

**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, 2023

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  
(State of Incorporation)

12830 El Camino Real, Suite 400  
San Diego, California  
(Address of Principal Executive Offices)

06-1376651  
(I.R.S. Employer Identification No.)

92130  
(Zip Code)

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

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

<u>Title of Each Class</u>	<u>Trading Symbol</u>	<u>Name of Each Exchange on Which Registered</u>
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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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 25, 2023:

<u>Class</u>	<u>Number of Shares Outstanding</u>
Common Stock, \$0.0001 par value	164,180,377

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, 2023 (unaudited)	December 31, 2022
<b>Assets</b>		
Cash and cash equivalents	\$ 98,193	\$ 114,846
Investment securities, available-for-sale	247,727	301,977
Accounts receivable, net	92,802	62,195
Interest and other receivables	1,730	885
Inventory	20,768	6,636
Prepaid expenses	37,950	21,398
Total current assets	499,170	507,937
Property and equipment, net	4,884	6,021
Operating lease right-of-use assets	50,758	55,573
Intangible assets, net	66,855	—
Restricted cash	5,770	5,770
Long-term inventory	4,628	4,924
Other assets	475	7,587
Total assets	\$ 632,540	\$ 587,812
<b>Liabilities and stockholders' equity</b>		
Accounts payable	\$ 12,310	\$ 12,746
Accrued liabilities	197,293	112,884
Total current liabilities	209,603	125,630
Operating lease liabilities	48,103	52,695
Other long-term liabilities	12,660	9,074
Total liabilities	270,366	187,399
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized at September 30, 2023 and December 31, 2022; no shares issued and outstanding at September 30, 2023 and December 31, 2022	—	—
Common stock, \$0.0001 par value; 225,000,000 shares authorized at September 30, 2023 and December 31, 2022; 163,968,949 shares and 162,064,872 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	16	16
Additional paid-in capital	2,839,111	2,770,923
Accumulated deficit	(2,476,634)	(2,369,551)
Accumulated other comprehensive loss	(319)	(975)
Total stockholders' equity	362,174	400,413
Total liabilities and stockholders' equity	\$ 632,540	\$ 587,812

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

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
<b>Revenues</b>				
Product sales, net	\$ 211,699	\$ 130,714	\$ 495,396	\$ 380,745
Total revenues	211,699	130,714	495,396	380,745
<b>Operating expenses</b>				
Cost of product sales	14,622	2,136	23,747	7,753
Research and development	156,963	81,336	284,878	285,837
Selling, general and administrative	97,890	78,108	295,094	264,688
Total operating expenses	269,475	161,580	603,719	558,278
Loss from operations	(57,776)	(30,866)	(108,323)	(177,533)
Interest income, net	4,125	2,295	12,475	2,980
Other income	1,508	2,156	5,109	1,999
Loss before income taxes	(52,143)	(26,415)	(90,739)	(172,554)
Income tax expense	13,033	768	16,344	1,696
Net loss	\$ (65,176)	\$ (27,183)	\$ (107,083)	\$ (174,250)
Net loss per common share, basic and diluted	\$ (0.40)	\$ (0.17)	\$ (0.65)	\$ (1.08)
Weighted average common shares outstanding, basic and diluted	164,234	161,852	163,488	161,580

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

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Net loss	\$ (65,176)	\$ (27,183)	\$ (107,083)	\$ (174,250)
Other comprehensive income (loss):				
Unrealized gain (loss) on investment securities	223	(527)	662	(1,187)
Foreign currency translation adjustments	(7)	6	(6)	14
Comprehensive loss	<u>\$ (64,960)</u>	<u>\$ (27,704)</u>	<u>\$ (106,427)</u>	<u>\$ (175,423)</u>

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

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

	<b>Nine Months Ended September 30,</b>	
	<b>2023</b>	<b>2022</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (107,083)	\$ (174,250)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	48,398	53,787
Amortization of premiums and accretion of discounts on investment securities	(5,754)	(642)
Amortization of intangible assets	2,728	—
Gain on strategic investment	(5,109)	(1,998)
Loss on sale of investment securities	524	—
Depreciation	1,187	1,537
Changes in operating assets and liabilities:		
Accounts receivable, net	(30,607)	8,633
Interest and other receivables	(845)	575
Inventory	(13,741)	2,105
Prepaid expenses	(16,552)	899
Other assets	(32)	4,845
Operating lease right-of-use assets	5,029	(48)
Accounts payable	(436)	3,132
Accrued liabilities	55,037	17,771
Operating lease liabilities	(5,017)	(5,959)
Long-term liabilities	3,586	(568)
Net cash used in operating activities	<u>(68,687)</u>	<u>(90,181)</u>
<b>Cash flows from investing activities</b>		
Purchases of investment securities	(265,878)	(269,626)
Sale and maturity of investment securities	326,020	360,615
Proceeds from sales of strategic investment	12,253	—
Purchases of property and equipment	(50)	—
Intangible assets	(40,000)	—
Net cash provided by investing activities	<u>32,345</u>	<u>90,989</u>
<b>Cash flows from financing activities</b>		
Proceeds from issuance of common stock, net of issuance costs	19,695	6,585
Net cash provided by financing activities	<u>19,695</u>	<u>6,585</u>
Effect of exchange rate changes on cash	(6)	14
Net (decrease) increase in cash, cash equivalents and restricted cash	<u>(16,653)</u>	<u>7,407</u>
<b>Cash, cash equivalents and restricted cash</b>		
Beginning of period	120,616	153,205
End of period	<u>\$ 103,963</u>	<u>\$ 160,612</u>
<b>Supplemental disclosure of noncash information:</b>		
Accrued milestone and contingent payments in connection with asset acquisition	\$ 29,583	\$ —

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

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2023</b>	<b>2022</b>	<b>2023</b>	<b>2022</b>
<b>Total stockholders' equity, beginning balances</b>	<b>\$ 395,793</b>	<b>\$ 434,848</b>	<b>\$ 400,413</b>	<b>\$ 540,894</b>
Common stock:				
Beginning balance	16	16	16	16
Ending balance	16	16	16	16
Additional paid-in capital:				
Beginning balance	2,807,770	2,736,318	2,770,923	2,694,646
Issuance of common stock from exercise of stock options and units	12,751	287	17,032	3,560
Issuance of common stock pursuant to employee stock purchase plan	—	—	2,663	3,025
Stock-based compensation	18,590	18,256	48,493	53,630
Ending balance	2,839,111	2,754,861	2,839,111	2,754,861
Accumulated deficit:				
Beginning balance	(2,411,458)	(2,300,643)	(2,369,551)	(2,153,576)
Net loss	(65,176)	(27,183)	(107,083)	(174,250)
Ending balance	(2,476,634)	(2,327,826)	(2,476,634)	(2,327,826)
Other comprehensive (loss) income:				
Beginning balance	(535)	(843)	(975)	(192)
Other comprehensive income (loss)	216	(522)	656	(1,173)
Ending balance	(319)	(1,365)	(319)	(1,365)
<b>Total stockholders' equity, ending balances</b>	<b>\$ 362,174</b>	<b>\$ 425,686</b>	<b>\$ 362,174</b>	<b>\$ 425,686</b>

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

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

**1. Organization and Business**

Acadia Pharmaceuticals Inc. (the Company), based in San Diego, California, is a biopharmaceutical company focused on the development and commercialization of innovative medicines to address unmet medical needs in central nervous system (CNS) disorders and rare diseases.

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.

**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, 2022 included in the Company's Annual Report on Form 10-K (Annual Report) filed with the Securities and Exchange Commission (the SEC). The accompanying 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 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 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 financial statements and the accompanying notes. Actual results could differ materially from those estimates.

*Risk and Uncertainties*

Global economic and business activities continue to face widespread macroeconomic uncertainties, including labor shortages, inflation and monetary supply shifts, recession risks, recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures and potential disruptions from the ongoing Russia-Ukraine conflict and related sanctions, and the ongoing conflict in Israel. 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 following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the condensed consolidated statements of cash flows that sum to the total of the same such amounts shown in the condensed consolidated statements of cash flows (in thousands):

	<b>Nine Months Ended September 30, 2023</b>		<b>Nine Months Ended September 30, 2022</b>	
	<b>Beginning of period</b>	<b>End of period</b>	<b>Beginning of period</b>	<b>End of period</b>
Cash and cash equivalents	\$ 114,846	\$ 98,193	\$ 147,435	\$ 154,842
Restricted cash	5,770	5,770	5,770	5,770
Total cash, cash equivalents and restricted cash shown in the condensed consolidated statements of cash flows	<u>\$ 120,616</u>	<u>\$ 103,963</u>	<u>\$ 153,205</u>	<u>\$ 160,612</u>



## 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. The Company has not historically experienced significant credit losses. Based on its assessment, as of September 30, 2023 the Company determined that an allowance for credit loss was not required.

## 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, all of which are sales in the U.S. Revenues by product are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
NUPLAZID	\$ 144,828	\$ 130,714	\$ 405,308	\$ 380,745
DAYBUE	66,871	—	90,088	—
Product sales, net	<u>\$ 211,699</u>	<u>\$ 130,714</u>	<u>\$ 495,396</u>	<u>\$ 380,745</u>

## 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.

In connection with the first commercial sale of DAYBUE in April 2023, the Company made a milestone payment of \$40.0 million pursuant to its 2018 license agreement with Neuren Pharmaceuticals Limited (Neuren), as disclosed in Note 9. The Company capitalized the \$40.0 million payment as an intangible asset and began amortizing the asset in April 2023 on a straight-line basis over the estimated useful life of the licensed patents through early 2036. The Company recorded amortization expense related to this intangible asset of \$0.8 million and \$1.6 million for the three and nine months ended September 30, 2023, respectively. As of September 30, 2023, estimated future amortization expense related to the Company's intangible asset was \$0.8 million for the remainder of 2023, and \$3.1 million for each subsequent year.

Following the FDA approval of DAYBUE, the Company was granted a Rare Pediatric Disease Priority Review Voucher (PRV). 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. If the PRV is sold, the amount to be paid will be the sale value net of applicable fees. If the PRV is not sold but used by the Company, the amount to be paid will be the average price of the three most recent publicly announced sales of Rare Pediatric Disease PRVs immediately preceding the issuance of the PRV to the Company. The Company capitalized the \$29.6 million for the estimated PRV value owed to Neuren as an intangible asset and began amortizing it in April 2023 on a straight-line basis over the estimated useful life of the licensed patents through early 2036. The Company recorded amortization expense related to this intangible asset of \$0.6 million and \$1.2 million for the three and nine months ended September 30, 2023, respectively. As of September 30, 2023, estimated future amortization expense related to the Company's intangible asset was \$0.6 million for the remainder of 2023, and \$2.3 million for each subsequent year.

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

## Intangible Assets

Finite-lived intangible assets are recorded at cost, net of accumulated amortization, and, if applicable, impairment charges. Amortization of finite-lived intangible assets is recorded over the assets' estimated useful lives on a straight-line basis or based on the pattern in which economic benefits are consumed, if reliably determinable. We review our finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If such intangible assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of intangible the 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, 2023.

### 3. Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss 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 this calculation, stock options, employee stock purchase plan rights and restricted stock units are considered to be common stock equivalents but are not included in the calculations of diluted net loss per share for the periods presented as their effect would be anti-dilutive. The Company incurred net losses for all periods presented and there were no reconciling items for potentially dilutive securities. More specifically, at September 30, 2023 and 2022, stock options, employee stock purchase plan rights, restricted stock units, and warrants totaling approximately 22,109,000 shares and 21,652,000 shares, respectively, were excluded from the calculation of diluted net loss per share as their effect would have been anti-dilutive.

### 4. Stock-Based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Cost of product sales	\$ 276	\$ 344	\$ 644	\$ 1,013
Research and development	5,063	6,452	12,701	19,148
Selling, general and administrative	13,200	11,516	35,053	33,626
	<u>\$ 18,539</u>	<u>\$ 18,312</u>	<u>\$ 48,398</u>	<u>\$ 53,787</u>

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. Performance-based stock awards vest upon the achievement of certain pre-defined company-specific performance-based criteria. Expense related to these performance-based stock awards is generally recognized ratably over the expected performance period once the pre-defined performance-based criteria for vesting becomes probable.

