-2591 Product in the Initial Territory greater than Two Hundred and Fifty Million Dollars (US$250,000,000) but less than or equal to Five Hundred Million Dollars (US$500,000,000) (i.e. > US$250,000,000 but ≤ US$500,000,000)	Twelve Percent (12%)
For the portion of aggregate annual Net Revenue of all NNZ-2591 Product in the Initial Territory greater than Five Hundred Million Dollars (US$500,000,000) but less than or equal to Seven Hundred and Fifty Million Dollars (US$750,000,000) (i.e. > US$500,000,000 and ≤ US$750,000,000)	Fourteen Percent (14%)
For the portion of aggregate annual Net Revenue of all NNZ-2591 Product in the Initial Territory greater than Seven Hundred and Fifty Million Dollars (US$750,000,000) (i.e. > US$750,000,000)	Fifteen Percent (15%)

For example, if the Annual Net Revenue for NNZ-2591 Product in the Initial Territory is US$3,000,000, comprised of Annual Net Revenue in the United States of US$2,500,000 and US$500,000 in Mexico. If a Generic Product in respect of that NNZ-2591 Product is sold in Mexico during such Quarter, then the royalty payable pursuant to this clause 4.4 in Mexico would be subject to the 50% royalty reduction set forth in clause 4.3(a). Total royalties payable on total Annual Net Revenues would be US$275,000 calculated as:

(Annual Net Revenue in the United States (US$2,500,000) multiplied by the applicable royalty rate (10%)) plus

(Annual Net Revenue in Mexico (US$500,000) multiplied by the reduced applicable royalty rate (5%) for such country).

4.5 Royalty Payments – NNZ-2591 Product, New Territory

During the applicable Exclusivity Period, ACADIA shall pay to Neuren, on a Quarterly basis, a running royalty on aggregate net revenues for all NNZ-2591 Product in Region A, Region B and Region C in the Territory at the following incremental royalty rates calculated on a Region-by-Region basis on total Net Revenue of all NNZ-2591 Product in that Region in the applicable Quarter:

Aggregate Annual Net Revenue – Region A, Region B and Region C in the New Territory	Royalty Rate
For the portion of aggregate annual Net Revenue of all NNZ-2591 Product in the relevant Region less than or equal to […***…]	Region A: […***…] Percent ([…***…]%) Region B: […***…] Percent ([…***…]%) Region C: […***…] Percent ([…***…]%)
For the portion of aggregate annual Net Revenue of all NNZ-2591 Product in the relevant Region greater than […***…] but less than or equal to […***…]	Region A: […***…] Percent ([…***…]%) Region B: […***…] Percent ([…***…]%) Region C: […***…] Percent ([…***…]%)

Aggregate Annual Net Revenue – Region A, Region B and Region C in the New Territory	Royalty Rate
For the portion of aggregate annual Net Revenue of all NNZ-2591 Product in the relevant Region greater than […***…]	Region A: […***…] Percent ([…***…]%) Region B: […***…] Percent ([…***…]%) Region C: […***…] Percent ([…***…]%)

4.6 Royalty Reduction – NNZ-2591 Product

(a) Generic Entry. The royalty rates set forth in clauses 4.4 of this Fee Schedule that are applied to the Net Revenue of NNZ-2591 Product in a country shall be reduced by […***…]% if a Generic Product in respect of that NNZ-2591 Product is sold in such country, beginning in the first Quarter during which such Generic Product is sold in such country.

(b) Third Party Licences. ACADIA shall be responsible for paying the licence fees, royalties, and milestones with respect to Third Party licences for intellectual property that ACADIA reasonably believes are necessary or reasonably useful for the Development, Manufacturing or Commercialization of the NNZ-2591 Product in the Territory. For such Third Party licences, ACADIA will be entitled to deduct up to […***…]% of all such amounts due to such Third Party from Royalties payable to Neuren pursuant to clause 4.4 of this Fee Schedule.

5 Sub-Licensee Fee

5.1 Sub-Licensee Fee –in New Territory

If:

(a) ACADIA appoints a Sub-Licensee for any Product in a country or region in the New Territory pursuant to a sub-licence agreement executed during the two year period commencing on the Commencement Date, and

(b) ACADIA receives from the Sub-Licensee any:

(i) upfront fee; or

(ii) pre-launch milestone fee (including any first commercial sale milestone fee),

(collectively, **Relevant Fees**),

ACADIA will pay to Neuren a percentage of the Relevant Fees, as set out in the following table:

When sub-licence agreement is executed	Neuren percentage of Relevant Fees
During the 12 month period commencing on the Commencement Date and ending on the day prior to the first anniversary the Commencement Date	[…***…]%
During the 12 month period commencing on the first anniversary of the Commencement Date and ending on the day prior to the second anniversary of the Commencement Date	[…***…]%

5.2 Credit of Sub-Licensee Fee

Any Sub-Licensee Fee paid by ACADIA to Neuren under clause 5.1 in respect of any Product in any country or region of the New Territory will be credited against any Development Milestones, Sales Milestones or Royalty payments payable by ACADIA to Neuren for that Product in that country or region of the New Territory.

Schedule of Patents and Patent Applications

1 Part A –Trofinetide Patents

Territory	Patent number	Title	Filing	Grant date
[...***...]	[...***...]	[...***...]	[...***...]	[...***...]

Territory	Application number	Title	International Filing Date
[...***...]	[...***...]	[...***...]	[...***...]

2 Part B – NNZ-2591 Patents

Territory	Patent number	Title	Filing	Grant date
[...***...]	[...***...]	[...***...]	[...***...]	[...***...]

Territory	Application number	Title	International Filing Date
[...***...]	[...***...]	[...***...]	[...***...]

EXHIBIT A - DEFINITION OF COMPOUND

[…***…]

Signing Page

EXECUTED as an **agreement**

EXECUTED by **NEUREN PHARMACEUTICALS LIMITED** by its duly authorised signatory:)
)
)

/s/ Jon Pilcher
Signature of authorised signatory

Jon Pilcher
Full name of authorised signatory (print)

EXECUTED by **ACADIA PHARMACEUTICALS INC.** by its duly authorised signatory:)
)
)

/s/ Steve Davis
Signature of authorised signatory

Steve Davis
Full name of authorised signatory (print)

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: November 4, 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: November 4, 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 September 30, 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: November 4, 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 September 30, 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: November 4, 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.