## 5. Balance Sheet Details

Inventory consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Finished goods	\$ 4,927	\$ 1,926
Work in process	4,209	4,427
Raw material	16,260	5,207
	<u>\$ 25,396</u>	<u>\$ 11,560</u>
Reported as:		
Inventory	\$ 20,768	\$ 6,636
Long-term inventory	4,628	4,924
Total	<u>\$ 25,396</u>	<u>\$ 11,560</u>

Amount reported as long-term inventory consisted of raw materials for NUPLAZID as of September 30, 2023 and December 31, 2022. The Company has raw materials beyond a one year production plan that help limit the exposures from potential supply interruption. Those raw materials beyond the one year production plan were classified as long-term inventory.

Accrued liabilities consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Accrued sales allowances	\$ 66,358	\$ 26,046
Accrued compensation and benefits	34,160	28,023
Accrued contingent payments	29,583	—
Accrued research and development services	25,304	35,048
Accrued consulting and professional fees	15,457	11,377
Current portion of lease liabilities	9,031	9,305
Accrued taxes	8,452	377
Other	8,948	2,708
	<u>\$ 197,293</u>	<u>\$ 112,884</u>

## 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, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury notes	\$ 42,180	\$ —	\$ (90)	\$ 42,090
Government sponsored enterprise securities	205,876	28	(267)	205,637
	<u>\$ 248,056</u>	<u>\$ 28</u>	<u>\$ (357)</u>	<u>\$ 247,727</u>
	December 31, 2022			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury notes	\$ 15,956	\$ —	\$ (11)	\$ 15,945
Government sponsored enterprise securities	81,216	16	(291)	80,941
Corporate debt securities	20,873	—	(98)	20,775
Commercial paper	184,923	30	(637)	184,316
	<u>\$ 302,968</u>	<u>\$ 46</u>	<u>\$ (1,037)</u>	<u>\$ 301,977</u>

The Company has classified all of its available-for-sale investment securities as current assets on its 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 Company has classified all equity securities as other assets on its condensed consolidated balance sheets.

At September 30, 2023 and December 31, 2022, the Company had 29 and 43 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, 2023 and December 31, 2022, 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
<b>September 30, 2023</b>						
U.S. Treasury notes	\$ 42,090	\$ (90)	\$ —	\$ —	\$ 42,090	\$ (90)
Government sponsored enterprise securities	168,112	(267)	—	—	168,112	(267)
Total	<u>\$ 210,202</u>	<u>\$ (357)</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 210,202</u>	<u>\$ (357)</u>

	Less Than 12 Months		12 Months or Greater		Total	
	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses
<b>December 31, 2022</b>						
U.S. Treasury notes	\$ 15,945	\$ (11)	\$ —	\$ —	\$ 15,945	\$ (11)
Government sponsored enterprise securities	58,254	(291)	—	—	58,254	(291)
Corporate debt securities	20,775	(98)	—	—	20,775	(98)
Commercial paper	135,200	(637)	—	—	135,200	(637)
Total	<u>\$ 230,174</u>	<u>\$ (1,037)</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 230,174</u>	<u>\$ (1,037)</u>

During the first quarter of 2023, the Company made a sale of all of its investments in commercial paper. The proceeds from sales of these securities were \$183.0 million and net realized losses from the related sales were \$0.5 million. There were no other sales of available-for-sale investment securities in prior periods.

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, 2023, 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, 2023.

## 7. Fair Value Measurements

The Company's investments include cash equivalents, available-for-sale investment securities consisting of money market funds, municipal bonds, and government sponsored enterprises in accordance with the Company's investment policy, and equity securities. 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, available-for-sale investment securities and equity securities are classified within the fair value hierarchy as defined by authoritative guidance. The Company's investment securities and equity 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, 2023 and December 31, 2022.

In November 2021, the Company established a plan whereby substantially all full-time employees excluding executive management are eligible to receive a series of cash bonuses based on achievement of certain conditions as described in more detail in Note 8 to the condensed consolidated financial statements included in this quarterly report on Form 10-Q (this Quarterly Report). The Company estimated the fair value of the cash awards using a Monte Carlo simulation, which utilizes level 3 inputs such as volatility, probabilities of success, and other inputs that are not observable in active markets. The cash awards are required to be measured at fair value on a recurring basis each reporting period, with changes in the fair value recognized as compensation cost over the derived service period of the awards.

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, 2023 and December 31, 2022 consisted of the following (in thousands):

	September 30, 2023	Fair Value Measurements at Reporting Date Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets</b>				
Money market fund	\$ 43,908	\$ 43,908	\$ —	\$ —
U.S. Treasury notes	42,090	42,090	—	—
Government sponsored enterprise securities	205,637	—	205,637	—
Total	<u>\$ 291,635</u>	<u>\$ 85,998</u>	<u>\$ 205,637</u>	<u>\$ —</u>
<b>Liabilities</b>				
Cash awards	\$ 1,114	\$ —	\$ —	\$ 1,114
Total	<u>\$ 1,114</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,114</u>

	Fair Value Measurements at Reporting Date Using			
	December 31, 2022	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets</b>				
Money market fund	\$ 72,578	\$ 72,578	\$ —	\$ —
U.S. Treasury notes	15,945	15,945	—	—
Equity securities	7,180	7,180	—	—
Government sponsored enterprise securities	94,803	—	94,803	—
Municipal bonds	20,775	—	20,775	—
Commercial paper	184,316	—	184,316	—
Total	<u>\$ 395,597</u>	<u>\$ 95,703</u>	<u>\$ 299,894</u>	<u>\$ —</u>
<b>Liabilities</b>				
Cash awards	\$ 898	\$ —	\$ —	\$ 898
Total	<u>\$ 898</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 898</u>

Changes in estimated fair value of contingent cash awards during the nine months ended September 30, 2023 are as follows (in thousands):

Balance as of December 31, 2022	\$ 898
Vesting of awards	508
Expense forfeited	(117)
Change in fair value	(175)
Balance as of September 30, 2023	<u>\$ 1,114</u>

## 8. Stockholders' Equity

### Contingent Cash Awards

In November 2021, the Company established a plan whereby substantially all full-time employees excluding executive management are eligible to receive a series of cash bonuses over certain periods based on continued employment and the Company's stock price reaching a pre-specified target. The maximum potential payout of the cash awards at the grant date was \$15.1 million. The Company has determined that the cash awards were classified as liabilities pursuant to ASC Topic 718, *Compensation – Stock Compensation*. The Company estimates the fair value of the awards at each reporting period using a Monte Carlo simulation, which is recognized as compensation cost over the derived service period. Total fair value of the awards at the grant date was \$4.4 million. The maximum potential payout at September 30, 2023 after adjusting for forfeitures was \$10.3 million. The fair value of the awards at September 30, 2023 was approximately \$1.5 million. During the three months ended September 30, 2023, the Company recorded a reversal of \$1.0 million of compensation cost related to the awards. During the three months ended September 30, 2022, the Company recorded \$0.3 million of compensation cost related to the awards. During the nine months ended September 30, 2023 and 2022, the Company recorded a total of \$0.2 million and \$0.4 million of compensation cost related to the awards, respectively.

### 2023 Inducement Plan

The Board adopted the Company's 2023 Inducement Plan (Inducement Plan) on February 1, 2023. The Inducement Plan permits the grant of stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock 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 Company's 2010 Equity Incentive Plan. The maximum number of shares of Company common stock that may be issued under the Inducement Plan is 1,750,000 shares. At September 30, 2023, there were 850,334 shares available for new grants.

## 9. Commitments and Contingencies

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

The Company has entered into various collaboration, licensing and merger agreements which provide the Company with rights to certain know-how, technology and patent rights. The agreements generally include upfront license fees, development and commercial milestone payments upon achievement of certain clinical and commercial development and annual net sales milestones, as well as royalties calculated as a percentage of product revenues, with rates that vary by agreement. As of September 30, 2023, the Company may be required to make milestone payments up to \$2.8 billion in the aggregate for candidates in its pipeline.

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

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

In January 2022, the Company entered into a license and collaboration agreement with Stoke Therapeutics, Inc. (Stoke) to discover, develop and commercialize novel RNA-based medicines for the potential treatment of severe and rare genetic neurodevelopmental diseases of the CNS. The collaboration includes SYNGAP1 syndrome, Rett syndrome (MECP2), and an undisclosed neurodevelopmental target. For the SYNGAP1 program, the two companies will jointly share global research, development and commercialization responsibilities and share 50/50 in all worldwide costs and future profits. In addition, Stoke is eligible to receive potential development, regulatory, first commercial sales and sales milestones. For the MECP2 program and the undisclosed neurodevelopmental program, the Company acquired an exclusive worldwide license to develop and commercialize MECP2 program and the undisclosed neurodevelopmental program. Stoke will lead research and pre-clinical development activities, while the Company will lead clinical development and commercialization activities. The Company will fund research and pre-clinical development activities related to these two targets and Stoke is eligible to receive potential development, regulatory, first commercial sales and sales milestones as well as tiered royalty payments on worldwide sales starting in the mid-single digit range and escalating to the mid-teens based on revenue levels. 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 \$907.5 million in milestones as well as royalties on future sales.

### ***Corporate Credit Card Program***

In connection with the Company's credit card program, the Company established a letter of credit for \$2.0 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 cases have been assigned to the Honorable Richard G. Andrews. On September 1, 2020, Aurobindo filed its answer and counterclaims seeking declaratory judgments of noninfringement and invalidity. On September 22, 2020, the Company filed its answer to Aurobindo's counterclaims. On August 31, 2020, Teva filed its answer and counterclaims seeking declaratory judgments of noninfringement and invalidity. On September 21, 2020, the Company filed its answer to Teva's counterclaims. On October 5, 2020, Hetero filed its answer and counterclaims seeking declaratory judgments of noninfringement and invalidity. On October 26, 2020, the Company filed its answer to Hetero's counterclaims. On September 30, 2020, MSN filed its answer and counterclaims seeking declaratory judgments of noninfringement and invalidity regarding certain of the Company's Orange Book-listed patents covering NUPLAZID. On November 5, 2020, the Company filed its first amended complaint against MSN 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. On November 19, 2020, MSN filed its answer and counterclaims seeking declaratory judgments of noninfringement and invalidity regarding certain of the Company's Orange Book-listed patents covering NUPLAZID. On December 10, 2020, the Company filed its answer to MSN's counterclaims. On November 2, 2020, Zydus filed its answer and counterclaims seeking declaratory judgments of noninfringement and invalidity. On November 23, 2020, the Company filed its answer to Zydus's counterclaims. On December 8, 2020, the parties' joint proposed scheduling order was entered by Judge Andrews. On April 7, 2021, the Company filed its first amended complaints against Hetero and Teva and its second amended complaint against MSN, to include an additional Orange Book-listed patent covering NUPLAZID. On April 8, 2021, the Company filed its first amended complaint against Zydus and on April 9, 2021, the Company filed its first amended complaint against Aurobindo. On April 20, 2021, MSN filed its answer, affirmative defenses, and counterclaims to the Company's second amended complaint, seeking declaratory judgments of noninfringement and invalidity regarding certain of the Company's Orange Book-listed patents covering NUPLAZID. On April 21, 2021, Teva filed its answer, affirmative defenses, and counterclaims to the Company's first amended complaint, seeking declaratory judgments of noninfringement and invalidity. On April 22, 2021, Zydus filed its answer, affirmative defenses, and counterclaims to the Company's first amended complaint, seeking declaratory judgments of noninfringement and invalidity.

On April 22, 2021, Aurobindo filed its answer, affirmative defenses, and counterclaims to the Company's first amended complaint, seeking declaratory judgments of noninfringement and invalidity. On May 11, 2021, the Company filed its answer to MSN's counterclaims. On May 12, the Company filed its answer to Teva's counterclaims. On May 13, the Company filed its answer to Zydus's counterclaims and its answer to Aurobindo's counterclaims. A joint trial in the matters is scheduled for May 15, 2023. 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 August 27, 2021, the Company filed its second amended complaint against Zydus to include an additional Orange Book-listed patent covering NUPLAZID. On September 10, 2021, Zydus filed its answer, affirmative defenses, and counterclaims to the Company's second amended complaint, seeking declaratory judgments of noninfringement and invalidity. Also on September 10, 2021, the parties filed their Joint Claim Construction Chart. On October 1, 2021, the Company filed its answer to Zydus's counterclaims. On November 30, 2021, the Company filed a stipulation and proposed order to dismiss two of its Orange Book-listed patents covering NUPLAZID against Teva, which was ordered by the Court on December 1, 2021. On January 28, 2022, the parties filed their Joint Claim Construction Brief and Appendix. On February 23, 2022, the Court heard oral argument on claim construction. On April 6, 2022, the Court issued a Memorandum Opinion construing several terms at issue, adopting the Company's construction on two terms, Defendants' construction on two terms, and one agreed-upon construction. On February 28, 2022, the Company filed a stipulation and proposed order to dismiss one patent against MSN, which was ordered by the Court on March 1, 2022. On March 10, 2022, the Company filed a stipulation and proposed order to dismiss one patent against Teva, which was ordered by the Court on March 10, 2022. On March 22, 2022, the Company filed a stipulation and proposed order to dismiss seven patents against Aurobindo, which was ordered by the Court on March 22, 2022. On March 30, 2022, the Company filed a stipulation and proposed order to dismiss two patents against Zydus, which was ordered by the Court on March 31, 2022. On April 22, 2022, the Company filed a stipulation and proposed order of non-infringement against Aurobindo regarding certain of the Company's Orange Book-listed patents covering NUPLAZID, which was ordered by the Court on April 22, 2022. On April 26, 2022, the Company filed a stipulation and proposed order of non-infringement against MSN regarding certain of the Company's Orange Book-listed patents covering NUPLAZID, which was ordered by the Court on April 26, 2022. On April 26, 2022, the Company filed a stipulation and proposed



order of non-infringement against Teva regarding certain of the Company's Orange Book-listed patents covering NUPLAZID, which was ordered by the Court on April 27, 2022. On May 10, 2022, the Company filed its second amended complaint against Teva to include an additional Orange Book-listed patent covering NUPLAZID. On May 18, 2022, the Company filed a stipulation and proposed order of non-infringement against Zydus regarding certain of the Company's Orange Book-listed patents covering NUPLAZID, which was ordered by the Court on May 19, 2022. On May 24, 2022, Teva filed its answer, affirmative defenses, and counterclaims to the Company's second amended complaint, seeking declaratory judgments of noninfringement and invalidity regarding certain of the Company's Orange Book-listed patents covering NUPLAZID. On June 1, 2022, the Company filed its second amended complaint against Aurobindo alleging infringement of certain of the Company's Orange Book-listed patents covering NUPLAZID. On June 2, 2022, the Company filed its third amended complaint against Zydus alleging infringement of certain of the Company's Orange Book-listed patents covering NUPLAZID. On June 14, 2022, the Company filed its answer to Teva's counterclaims. June 15, 2022, Aurobindo filed its answer, affirmative defenses, and counterclaims to the Company's second amended complaint, seeking declaratory judgments of noninfringement and invalidity regarding certain of the Company's Orange Book-listed patents covering NUPLAZID. On June 16, 2022, Zydus filed its answer, affirmative defenses, and counterclaims to the Company's third amended complaint, seeking declaratory judgments of noninfringement and invalidity regarding certain of the Company's Orange Book-listed patents covering NUPLAZID. On July 6, 2022, the Company filed its answer to Aurobindo's counterclaims.

On September 7, 2022, the consolidated cases were reassigned to the Honorable Judge Gregory B. Williams. 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, which was ordered by the Court on October 4, 2022. On October 21, 2022, the Company filed 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).

On March 29, 2023, following Aurobindo's conversion of various patent certifications from Paragraph IV certifications to Paragraph III certifications in connection with the Pimavanserin I Case, the Company filed a stipulation and proposed order in the Pimavanserin I Case to dismiss the remaining asserted patents against Aurobindo. This stipulation was ordered by the Court on March 30, 2023.

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 products on September 23, 2036 and 34 mg products on February 27, 2038, subject to certain triggers for earlier launch. On April 4, 2023, the Company filed a stipulation and proposed order to dismiss all claims and counterclaims between the Company and Zydus in the Pimavanserin I Cases and Pimavanserin II Cases, which was ordered by the Court on April 5, 2023.

In connection with the Pimavanserin I Cases, only MSN remains as an active defendant. On April 6, 2023, the Company and MSN filed a stipulation and proposed order requesting adjournment of the final pre-trial conference and trial, and requesting resolution of the remaining issue – MSN's validity challenge of the sole patent in suit – through summary judgment briefing by the parties, which was ordered by the Court on April 10, 2023. Briefing was completed on June 28, 2023 and oral argument took place on September 27, 2023.

In connection with the Pimavanserin II cases, MSN and Aurobindo are the remaining defendants. A claim construction hearing is scheduled for December 19, 2023. Trial is scheduled in the matter for December 2, 2024.

#### *Securities Class Action*

On April 19, 2021, a purported stockholder of the Company filed a putative securities class action complaint (captioned *Marechal 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 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 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. Defendants filed a motion to dismiss the amended complaint on February 15, 2022. On September 27, 2022, the Court issued an order denying Defendants' motion to dismiss. Defendants filed their answer to the amended complaint on October 19, 2022, and filed a motion for reconsideration on October 25, 2022. On February 2, 2023, the Court issued an order denying the motion for reconsideration. On August 21, 2023, plaintiffs filed a motion for class certification. Briefing on that motion is scheduled to conclude on January 12, 2024. The parties are currently engaged in discovery. The cutoff for fact discovery is March 15, 2024.

Management currently believes that none of the foregoing claims or other actions pending against the Company as of September 30, 2023 is likely to have, individually or in the aggregate, a material adverse effect on the Company's business, liquidity, financial position, or results of operations. Given the unpredictability inherent in litigation, however, 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 7.7 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,	
	2023	2022	2023	2022
Operating lease cost	\$ 2,706	\$ 2,128	\$ 7,628	\$ 5,976

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,	
	2023	2022	2023	2022
Cash paid for amounts included in the measurement of lease liabilities:				
Operating cash flows from operating leases	\$ 2,342	\$ 2,294	\$ 7,062	\$ 6,722
Right-of-use assets obtained in exchange for operating lease obligations:	—	880	214	3,201

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

	September 30, 2023	December 31, 2022
Operating lease liabilities		
Current portion included in accrued liabilities	\$ 9,031	\$ 9,305
Operating lease liabilities	48,103	52,695
Total operating lease liabilities	\$ 57,134	\$ 62,000

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

	Operating Leases
Remainder of 2023	\$ 2,364
Years ending December 31,	
2024	9,228
2025	9,308
2026	8,672
2027	8,361
Thereafter	28,690
Total lease payments	66,623
Less:	
Imputed interest	(9,489)
Total operating lease liabilities	\$ 57,134

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, 2023, the weighted average remaining lease term was 7.3 years and the weighted average discount rate used to determine the operating lease liability was 4.4%.

In the fourth quarter of 2018, the Company entered into an agreement to lease the 4<sup>th</sup> and 5<sup>th</sup> floors of corporate office space in San Diego, California with total minimum lease payments of \$50.4 million over an initial term of 10 years and 9 months. In February 2020, the Company entered into the first amendment to the lease agreement to lease the 2<sup>nd</sup> floor of corporate office space in San Diego, California with total minimum lease payments of \$25.3 million over an initial term of approximately 10 years and 7 months. In March 2020, the Company entered into the second amendment to the lease agreement which increased the total minimum lease payments of the original corporate office space to \$51.4 million. In the third quarter of 2020, the lease for the 4<sup>th</sup> and 5<sup>th</sup> 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 2<sup>nd</sup> 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 2<sup>nd</sup> 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 the full procession of its 2<sup>nd</sup> floor of corporate office space to the sublessee in August 2023. Pursuant to the sublease agreement, the Company expects sublease payments to begin in December 2023.

## **11. Income Taxes**

For the three months ended September 30, 2023 and 2022, the Company recognized an income tax expense of \$13.0 million on a pre-tax loss of \$52.1 million and income tax expense of \$0.8 million on a pre-tax loss of \$26.4 million, respectively, resulting in effective tax rates of -25.0% and -2.9%, respectively. The effective tax rate for the three months ended September 30, 2023 varies from the U.S. federal statutory tax rate of 21% due to federal and state income tax expense as a result of current taxable income, offset by valuation allowance. The effective tax rate for the three months ended September 30, 2022 varies from the U.S. federal statutory tax rate of 21% due to state income tax expense as a result of current taxable income, offset by valuation allowance.

For the nine months ended September 30, 2023 and 2022, the Company recognized an income tax expense of \$16.3 million on a pre-tax loss of \$90.7 million and income tax expense of \$1.7 million on a pre-tax loss of \$172.6 million, respectively, resulting in effective tax rates of -18.0% and -1.0%, respectively. The effective tax rate for the nine months ended September 30, 2023 varies from the U.S. federal statutory tax rate of 21% due to federal and state income tax expense as a result of current taxable income, offset by valuation allowance. The effective tax rate for the nine months ended September 30, 2022 varies from the U.S. federal statutory tax rate of 21% due to state income tax expense as a result of current taxable income, offset by valuation allowance.

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

The following discussion and analysis of our condensed consolidated financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included in this Quarterly Report and the audited financial statements and notes thereto as of and for the year ended December 31, 2022 included with our Annual Report, filed with the SEC. 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 NUPLAZID, DAYBUE and other drug candidates, the potential market opportunities for pimavanserin and other drug candidates, our strategy for the commercialization of NUPLAZID and DAYBUE, our plans for exploring and developing pimavanserin and trofinetide for indications other than in PDP or Rett syndrome, respectively, our plans and timing with respect to seeking regulatory approvals, the potential commercialization of any of our drug candidates that receive regulatory approval, the progress, timing, results or implications of clinical trials and other development activities involving NUPLAZID, DAYBUE and other drug candidates, our strategy for discovering, developing and, if approved, commercializing drug 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, possible changes in legislation, and other statements that are not historical facts, including statements which may be preceded by the words “believes,” “expects,” “hopes,” “may,” “will,” “plans,” “intends,” “estimates,” “could,” “should,” “would,” “continues,” “seeks,” “aims,” “projects,” “predicts,” “pro forma,” “anticipates,” “potential” or similar words. 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. 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 the development and commercialization of innovative medicines that address unmet medical needs in CNS disorders and rare diseases. We have a portfolio of commercial stage products, in-development product opportunities, and research programs that are designed to address significant unmet needs in CNS disorders and rare diseases. In order to achieve significant long-term growth, we will develop our current portfolio, expand our pipeline of early and late-stage programs through strategic business development, and invest in targeted internal research efforts.

Our commercial portfolio includes two products. In April 2016, the FDA approved NUPLAZID for the treatment of hallucinations and delusions associated with PDP, which is the first and only drug approved in the United States for this condition. In September 2023, we announced that the FDA made two changes to the NUPLAZID label clarifying its use in patients with Parkinson’s disease-related hallucinations and delusions, with or without dementia, which is consistent with the current indication. In March 2023, the FDA approved DAYBUE for the treatment of Rett syndrome, which is the first and only drug approved for this condition. DAYBUE became available for prescription in the United States in April 2023.

NUPLAZID is a selective serotonin inverse agonist/antagonist, preferentially targeting 5-HT<sub>2A</sub> receptors with no appreciable affinity for dopaminergic, histaminergic, or muscarinic receptors. Through this novel mechanism, NUPLAZID demonstrated significant efficacy in reducing the hallucinations and delusions associated with PDP without negatively impacting motor function in our Phase 3 pivotal trial. NUPLAZID has the potential to avoid many of the debilitating side effects of existing antipsychotics, none of which are approved by the FDA for the treatment of PDP. We hold worldwide commercialization rights to pimavanserin.

In August 2018, we acquired an exclusive North American license to develop and commercialize DAYBUE for Rett syndrome and other indications from Neuren. Rett syndrome is a debilitating neurological disorder that occurs predominantly in females following apparently normal development for the first six months of life. Rett syndrome also occurs in boys, albeit far less frequently. Typically, between six to eighteen months of age, patients experience a period of rapid decline with loss of purposeful hand use and spoken communication and inability to independently conduct activities of daily living. Symptoms also include seizures, hand movements or stereotypies, disorganized breathing patterns, scoliosis and sleep disturbances, among others. The FDA approval of DAYBUE for the treatment of Rett syndrome was based on the positive results from our pivotal Phase 3 Lavender™ study which demonstrated statistically significant improvement over placebo for both co-primary endpoints as well as the key secondary endpoint.

In connection with the FDA approval of DAYBUE in March 2023, we were required to make a milestone payment of \$40.0 million to Neuren following the first commercial sale of DAYBUE pursuant to the license agreement. The \$40.0 million milestone was paid in June 2023. We capitalized the \$40.0 million milestone payment as an intangible asset as it was deemed probable of occurring as of March 31, 2023 and began amortizing it on a straight-line basis over the estimated useful life in April 2023. In addition, we were granted a Rare Pediatric Disease PRV following the FDA approval of DAYBUE. Pursuant to the license agreement, we are required to pay Neuren one third of the value of the PRV at the time of sale or use of the PRV. If the PRV is sold, the amount to be paid will be the sale value net applicable fees. If the PRV is not sold but used by us, the amount to be paid will be the average price of most recent three publicly announced sales of Rare Pediatric Disease PRVs immediately preceding the issuance of the PRV to us. We capitalized the \$29.6 million for the estimated PRV value owed to Neuren as an intangible asset and began amortizing it on a straight-line basis over the estimated useful life in April 2023.

In July 2023, we expanded our current licensing agreement for trofinetide with Neuren to acquire rights to the drug outside of North America as well as global rights in Rett syndrome and Fragile X syndrome to Neuren's development candidate NNZ-2591. Under the terms of the expanded agreement, Neuren received an upfront payment of \$100.0 million and is eligible to receive up to an additional \$426.3 million in milestone payments based on the achievement of certain commercial and sales milestones for trofinetide outside of North America and up to \$831.3 million in milestone payments based on the achievement of certain development and sales milestones for NNZ-2591. In addition, we will be required to pay Neuren tiered, escalating, double-digit percentage royalties based on net sales of trofinetide and NNZ-2591.

Through its unique mechanism and the clinical studies conducted to date, we believe that pimavanserin has the potential to address important unmet medical needs in neurological and psychiatric disorders in addition to PDP. Today we are evaluating pimavanserin for the treatment of the negative symptoms of schizophrenia in a Phase 3 clinical development program. The negative symptoms of schizophrenia have been associated with poor long-term outcomes and disability even when the positive symptoms are well-controlled, and today there are no FDA-approved therapies. In the fourth quarter of 2019 we announced positive results from our pivotal ADVANCE study and in the third quarter of 2020, we initiated a second pivotal study, ADVANCE-2. The Phase 3 program is evaluating the efficacy of pimavanserin in patients with predominantly negative symptoms of schizophrenia who have achieved adequate control of positive symptoms with their existing antipsychotic treatment. We completed enrollment in ADVANCE-2 and expect that top-line results will be available in the first quarter of 2024.

In June 2023, we announced that we added a new Phase 3 development candidate to our rare disease portfolio, ACP-101 (intranasal carbetocin), for the treatment of hyperphagia (an intense persistent sensation of hunger accompanied by food preoccupations, an extreme drive to consume food, food-related behavior problems, and a lack of normal satiety) in Prader-Willi syndrome (PWS). We acquired worldwide rights to develop and commercialize ACP-101 with the acquisition of Levo Therapeutics in June 2022. After aligning on plans with the FDA, we plan to initiate a Phase 3 placebo-controlled study of ACP-101 for the treatment of hyperphagia in PWS in the fourth quarter of 2023.

In addition, in August 2022 we announced that we are developing an internally discovered new molecule, ACP-204, which builds upon the learnings of pimavanserin in the treatment of neuropsychiatric symptoms. We completed Phase 1 development of ACP-204 which demonstrated a favorable safety and tolerability profile, and supports its target product profile as a potential treatment for Alzheimer's disease psychosis (ADP). We met with the FDA and aligned on dosing, and we plan to initiate a Phase 2 study of ACP-204 as a potential treatment for ADP in the fourth quarter of 2023. ACP-204 is a new chemical entity for which we hold the worldwide rights.

In January 2022, we entered into a license and collaboration agreement with Stoke to discover, develop and commercialize novel RNA-based medicines for the potential treatment of severe and rare genetic neurodevelopmental diseases of the CNS. The collaboration includes SYNGAP1 syndrome, Rett syndrome (MECP2), and an undisclosed neurodevelopmental target. For the SYNGAP1 program, the two companies will jointly share global research, development and commercialization responsibilities and share 50/50 in all worldwide costs and future profits. For the Rett syndrome (MECP2) and the undisclosed neurodevelopmental program, Stoke will lead research and pre-clinical development activities, while we will lead clinical development and commercialization activities.

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, 2023, we had an accumulated deficit of \$2.5 billion. Contingent on the level of business development activities we may complete as well as pipeline programs we may advance, we may continue to incur operating losses for the next few years as we incur significant research and development costs and costs for commercialization of DAYBUE.

We maintain a website at [www.acadia.com](http://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.

### ***Impact of COVID-19 on our Business***

As a result of the COVID-19 pandemic, there have been changes in the practice of medical care and medical education. For example, many health care providers initially expanded their utilization of telemedicine to conduct patient visits, and in many regions within the United States the ability of our commercial and medical field teams to call upon medical clinics, hospitals, long-term care facilities and skilled nursing facilities was restricted or converted to virtual access. We continue to access our customers both in person and virtually. Currently, health care providers are conducting patient visits in-person and through telemedicine and our sales force has been able to call upon medical clinics, hospitals, long-term care facilities and skilled nursing facilities either in person in accordance with applicable regulatory guidance and local policies or virtually. Most medical congresses, an important means for medical education, are being conducted both in person and virtually and enrollment in clinical trials is being assessed based on local COVID-19 conditions and regional regulation and public health guidance.

During the pandemic, the growth of sales of NUPLAZID was negatively impacted by a reduction in patient office visits, reduced occupancy rates at long-term care facilities, and reduced access to healthcare professionals. While we have observed incremental improvements in some of these factors since 2021, their levels are still below where they were pre-pandemic. No assurances can be given that the changes in medical care resulting from the pandemic will not continue to have additional negative impacts on our business, results of operations, financial condition and prospects.

### **Financial Operations Overview**

#### ***Product Revenues***

Net product sales consist of sales of NUPLAZID and DAYBUE. 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.

#### ***Cost of Product Sales***

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

Cost of sales for a newly launched product does not include the full cost of manufacturing until the initial pre-launch inventory is depleted, and additional inventory is manufactured and sold. Thus the cost of sales as a percentage of net sales of DAYBUE for the three and nine months ended September 30, 2023 was affected by use of the initial pre-launch inventory, which was previously expensed as research and development expense, and is referred to as zero cost inventories. However, we do not expect that the cost of sales as a percentage of net sales of DAYBUE will increase significantly once we commence the sales of full cost inventories.

## 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, ACP-204 and other early-stage programs. We currently are responsible for all costs incurred in the ongoing development of pimavanserin. In connection with the FDA approval of NUPLAZID, we committed to conduct four post-marketing studies. The fourth commitment, a randomized, placebo-controlled eight-week study or studies in predominantly frail and elderly patients that would add to the NUPLAZID safety database by exposing an aggregate of at least 500 patients to NUPLAZID, is completed and pending for FDA's acknowledgement and acceptance. 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 drug interaction studies. We will be responsible for all costs incurred for these post-marketing requirements. In addition, we expect to incur increased research and development expenses as a result of advancement of our early-stage development pipeline programs.

We use external service providers to manufacture our product candidates and for the majority of the services performed in connection with the preclinical and clinical development of pimavanserin, trofinetide, and our early-stage programs. 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 basis. To the extent that external expenses are not attributable to a specific project, they are included in other early-stage programs. The following table summarizes our research and development expenses for the three and nine months ended September 30, 2023 and 2022 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Costs of external service providers:				
NUPLAZID (pimavanserin)	\$ 11,336	\$ 15,991	\$ 41,423	\$ 47,581
DAYBUE (trofinetide)	3,842	16,734	26,696	46,944
Early-stage programs	22,175	14,984	59,665	48,530
Upfront and milestone payments*	100,000	12,500	100,000	78,234
Subtotal	137,353	60,209	227,784	221,289
Internal costs	14,547	14,675	44,393	45,400
Stock-based compensation	5,063	6,452	12,701	19,148
Total research and development expenses	\$ 156,963	\$ 81,336	\$ 284,878	\$ 285,837

\* 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 for the ongoing or additional development of pimavanserin for the negative symptoms of schizophrenia or to support the commercialization of DAYBUE, as well as the further development of our early-stage pipeline programs. 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. While our current development efforts are primarily focused on advancing the development of pimavanserin for the treatment of the negative symptoms of schizophrenia and the development of ACP-204, 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 opportunity and our financial position. We cannot forecast with any degree of certainty which product opportunities will be subject to future collaborative or licensing arrangements, when such arrangements will be secured, if at all, and to what degree any such arrangements would affect our development plans and capital requirements. Similarly, we are unable to estimate with certainty the costs we will incur for post-marketing studies that we committed to conduct in connection with FDA approval of NUPLAZID.

We expect our research and development expenses will continue to be substantial as we conduct studies pursuant to our post-marketing commitments and pursue the development of pimavanserin for the negative symptoms of schizophrenia and the further development of ACP-204 and other early-stage pipeline programs. The lengthy process of completing clinical trials and supporting development activities and seeking regulatory approval for our product opportunities 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 force, 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 NUPLAZID and DAYBUE, 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, the Rett syndrome market and our further development of pimavanserin in additional indications other than PDP.

## ***Income Tax Expense***

Because the Company maintains a full valuation allowance against its net deferred tax assets, income tax expense is expected to primarily consist of current federal and state tax expense as a result of taxable income anticipated or incurred in certain jurisdictions. Income tax expense may fluctuate from quarter to quarter due to adjustments related to non-recurring transactions, timing of revenue and expense across different tax jurisdictions and changes in certain tax assessments.

## ***Critical Accounting Policies and Estimates***

Our discussion and analysis of our financial condition and results of operations is based on our 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, 2022. For a description of our critical accounting policies that affect our significant judgments and estimates used in the preparation of our 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 NUPLAZID and DAYBUE and the extent to which we generate revenue from product sales, our development of pimavanserin for the negative symptoms of schizophrenia, our further development of the early-stage pipeline programs and the progress and timing of expenditures related to studies of NUPLAZID in PDP pursuant to our post-marketing commitments. Further, we expect our sales allowances to vary from quarter to quarter due to fluctuations in our Medicare Part D Coverage Gap liability and 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 macroeconomic developments, including recent and potential future bank failures, the ongoing conflict between Ukraine and Russia and the ongoing conflict in Israel 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, 2023 and 2022***

#### ***Product Sales, Net***

Net product sales, comprised of NUPLAZID and DAYBUE, were \$211.7 million and \$130.7 million for the three months ended September 30, 2023 and 2022, respectively.

Net product sales of NUPLAZID were \$144.8 million and \$130.7 million for the three months ended September 30, 2023 and 2022, respectively. The increase in net product sales of NUPLAZID of \$14.1 million was due to the growth in NUPLAZID unit sales as well as a higher average net selling price of NUPLAZID in 2023 compared to 2022. Net product sales of DAYBUE were \$66.9 million for the three months ended September 30, 2023. There were no net product sales of DAYBUE during the three months ended September 30, 2022.



### Cost of Product Sales

Cost of product sales was \$14.6 million and \$2.1 million for the three months ended September 30, 2023 and 2022, respectively, or approximately 7% and 2% of net product sales, respectively. Cost of product sales as a percentage of net product sales for NUPLAZID remains flat in 2023 as compared to 2022. The increase in cost of product sales was primarily due to the \$8.1 million in license fees and royalties expensed during the three months ended September 30, 2023, including royalties due to Neuren based on net sales of DAYBUE and the amortization of the milestone payments capitalized under our 2018 license agreement with Neuren. There were no license fees and royalties in the same period of 2022.

Certain manufacturing related expenses incurred prior to DAYBUE receiving FDA approval were classified as research and development expenses, resulting in zero cost inventory. If cost of product sales included previously expensed inventories, the total cost of sales with these manufacturing costs included for the three months ended September 30, 2023 would have increased by approximately \$3.9 million.

### Research and Development Expenses

Research and development expenses increased to \$157.0 million for the three months ended September 30, 2023, including \$5.1 million in stock-based compensation expense, from \$81.3 million for the three months ended September 30, 2022, including \$6.5 million in stock-based compensation expense. The increase in research and development expenses was mainly due to the \$100.0 million upfront payment to Neuren under the expanded license agreement during the three months ended September 30, 2023, offset in part by other reductions in research and development expenses.

### Selling, General and Administrative Expenses

Selling, general and administrative expenses increased to \$97.9 million for the three months ended September 30, 2023, including \$13.2 million in stock-based compensation expense, from \$78.1 million for the three months ended September 30, 2022, including \$11.5 million in stock-based compensation expense. The increase in selling, general and administrative expenses was primarily due to increased commercial costs associated with the DAYBUE launch, partially offset by reductions in expenses associated with NUPLAZID.

### Comparison of the Nine Months Ended September 30, 2023 and 2022

#### Product Sales, Net

Net product sales, comprised of NUPLAZID and DAYBUE, were \$495.4 million and \$380.7 million for the nine months ended September 30, 2023 and 2022, respectively.

Net product sales of NUPLAZID were \$405.3 million and \$380.7 million for the nine months ended September 30, 2023 and 2022, respectively. The increase in net product sales of NUPLAZID of \$24.6 million was due to the growth in NUPLAZID unit sales and a higher average net selling price of NUPLAZID in 2023 compared to 2022. Net product sales of DAYBUE were \$90.1 million for the nine months ended September 30, 2023. No sales of DAYBUE were recognized during the nine months ended September 30, 2022.

The following table provides a summary of activity with respect to our sales allowances and accruals for the nine months ended September 30, 2023 (in thousands):

	Distribution Fees, Discounts & Chargebacks	Co-Pay Assistance	Rebates, Data Fees & Returns	Total
Balance as of December 31, 2022	\$ 10,923	\$ (340)	\$ 26,046	\$ 36,629
Provision related to current period sales	66,789	3,060	83,472	153,321
Credits/payments for current period sales	(57,551)	(2,966)	(33,224)	(93,741)
Credits/payments for prior period sales	(10,923)	340	(15,695)	(26,278)
Balance as of September 30, 2023	\$ 9,238	\$ 94	\$ 60,599	\$ 69,931

### *Cost of Product Sales*

Cost of product sales was \$23.7 million and \$7.8 million for the nine months ended September 30, 2023 and 2022, respectively, or approximately 5% and 2% of net product sales, respectively. The increase in cost of product sales was primarily due to the \$11.7 million in license fees and royalties expensed for the nine months ended September 30, 2023, including royalties due to Neuren based on net sales of DAYBUE and the amortization of the milestone payments capitalized under our 2018 license agreement with Neuren. There were no license fees and royalties during the same period in 2022.

Certain manufacturing related expenses incurred prior to DAYBUE receiving FDA approval were classified as research and development expenses, resulting in zero cost inventory. Prior to receiving FDA approval for DAYBUE in March 2023, we manufactured inventory and recorded approximately \$29.9 million related to the zero cost inventory as research and development expense. Utilizing the actual direct costs to manufacture DAYBUE prior to receiving FDA approval, had the previously expensed inventory been capitalized and recognized when sold, the total cost of sales with these manufacturing costs included for the nine months ended September 30, 2023 would have increased by approximately \$5.3 million. We do not expect our cost of product sales for DAYBUE to increase significantly as a percentage of net product sales in future periods as we continue to produce inventory for future sales.

Subsequent to using our entire zero cost inventories, we estimate our overall cost of product sales as a percentage of total net product sales will be in the range of a mid-single digit to high single digit percentage.

### *Research and Development Expenses*

Research and development expenses decreased to \$284.9 million for the nine months ended September 30, 2023, including \$12.7 million in stock-based compensation expense, from \$285.8 million for the nine months ended September 30, 2022, including \$19.1 million in stock-based compensation expense. The decrease in research and development expenses was mainly due to a reduction in overall program spend offset by increased upfront payments in 2023 as compared to 2022.

### *Selling, General and Administrative Expenses*

Selling, general and administrative expenses increased to \$295.1 million for the nine months ended September 30, 2023, including \$35.1 million in stock-based compensation expense, from \$264.7 million for the nine months ended September 30, 2022, including \$33.6 million in stock-based compensation expense. The increase in selling, general and administrative expenses was primarily due to increased commercial costs associated with the DAYBUE launch, partially offset by reductions in expenses associated with NUPLAZID.

### **Liquidity and Capital Resources**

We have funded our operations primarily through sales of our equity securities, payments received under our collaboration agreements, debt financings, interest income, and with revenues from sales of NUPLAZID and DAYBUE since their approvals. 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 NUPLAZID, our commercialization of DAYBUE for the treatment of Rett syndrome, our ongoing and planned development activities for pimavanserin for the negative symptoms of schizophrenia, studies to be conducted pursuant to our post-marketing commitments and our ongoing and planned development activities for the early-stage pipeline programs. We expect that our cash, cash equivalents, and investment securities 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 NUPLAZID to be conducted over the next several years, and ongoing and planned commercial activities for NUPLAZID;

- the costs of our development activities for our early-stage pipeline programs;
- the costs of commercializing NUPLAZID, including the maintenance and development of our sales and marketing capabilities;
- the costs of commercializing and successfully launching DAYBUE, including the maintenance and development of our sales and marketing capabilities;
- the costs of establishing, or contracting for, sales and marketing capabilities for our product candidates;
- the amount of U.S. product sales from NUPLAZID and DAYBUE;
- the costs of preparing applications for regulatory approvals for NUPLAZID in jurisdictions other than the U.S., and in additional indications other than PDP and for other product candidates, as well as the costs required to support review of such applications;
- the costs of manufacturing and distributing NUPLAZID and DAYBUE for commercial use in the U.S.;
- our ability to obtain regulatory approval for, and subsequently generate product sales from, NUPLAZID in jurisdictions other than the U.S. or for the negative symptoms of schizophrenia, or from DAYBUE, and other 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 NUPLAZID or DAYBUE.

Unless and until we can generate significant cash from our operations, we expect to satisfy our future cash needs through our existing cash, cash equivalents and investment securities, public or private sales of our securities, debt financings, or strategic collaborations. 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 recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures, the Ukraine-Russia conflict and related sanctions, and the ongoing conflict in Israel, the global credit and financial markets have experienced extreme volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. These events, coupled with other factors, may limit our access to additional financing in the future. We cannot be certain that additional funding will be available to us on acceptable terms, or at all. If adequate funds are not available when needed, we will be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts. We also may be required to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Additional funding, if obtained, may significantly dilute existing stockholders and could negatively impact the price of our stock.

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

### ***Material Cash Requirements***

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

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

As discussed above, in connection with the FDA approval of DAYBUE in March 2023, we were required to make a milestone payment of \$40.0 million to Neuren following the first commercial sale of DAYBUE pursuant to the license agreement. The milestone was paid in June 2023. We were granted a PRV following the FDA approval of DAYBUE. Pursuant to the license agreement, we are required to pay Neuren one third of the value of the PRV upon sale or use of the PRV. In addition, under the terms of the expanded agreement in July 2023, we made an upfront payment to Neuren of \$100.0 million.

### **Cash Flows**

At September 30, 2023, we had \$345.9 million in cash, cash equivalents, and investment securities, compared to \$416.8 million at December 31, 2022. This \$70.9 million decrease was primarily due to cash used in operating activities, including the \$100.0 million upfront payment under the expanded Neuren agreement as well as the \$40.0 million milestone payment paid to Neuren following the first commercial sale of DAYBUE.

Net cash used in operating activities decreased to \$68.7 million for the nine months ended September 30, 2023 compared to \$90.2 million for the nine months ended September 30, 2022. This decrease in cash used in operations primarily resulted from an increase in our net revenues offset by the \$100.0 million upfront payment under the expanded Neuren agreement.

Net cash provided by investing activities totaled \$32.3 million for the nine months ended September 30, 2023 compared to \$91.0 million for the nine months ended September 30, 2022. The decrease in net cash provided by investing activities for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 was primarily due to milestone payment of \$40 million to Neuren and decreased net sale and maturities of investment securities.

Net cash provided by financing activities increased to \$19.7 million for the nine months ended September 30, 2023 compared to \$6.6 million for the nine months ended September 30, 2022. This increase in net cash provided by financing activities for the nine months ended September 30, 2023 was attributable primarily to an increase in proceeds resulting from the exercise of employee stock options.

### **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, municipal bonds, 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, 2023, this change would not have had a material effect on the fair value of our investment portfolio as of that date. Although we are seeing, and expect to continue to see, increased interest rates, 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, 2023, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), 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, 2023.

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), 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 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 continued successful commercialization of NUPLAZID and the successful commercialization of DAYBUE. To the extent we cannot maintain or increase sales of NUPLAZID or successfully launch DAYBUE, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.
- The terms of the FDA’s approval of NUPLAZID for the treatment of hallucinations and delusions associated with PDP may limit its commercial potential. Additionally, NUPLAZID is still subject to an ongoing post-marketing commitment.
- We rely on a limited internal commercial team and a limited network of third-party distributors and pharmacies to market and sell NUPLAZID and DAYBUE. If this approach ceases to be effective, our commercialization of NUPLAZID and DAYBUE may be adversely affected, and NUPLAZID and DAYBUE may not be profitable.
- If we do not obtain regulatory approval of pimavanserin for other indications in addition to treatment of PDP in the U.S., we will not be able to market pimavanserin for other indications in the U.S., which will limit our commercial revenues.
- If we are unable to effectively train and equip our sales force, our ability to successfully commercialize NUPLAZID and DAYBUE will be harmed.
- NUPLAZID and DAYBUE may not gain maximal acceptance among physicians, patients, and the medical community, thereby limiting our potential to generate revenues.
- Our ability to generate product revenues will be diminished if coverage for our products from payors is decreased or if patients have unacceptably high co-pay amounts.
- Delays, suspensions and terminations in our clinical trials 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.
- Our net losses may continue for the next few years and we are unable to predict the extent of future losses or when we will become profitable, if ever.
- If we fail to obtain the capital necessary to fund our operations, we will be unable to successfully continue the development and commercialization of NUPLAZID and DAYBUE or successfully develop and commercialize our other product candidates.
- We expect that our results of operations will fluctuate, which may make it difficult to predict our future performance from period to period.
- Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

- Public health threats have impacted our clinical trials and could have an adverse effect on our operations and financial results, or may cause us to modify or suspend our financial guidance.
- We previously have depended, and in the future may depend, on collaborations with third parties to develop and commercialize selected product candidates other than pimavanserin, and we have limited control over how those third parties conduct development and commercialization activities for such product candidates.
- We currently depend, and in the future will continue to depend, on third parties to manufacture NUPLAZID, DAYBUE and any other product candidates. If these manufacturers fail to provide us or our collaborators with adequate supplies of clinical trial materials and commercial product or fail to comply with the requirements of regulatory authorities, we may be unable to develop or commercialize NUPLAZID, DAYBUE or any other product candidates.
- If we fail to comply with the obligations in agreements under which we license intellectual property rights from third parties, we could lose license rights to certain of our product candidates.
- Our ability to compete may decline if we do not adequately protect our proprietary rights.
- Healthcare reform measures may negatively impact our ability to sell NUPLAZID, DAYBUE or our product candidates, if approved, profitably.
- If our competitors develop and market products that are more effective than NUPLAZID, DAYBUE or our other product candidates, they may reduce or eliminate our commercial opportunity.
- Our stock price historically has been, and is likely to remain, highly volatile.

### **Risks Related to Our Business**

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

In March 2023, we announced FDA approval of DAYBUE for the treatment of Rett syndrome in adult and pediatric patients two years of age and older, and DAYBUE became available for prescription in the United States in April 2023. NUPLAZID has been approved for the treatment of hallucinations and delusions associated with PDP, in the U.S. since April 2016.

The successful commercialization of NUPLAZID and DAYBUE is subject to many risks, and there is no guarantee that we will be able to maintain or increase sales of NUPLAZID and successfully launch DAYBUE. There are numerous examples of failures to meet high expectations of market potential, including by pharmaceutical companies with more experience and resources than us. While we have established our commercial team and have hired our U.S. sales force, we may need to further expand and develop the team in order to successfully commercialize NUPLAZID and DAYBUE for additional indications. Even if we are successful in developing our commercial team, there are many factors that could negatively impact the sales of our products or cause the continued commercialization of our products to be unsuccessful, including a number of factors that are outside our control. The continued commercial success of NUPLAZID currently depends on the extent to which patients, caregivers and physicians recognize and diagnose PDP and accept and adopt NUPLAZID as a treatment for hallucinations and delusions associated with PDP, and we do not know whether our or others' estimates in this regard will be accurate. We have changed, and may continue to change, the price of NUPLAZID from time to time. Physicians may not prescribe NUPLAZID and patients may be unwilling to use NUPLAZID if coverage is not provided, coverage changes in the future or reimbursement is inadequate to cover a significant portion of the cost. Similarly, the successful commercial launch of DAYBUE currently depends on the extent to which patients, caregivers and physicians recognize and diagnose Rett syndrome and accept and adopt DAYBUE as a treatment for Rett syndrome, and we do not know whether our or others' estimates in this regard will be accurate. Physicians may not prescribe DAYBUE and patients may be unwilling to use DAYBUE if coverage is not provided, coverage changes in the future or reimbursement is inadequate to cover a significant portion of the cost. While we have established our commercial team and have hired our U.S. sales force for DAYBUE, we may need to further expand and develop the team in order to successfully commercialize DAYBUE. Thus, significant uncertainty remains regarding the commercial potential of DAYBUE.

Additionally, any negative publicity related to NUPLAZID or DAYBUE, or negative development for NUPLAZID or DAYBUE in our post-marketing commitments, in clinical development in additional indications, or in regulatory processes in other jurisdictions, may adversely impact our commercial results and potential of NUPLAZID or DAYBUE. Thus, significant uncertainty remains regarding the commercial potential of NUPLAZID and DAYBUE.

If the commercialization of our products and future sales are 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.

***The terms of the FDA's approval of NUPLAZID for the treatment of hallucinations and delusions associated with PDP may limit its commercial potential. Additionally, NUPLAZID is still subject to an ongoing post-marketing commitment.\****

The scope and terms of the FDA's approval of NUPLAZID may limit our ability to commercialize NUPLAZID and, therefore, our ability to generate substantial sales revenues. The FDA has approved NUPLAZID only for the treatment of hallucinations and delusions associated with PDP. The label for NUPLAZID also contains a "boxed" warning that elderly patients with dementia-related psychosis (DRP) treated with dementia who experience psychosis unless their hallucinations and delusions are related to Parkinson's Disease.

In connection with the FDA approval, we agreed to four post-marketing commitments (PMCs): (i) a randomized withdrawal trial of pimavanserin 34 mg/day compared to placebo, (ii) a placebo-controlled trial (or trials) of pimavanserin 34 mg/day for eight weeks in at least 500 predominantly frail and elderly subjects, (iii) a drug-drug interaction study to measure the effect of a strong CYP3A4 inducer on the exposure to pimavanserin, and (iv) re-analysis of tissue samples from certain previously conducted preclinical studies. We have fulfilled three PMCs; the PMC covering a trial (or trials) in frail and elderly subjects is in process and expected to be completed in accordance with the timeline agreed with the FDA. Failure to complete the remaining PMC may result in regulatory action by the FDA. The results of any post-marketing study may cause the FDA to update the label and/or cause the FDA to request additional studies or require risk mitigation plans.

The manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for NUPLAZID will also continue to be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs, good clinical practices, international council for harmonization guidelines and good laboratory practices, each of which are regulations and guidelines enforced by the FDA 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 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, packaged or distributed, or failure to comply with regulatory requirements, may result in, among other things, restrictions on NUPLAZID or on us, including:

- withdrawal of approval, addition of warnings or narrowing of the approved indication in the product label;
- requirement of a Risk Evaluation and Mitigation Strategy to mitigate the risk of off-label use in populations where the FDA may believe that the potential risks of use may outweigh its benefits;
- voluntary or mandatory recalls;
- warning letters;
- suspension of any ongoing clinical studies;
- refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension 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; 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 NUPLAZID, 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.

***NUPLAZID and DAYBUE have only been studied in a limited number of patients. As we commercialize NUPLAZID and DAYBUE, they are becoming available to a much larger number of patients, and we do not know whether the results of NUPLAZID and DAYBUE use in such larger number of patients will be consistent with the results from our clinical studies.\****

Prior to commencing their commercial launch, NUPLAZID and DAYBUE were administered only to a limited number of patients in clinical studies. We do not know whether the results, when a larger number of patients are exposed to NUPLAZID and



DAYBUE, including results related to safety and efficacy, will be consistent with the results from the clinical studies of NUPLAZID and DAYBUE that served as the basis for their approval. New data relating to NUPLAZID and DAYBUE, including from adverse event reports and applicable post-marketing studies in the U.S., and from other ongoing clinical studies, may result in changes to the product label and may adversely affect sales, or result in withdrawal of NUPLAZID or DAYBUE from the market. The FDA and regulatory authorities in other jurisdictions may also consider the new data in reviewing NUPLAZID or DAYBUE marketing applications for indications other than in PDP or Rett syndrome, respectively, and/or in other jurisdictions, or impose additional post-approval requirements. If any of these actions were to occur, it could result in significant expense and delay or limit our ability to generate sales revenues.

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

We employ our own internal specialty sales force to commercialize NUPLAZID and DAYBUE as part of our commercialization strategy in the U.S. If we receive marketing approval for pimavanserin or trofinetide in any other indication, we will need to increase our U.S. sales force significantly, and expand our commercial, medical affairs and general and administrative support functions to support commercialization for that indication. We will be competing with other pharmaceutical and biotechnology companies to recruit, hire, train and retain such personnel. These efforts will be expensive and time consuming, and we cannot be certain that we will be able to successfully expand, refine and further develop our sales force and related functional teams.

Additionally, our strategy in the U.S. includes distributing NUPLAZID and DAYBUE solely through a limited network of third-party specialty distributors and specialty pharmacies. While we have entered into agreements with each of these distributors and pharmacies to distribute NUPLAZID and DAYBUE in the U.S., they may not perform as agreed or they may terminate their agreements with us. Also, we may need to enter into agreements with additional distributors or pharmacies, 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, or expand, if needed, our commercial team, including our U.S. sales force, or maintain and, if needed, expand, our network of third-party specialty distributors and specialty pharmacies, our ability to continue commercializing NUPLAZID and DAYBUE would be limited, and NUPLAZID and DAYBUE may not be profitable.

***If we do not obtain regulatory approval of pimavanserin for other indications in addition to treatment of PDP in the U.S., we will not be able to market pimavanserin for other indications in the U.S., which will limit our commercial revenues.***

While pimavanserin has been approved in the U.S. by the FDA for the treatment of hallucinations and delusions associated with PDP, it has not been approved by the FDA for any other indications, and it has not been approved in any other jurisdiction for this indication or for any other indication. In order to market pimavanserin for other indications or in other jurisdictions, we must obtain regulatory approval for each of those indications and in each of the applicable jurisdictions, and we may never be able to obtain such approval. Approval of NUPLAZID by the FDA for the treatment of hallucinations and delusions associated with PDP does not ensure that NUPLAZID will be approved by the FDA for any other indication. For example, following the successful completion of our Phase 3 HARMONY study, we submitted an sNDA to the FDA for the treatment of DRP on June 3, 2020. On April 2, 2021, we received a complete response letter (CRL) from the FDA, indicating that the FDA had completed its review of the application and determined that it could not be approved in its present form. In February 2022, we resubmitted the aforementioned sNDA refining the proposed indication to treatment of hallucinations and delusions associated with ADP. On August 4, 2022 we received a CRL from the FDA regarding our ADP sNDA resubmission. At this time, we are not planning to conduct any additional studies for pimavanserin in ADP.

We initiated a Phase 3 program for pimavanserin as an adjunctive treatment for major depressive disorder (MDD) in April 2019. In July 2020, we announced that our Phase 3 CLARITY study, which combined two identical, double-blind, placebo-controlled studies, did not achieve statistical significance on the primary endpoint. As a result, at this time we do not plan on initiating any additional Phase 3 studies to evaluate pimavanserin for adjunctive use with selective serotonin reuptake inhibitor (SSRI)/ serotonin-norepinephrine reuptake inhibitor (SNRI) drugs for the treatment of MDD.

We initiated the Phase 3 ADVANCE-2 study of pimavanserin for the treatment of the negative symptoms of schizophrenia in August 2020. We completed the enrollment with top-line results expected in the first quarter of 2024. There is no guarantee that our ongoing study will be successful, or that the FDA or any regulatory authority in foreign jurisdictions will approve pimavanserin for that indication.

The research, testing, manufacturing, labeling, approval, sale, import, export, marketing, and distribution of pharmaceutical product candidates are subject to extensive regulation by the FDA and other regulatory authorities in the U.S. and other countries, whose regulations differ from country to country. We will be required to comply with different regulations and policies of the

jurisdictions where we seek approval for our product candidates, and we have not yet identified all of the requirements that we will need to satisfy to submit NUPLAZID for approval for other indications or in other jurisdictions. This will require additional time, expertise and expense, including the potential need to conduct additional studies or development work for other jurisdictions beyond the work that we have conducted to support our NDA submission in PDP. If we do not receive marketing approval for NUPLAZID for any other indication, we will never be able to commercialize NUPLAZID for any other indication in the U.S. Even if we do receive additional regulatory approvals, we may not be successful in commercializing those opportunities.

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

***If we are unable to effectively train and equip our sales force, our ability to successfully commercialize NUPLAZID and DAYBUE will be harmed.\****

NUPLAZID is the first drug approved by the FDA for the treatment of hallucinations and delusions associated with PDP, and DAYBUE is the first drug approved by the FDA for the treatment of Rett syndrome. As a result, we are and will continue to be required to expend significant time and resources to train our sales force to be credible, persuasive, and compliant with applicable laws in marketing NUPLAZID and DAYBUE to neurologists, psychiatrists, pharmacists, physicians in long-term care facilities and other healthcare providers, as appropriate. In addition, we must ensure that consistent and appropriate messages about NUPLAZID and DAYBUE are being delivered to our potential customers by our sales force. If we are unable to effectively train our sales force and equip them with current, effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits of NUPLAZID and DAYBUE, and their proper administration, our efforts to successfully commercialize NUPLAZID and DAYBUE, could be put in jeopardy, which would negatively impact our ability to generate product revenues.

***NUPLAZID and DAYBUE may not gain maximal acceptance among physicians, patients, and the medical community, thereby limiting our potential to generate revenues.\****

The degree of market acceptance by physicians, healthcare professionals and third-party payors of NUPLAZID, DAYBUE and any other product for which we obtain regulatory approval, and our profitability and growth, will depend on a number of factors, including:

- the ability to provide acceptable evidence of safety and efficacy;
- the scope of the approved indication(s) for the product;
- the inclusion of any warnings or contraindications in the product label;
- the relative convenience and ease of administration;
- the prevalence and severity of any 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, and our ability to increase awareness of our approved products through marketing efforts;
- pricing and cost effectiveness, which may be subject to regulatory control;
- effectiveness of our or our collaborators' sales and marketing strategy;
- publicity concerning us, our products or competing products and treatments; and
- our ability to obtain and maintain sufficient third-party insurance coverage or adequate reimbursement levels.

If a product does not provide a treatment regimen that is at least as beneficial as the current standard of care or otherwise does not provide patient benefit, that product will not achieve market acceptance and will not generate sufficient revenues to achieve or maintain profitability.

With respect to NUPLAZID specifically, successful commercialization will depend on whether and to what extent physicians, long-term care facilities and pharmacies, over whom we have no control, determine to utilize NUPLAZID. NUPLAZID is available to treat hallucinations and delusions associated with PDP, an indication for which no other FDA-approved pharmaceutical treatment currently exists. Because of this, it is particularly difficult to estimate NUPLAZID's market potential and how physicians, payors and patients will respond to changes in the price of NUPLAZID. Additionally, the growth of NUPLAZID net sales was negatively impacted due to the COVID-19 pandemic. Industry sources and analysts have a divergence of estimates for the near- and long-term

market potential of NUPLAZID, and a variety of assumptions directly impact the estimates for NUPLAZID's market potential, including assumptions regarding the prevalence of PDP, the rate of diagnosis of PDP, the prevalence and rate of hallucinations and delusions in patients diagnosed with PDP, the rate of physician adoption of NUPLAZID, the potential impact of payor restrictions regarding NUPLAZID, and patient adherence and compliance rates. Small differences in these assumptions can lead to widely divergent estimates of the market potential of NUPLAZID. For example, 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 other drugs, even though they are not approved in PDP, instead of NUPLAZID. In addition, even if NUPLAZID is prescribed for the treatment of hallucinations and delusions associated with PDP, issues may arise with respect to patient adherence and compliance rates. If patients do not adhere to the recommended dosing of NUPLAZID, patients and physicians may believe that NUPLAZID is less effective, and as a result they may stop taking it and prescribing it.

The label for NUPLAZID also contains a "boxed" warning that elderly patients with DRP treated with antipsychotic drugs are at an increased risk of death, and that NUPLAZID is not approved for the treatment of patients with DRP unrelated to the hallucinations and delusions associated with PDP. 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. On September 20, 2018 the FDA issued a statement concluding: "The U.S. FDA has completed a review of all post marketing reports of deaths and serious adverse events (SAEs) reported with the use of NUPLAZID. Based on an analysis of all available data, FDA did not identify any new or unexpected safety findings with NUPLAZID, or findings that are inconsistent with the established safety profile currently described in the drug label. After a thorough review, FDA's conclusion remains unchanged that the drug's benefits outweigh its risks for patients with hallucinations and delusions of Parkinson's disease psychosis." Although the FDA did not identify any new or unexpected safety risks, the FDA indicated that some potentially concerning prescribing patterns were observed, such as the concomitant use of other antipsychotic drugs or drugs that can cause QT prolongation, a potential cause of heart rhythm disorder. The FDA reminded healthcare providers to be aware of the risks described in the NUPLAZID prescribing information and that none of the other antipsychotic medications are approved for the treatment of PDP. Regardless, perceptions that NUPLAZID is unsafe, even if unfounded, may discourage physicians from prescribing or patients from taking NUPLAZID.

The commercial success of NUPLAZID and DAYBUE 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 payors is decreased or if patients have unacceptably high co-pay amounts.\****

Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors, including governmental healthcare programs, such as Medicare and Medicaid, managed care organizations and commercial payors, among others, to reimburse all or part of the costs associated with their prescription drugs. Coverage and adequate reimbursement from third-party payors is 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 NUPLAZID, DAYBUE or other products we may market, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients may not use NUPLAZID and DAYBUE if coverage is not provided or reimbursement is inadequate to cover a significant portion of its cost.

In addition, the market for NUPLAZID and DAYBUE 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 NUPLAZID and DAYBUE are approved.

Third-party payors, whether governmental or commercial, 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. Selling NUPLAZID or DAYBUE 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 NUPLAZID or DAYBUE from time to time, however, we do not know if the price we have selected, or may select in the future, for NUPLAZID or DAYBUE 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

NUPLAZID or DAYBUE. In the U.S., no uniform policy of coverage and reimbursement for drug products exists among third-party payors. 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 NUPLAZID and DAYBUE 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 NUPLAZID and DAYBUE 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. If we are unable to obtain coverage of, and adequate payment levels for, NUPLAZID, DAYBUE or any other 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 NUPLAZID, DAYBUE or any other products we may market, and thereby adversely impact our profitability, results of operations, financial condition, and future success.

***We are solely responsible for the development and commercialization of pimavanserin and trofinetide.\****

We have full responsibility for the pimavanserin and trofinetide programs throughout the world. We expect our research and development costs for continued development of pimavanserin and trofinetide to be substantial. We are currently undertaking ongoing development work for pimavanserin, including clinical trials of pimavanserin for indications other than in PDP, and trofinetide. In the event of approval for additional indications or in jurisdictions outside the U.S., we would need to add significant resources, and possibly raise additional capital, in order to further commercialize pimavanserin and trofinetide, and to conduct the necessary sales and marketing activities, and to conduct further development activities.

With respect to NUPLAZID, our current strategy is to continue to commercialize NUPLAZID for the treatment of hallucinations and delusions associated with PDP in the U.S. using our specialty sales force focused primarily on neurologists, a small group of psychiatrists, and pharmacists and physicians in long-term care facilities who treat PDP patients. If we are approved to commercialize NUPLAZID in markets outside of the U.S., we may need to establish one or more strategic alliances in the future for that purpose. Without future additional resources or collaboration partners in the U.S. and abroad, we might not be able to realize the full value of NUPLAZID.

Furthermore, even though NUPLAZID is approved for the treatment of hallucinations and delusions associated with PDP, a failure in a subsequent pimavanserin study for another indication, including our ongoing study in schizophrenia, or any additional studies, or a failure in our post-marketing studies could harm our ability to successfully market NUPLAZID for the treatment of hallucinations and delusions associated with PDP or could lead to it being withdrawn from the market. Similarly, even though DAYBUE is approved for the treatment of Rett syndrome in adult and pediatric patients two years of age and older, a failure in a subsequent trofinetide study for another indication or any additional studies could harm our ability to successfully market DAYBUE for the treatment of Rett syndrome in adult and pediatric patients two years of age and older or could lead to it being withdrawn from the market.

If we are unable to develop pimavanserin or trofinetide for other indications or in other jurisdictions, we may not be able to maximize the potential of the compounds and that could have a material adverse effect on our future revenues and our success as a company.

***Drug development is a long, expensive and unpredictable process with a high risk of failure.***

Preclinical testing and clinical trials are long, expensive and unpredictable processes that can be subject to delays. It may take several years to complete the preclinical testing and clinical development necessary to commercialize a drug, and delays or failure can occur at any stage. Preliminary, initial, top-line or interim results of clinical trials do not necessarily predict final results and such results may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final results. In addition, success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials even after promising results in earlier trials.

Our drug development programs are at various stages of development and the historical rate of failures for product candidates is extremely high. In fact, we had an unsuccessful Phase 3 trial with NUPLAZID in 2009. An unfavorable outcome in any of our ongoing or future development efforts or in the post-marketing studies for NUPLAZID could be a major set-back for the program and for us, generally. In particular, an unfavorable outcome in our NUPLAZID program or in the post-marketing studies may require us to delay, devote additional substantial resources to, reduce the scope of, or eliminate this program and could have a material adverse effect on us and the value of our common stock.

In addition, based on positive top-line results from CLARITY, a Phase 2 study evaluating pimavanserin as an adjunctive treatment for MDD, we initiated our Phase 3 CLARITY program, consisting of two Phase 3 studies, CLARITY-2 and CLARITY-3, evaluating pimavanserin as an adjunctive treatment with SSRI/SNRI drugs for MDD. Despite the positive results observed in the Phase 2 CLARITY study, our Phase 3 CLARITY study, did not achieve statistical significance on the primary endpoint. In July 2019, we announced top-line results from the Phase 3 ENHANCE study evaluating pimavanserin as a treatment in inadequate response schizophrenia. In this study, pimavanserin did not achieve statistical significance on either the primary endpoint or the key secondary endpoint.

Following the successful completion of our Phase 3 HARMONY study, we submitted an sNDA to the FDA for pimavanserin for the treatment of DRP on June 3, 2020. On April 2, 2021, we received a CRL indicating that the FDA had completed its review of the application and determined that it could not be approved in its present form. In February 2022, we resubmitted the aforementioned DRP sNDA with updated labeling for the treatment of hallucinations and delusions associated with ADP to the FDA based on previously submitted studies and new analyses. On August 4, 2022, we received a CRL from the FDA regarding our submission of the sNDA. At this time, we are not planning to conduct any additional studies for pimavanserin for the treatment of hallucinations and delusions associated with ADP.

We are currently conducting several studies, including early stage studies of an internally-developed compound known as ACP-204, which is akin to pimavanserin, and ACP-101 for the treatment of hyperphagia in Prader-Willi syndrome and may conduct additional studies in the future.

In connection with clinical trials, we face risks that:

- 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 may not be consistent with positive results of earlier trials; and
- the results may not meet the level of statistical significance required by the FDA or other regulatory agencies.

If we do not successfully complete preclinical and clinical development, we will be unable to market and sell products derived from our product candidates and to generate product revenues. Even if we do successfully complete clinical trials, those results are not necessarily predictive of results of additional trials that may be needed before an NDA may be submitted to the FDA. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are approved for commercialization.

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

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

- demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organizations (CROs) and clinical trial sites;
- manufacturing sufficient quantities of a product candidate;
- obtaining clearance from the FDA to commence clinical trials pursuant to an Investigational New Drug application;
- obtaining approval to conduct clinical trials in countries 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 to conduct a clinical trial at a prospective clinical trial site; and
- patient recruitment, which is a function of many factors, including the size of the patient population, the nature of the protocol, 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 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 or institutional review boards;
- failure to conduct clinical trials in accordance with regulatory requirements;
- inability to monitor patients adequately during or after treatment;
- difficulty monitoring multiple study sites;
- patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, 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 ongoing 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 future enrollment in these studies, or 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 product candidate. If we experience delays, suspensions or terminations in a clinical trial, 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 CNS disorders, including neuropsychiatric and related disorders. 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 pimavanserin and trofinetide, and commercial activities for NUPLAZID and DAYBUE. We face competition for experienced scientists, clinical operations personnel, commercial and other personnel from numerous companies and academic and other research institutions. Competition for qualified personnel is particularly intense in the San Diego, California area. 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 will be limited. If we are unable to attract and retain the necessary personnel, it will significantly impede our commercialization efforts for NUPLAZID and DAYBUE, 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.

***If we receive approval of NUPLAZID or DAYBUE in additional indications, we may need to continue to increase the size of our organization. We may encounter difficulties with managing our growth, which could adversely affect our results of operations.\****

As of September 30, 2023, we employed approximately 580 employees. Our current infrastructure may be inadequate to support our development and commercialization efforts and expected growth. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, and integrate additional employees and retain existing employees, and may take time away from running other aspects of our business, including development and commercialization of our product candidates.

Our future financial performance and our ability to commercialize NUPLAZID, DAYBUE and any other product candidates that receive regulatory approval and to compete effectively will depend, in part, on our ability to manage any future growth effectively. In particular, we will need to support the training and ongoing activities of our sales force. To that end, we must be able to:

- manage our development efforts effectively;
- integrate additional management, administrative and manufacturing personnel;
- develop our marketing and sales organization; and
- maintain sufficient administrative, accounting and management information systems and controls.

We may not be able to accomplish these tasks or successfully manage our operations and, accordingly, may not achieve our research, development, and commercialization goals. Our failure to accomplish any of these goals could harm our financial results and prospects.

***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.\****

A key element of our 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 disorders, or for therapeutic indications that complement or augment our current 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 have limited experience in identifying acquisition targets, successfully 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. In particular, if we are unable to add additional commercial products to our portfolio, we may not be able to successfully leverage our commercial organization that we have assembled for the marketing and sale of NUPLAZID and DAYBUE.

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

In addition, if we fail to successfully commercialize and further develop NUPLAZID, DAYBUE or other product candidates, there is a greater likelihood that we will fail to successfully develop a pipeline of other product candidates, and our business and prospects would therefore be harmed.

***Our net losses may continue for the next few years and we are unable to predict the extent of future losses or when we will become profitable, if ever.\****

We have experienced significant net losses since our inception. As of September 30, 2023, we had an accumulated deficit of approximately \$2.5 billion. We may incur net losses over the next few years as we expect to invest in the commercialization of NUPLAZID and DAYBUE and advance our development programs, including developing additional internal systems and infrastructure and hiring additional personnel. We also expect such investments and advancements will increase our expenses in the coming years. Thus, our future operating results and profitability may fluctuate from period to period, and we will need to generate significant revenues to achieve and maintain profitability and positive cash flow on a sustained basis.

We expect that our revenues over the next few years will be entirely dependent on our ability to generate product sales. Substantially all of our revenues since May 2016 were from net product sales of NUPLAZID. To the extent that we cannot generate significant revenues from the sale of NUPLAZID and DAYBUE to cover our expenses, including the significant expenses associated with commercializing NUPLAZID and DAYBUE and continuing to develop pimavanserin and trofinetide in additional indications, we may never achieve profitability and/or may have to reduce our commercialization and/or research and development activities to become profitable, which would harm our future growth prospects. Additionally, to obtain revenues from product candidates other than NUPLAZID and DAYBUE, we must succeed, either alone or with others, in developing, obtaining regulatory approval for, manufacturing and marketing compounds with significant market potential. We may never succeed in these activities and may never generate revenues that are significant enough to achieve profitability.

***If we fail to obtain the capital necessary to fund our operations, we will be unable to successfully continue the development and commercialization of NUPLAZID and DAYBUE or successfully develop and commercialize our other product candidates.\****

We have consumed substantial amounts of capital since our inception. Our cash, cash equivalents, and investment securities totaled \$345.9 million at September 30, 2023. While we believe that our existing cash resources will be sufficient to fund our cash requirements through at least the next twelve months, we may require significant additional financing in the future to continue to fund our operations. Our future capital requirements will depend on, and could increase significantly as a result of, many factors including:

- the progress in, and the costs of, our ongoing and planned development activities for pimavanserin and trofinetide, post-marketing studies for NUPLAZID to be conducted over the next several years, ongoing and planned commercial activities for NUPLAZID and DAYBUE;
- the costs of our development activities for our early-stage pipeline programs and any other product candidates;
- the costs of commercializing NUPLAZID and DAYBUE, including the maintenance and development of our sales and marketing capabilities;
- the costs of establishing, or contracting for, sales and marketing capabilities for other product candidates;
- the amount of U.S. product sales from NUPLAZID and DAYBUE;
- the costs of preparing applications for regulatory approvals for NUPLAZID in jurisdictions other than the U.S., and in additional indications other than in PDP, and for DAYBUE and other product candidates, as well as the costs required to support review of such applications;
- the costs of manufacturing and distributing NUPLAZID and DAYBUE for commercial use in the U.S.;
- our ability to obtain regulatory approval for, and subsequently generate product sales from, NUPLAZID in jurisdictions other than the U.S. or in additional indications other than in PDP, or from DAYBUE, our early-stage pipeline programs and any other product candidates;
- 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 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 and supply 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 NUPLAZID and DAYBUE.

Unless and until we can generate significant cash from our operations, we expect to satisfy our future cash needs through our existing cash, cash equivalents and investment securities, strategic collaborations, public or private sales of our securities, debt financings, grant funding, or by licensing all or a portion of our product candidates or technology. 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, including recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures, the ongoing conflict between Ukraine and Russia and related sanctions, and the ongoing conflict in Israel, 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. This 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 acceptable terms, or at all. If 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 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 NUPLAZID in the U.S. for the treatment of hallucinations and delusions associated with PDP and DAYBUE in the U.S. for the treatment of Rett syndrome;
- the impact of geopolitical and macroeconomic developments, such as recent and potential future bank failures, general political, health and economic conditions, including the Ukraine-Russia conflict, COVID-19, economic slowdowns, recessions, inflation, rising interest rates and tightening of credit markets on our business;
- the status and cost of our post-marketing commitments for NUPLAZID;
- the variation in our gross-to-net adjustments from quarter to quarter, primarily because of the fluctuation in our share of the donut hole for Medicare Part D patients;
- the status and cost of development and commercialization of pimavanserin for indications other than for the treatment of hallucinations and delusions associated with PDP, and the status and cost of development and commercialization of trofinetide for indications other than for the treatment of Rett syndrome;
- the status and cost of development and commercialization of our product candidates, 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 or products;
- whether we generate revenues or reimbursements by achieving specified research, development or commercialization milestones under any agreements or otherwise receive potential payments under these agreements;
- whether we are required to make payments due to achieving specified milestones under any licensing or similar agreements or otherwise make payments under these agreements;
- the incurrence of preclinical or clinical expenses that could fluctuate significantly from period to period, including reimbursement obligations pursuant to our collaboration agreements;
- the initiation, termination, or reduction in the scope of our collaborations or any disputes regarding these collaborations;
- the timing of our satisfaction of applicable regulatory requirements;
- the rate of expansion of our clinical development, other internal research and development efforts, and pre-commercial and commercial efforts;

- the effect of competing technologies and products and market developments;
- the costs associated with litigation, including the costs incurred in defending against any product liability claims that may be brought against us related to NUPLAZID or DAYBUE; 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 net sales of NUPLAZID and DAYBUE and certain expense line items based on estimates and the judgment of management. If, for any reason, our actual net sales or expenses differ materially from our guidance, we may have to revise our previously announced financial guidance. 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 enacted in 2017 informally titled the Tax Cuts and Jobs Act, the Coronavirus Aid, Relief, and Economic Security Act and the Inflation Reduction Act enacted many significant changes to the U.S. tax laws. Effective January 1, 2022, the Tax Cuts and Jobs Act eliminated the option to deduct research and development expenses for tax purposes in the year incurred and requires taxpayers to capitalize and subsequently amortize such expenses over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. Although there have been legislative proposals to repeal or defer the capitalization requirement to later years, the provision may not actually be repealed or otherwise modified. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. 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 losses 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. Under current law, 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 losses is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to federal tax laws. 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. 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 recent and potential future bank failures, material shortages and related supply chain challenges, geopolitical developments such as the conflict between Ukraine and Russia and related sanctions and the ongoing conflict in Israel, and increasing inflation rates and the responses by central banking authorities to control such 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, inflation rates, particularly in the United States, have increased recently to levels not seen in years, and increased 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, the U.S. Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation, which coupled with 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.

***Public health threats have impacted our clinical trials and could have an adverse effect on our operations and financial results, or may cause us to modify or suspend our financial guidance.\****

The COVID-19 pandemic had a major impact on the financial markets, the global economy and the economies of particular countries or regions, and led to, among other things, travel restrictions, quarantines, “work-at-home” and “shelter-in-place” orders imposed by authorities and the extended shutdown of certain non-essential businesses in the U.S. throughout the world, including in countries where we have planned or active clinical trials. In an effort to protect the health and safety of our employees, our community, and our stakeholders, we have developed dynamic pandemic and workplace health policies applicable to all of our employees. These policies are localized based on current COVID-19 conditions, regulatory guidance, public health and scientific recommendations, and federal, state, and local laws. We have reopened our offices to allow employees to return, but will continue to closely monitor the COVID-19 situation. We may face several challenges or disruptions upon a return back to the workplace, including re-integration challenges by our employees and distractions to management related to such transition. The effects and duration of such measures could have a material adverse impact on our business, results of operations, financial condition and prospects.

Our sales force had physical access to hospitals, clinics, long-term care and skilled nursing facilities, healthcare providers and pharmacies curtailed, and we are still assessing the effects such curtailment had on our sales or may have on our future sales. Currently, healthcare providers are conducting patient visits in-person and through telemedicine and our sales force has been able to call upon medical clinics, hospitals, long-term care facilities and skilled nursing facilities either in person in accordance with applicable regulatory guidance and local policies or virtually. While digital tools are available to our field employees to facilitate remote meetings with healthcare providers that are unable to meet in-person, we cannot ensure that these methods will be effective. Additionally, patients who are currently using NUPLAZID or DAYBUE, or who are eligible to use NUPLAZID or DAYBUE, may be unable to meet with their healthcare providers in person, which may reduce the number of prescription refills or new patient starts, affecting our revenues both in our currently approved indication and potentially impacting our anticipated launches in other indications, if approved.

Our clinical trials were impacted by the COVID-19 pandemic as we temporarily paused enrollment in our ongoing clinical trials as well as commencement of new trials, and experienced delays in our data collection and site monitoring activities. While we have re-initiated enrollment in clinical trials and related activities on a study-by-study and site-by-site basis, it is possible that our studies could be impacted due to COVID-19 in the future.

During the pandemic, the growth of sales of NUPLAZID was negatively impacted by a reduction in patient office visits, reduced occupancy rates at long-term care facilities, and reduced access to healthcare professionals. While we have observed incremental improvements in some of these factors since 2021, their levels are still below where they were pre-pandemic. No assurances can be given that the changes in medical care resulting from the pandemic will not continue to have additional negative impacts on our business, results of operations, financial condition and prospects.

***The geo-political turmoil resulting from Russia's invasion of Ukraine, including the widespread and significant economic sanctions imposed on Russia, has caused significant disruptions of our clinical trial activities in Russia and Ukraine.\****

We have engaged CROs to conduct clinical trials worldwide. Certain of our trials have a limited number of clinical sites in Russia and Ukraine where patient recruiting and screening were not complete at the time of Russia's military aggression in Ukraine. The resulting geo-political turmoil has caused significant disruptions, including the suspension of further new enrollment of patients at our clinical trial sites in Ukraine and Russia. Existing patients may have been evacuated or relocated far from clinical sites, making it difficult for participation in our clinical trials. Site personnel and/or CRO personnel may be unavailable or otherwise unable to conduct clinical trial activities. Furthermore, the widespread sanctions imposed on Russia have affected clinical sites in Russia managed by our CROs. In addition, clinical sites, their personnel and patients may not be able to continue in the trials and therefore we have terminated the trials in Russia. While we have a limited number of clinical sites in Ukraine and Russia, these significant disruptions and the suspension/termination of clinical trial activities could potentially delay the completion of enrollment in our clinical trials and complicate the analysis of data, as affected clinical sites might not be able to have their data be validated or protocol assessments may be missed. Even if data collection can be completed, the FDA may be unable to audit clinical trial sites in Ukraine or Russia. Interruptions of clinical trials may further delay our clinical development and the potential authorization or approval of our product candidates, which could materially increase our costs and adversely affect our ability to commence product sales and generate revenues.

***Earthquake or fire damage to our facilities could delay our research and development efforts and adversely affect our business.***

Our headquarters and research and development facilities in San Diego are located in a seismic zone, and we face the possibility of one or more earthquakes, which could be disruptive to our operations and result in delays in our research and development efforts. In addition, while our facilities have not been adversely impacted by local wildfires, there is the possibility of future fires in the area. In the event of an earthquake or fire, if our facilities or the equipment in our facilities is significantly damaged or destroyed for any reason, we may not be able to rebuild or relocate our facilities or replace any damaged equipment in a timely manner and our business, financial condition, and results of operations could be materially and adversely affected. We do not have insurance for damages resulting from earthquakes. While we do have fire insurance for our property and equipment located in San Diego, any damage sustained in a fire could cause a delay in our research and development efforts and our results of operations could be materially and adversely affected.

***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.

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

***We previously have depended, and in the future may depend, on collaborations with third parties to develop and commercialize selected product candidates other than pimavanserin, and we have limited control over how those third parties conduct development and commercialization activities for such product candidates.***

In the past, we have selectively entered into collaboration agreements with third parties. We relied on our collaborators for financial resources and for development, regulatory, and commercialization expertise for selected product candidates and we had limited control over the amount and timing of resources that our collaborators devoted to our product candidates. We may choose to rely on collaborations in the future for certain portions of our pimavanserin program or other product candidates, or for the commercialization of NUPLAZID in certain territories outside of the U.S.

Our collaborators may fail to develop or effectively commercialize products using our product candidates 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;
- 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. We also will face competition in our search for new collaborators, if we seek a new partner for our pimavanserin program or other programs. Given the current economic and industry environment, it is possible that competition for new collaborators may increase. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all. If we are unable to find new collaborations, we may not be able to continue advancing our programs alone.

***If conflicts arise with our collaborators, they may act in their self-interests, which may be adverse to our interests.***

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; 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, we generally 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 in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, 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 their withdrawal of support for our product candidates or may otherwise result in lower demand for our potential products.

***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.***

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

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

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

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

***Even if we or our collaborators successfully complete the clinical trials of product candidates, the product candidates may fail for other reasons.***

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. We cannot assure you that, even if clinical trials are completed, either we or our collaborators will submit applications for required authorizations to manufacture and/or market potential products or that any such application will be reviewed and approved by the appropriate regulatory authorities in a timely manner, if at all. Even if we or our collaborators successfully complete the clinical trials of product candidates and apply for such required authorizations, the product candidates, such as pimavanserin, may fail for other reasons, including the possibility that the product candidates will:

- fail to receive the regulatory clearances required to market them as drugs;

- be subject to proprietary rights held by others requiring the negotiation of a license agreement prior to marketing;
- be difficult or expensive to manufacture on a commercial scale;
- have adverse side effects that make their use less desirable; or
- fail to compete with product candidates or other treatments commercialized by competitors.

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

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

We have contracted with Patheon Pharmaceuticals Inc. to manufacture NUPLAZID 10 mg tablet and 34 mg capsule drug product for commercial use in the U.S. We have also contracted with a second contract manufacturing organization to manufacture NUPLAZID 34 mg drug product for commercial use in the U.S. Additionally, we have contracted with Siegfried AG to manufacture active pharmaceutical ingredient (API), to be used in the manufacture of NUPLAZID 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, and we may face delays or increased costs in our supply chain that could jeopardize the commercialization of NUPLAZID. While we currently have sufficient API for both NUPLAZID and DAYBUE and NUPLAZID and DAYBUE finished products on hand to continue our commercial and clinical operations as planned, depending on the effects of geopolitical and macroeconomic developments and whether such developments cause disruptions, we may face such delays or costs in future years. If any third party in our supply or distribution chain for materials or finished product is adversely impacted by geopolitical and macroeconomic developments, such as recent and potential future bank failures, the ongoing conflict between Ukraine and Russia and related sanctions, and the ongoing conflict in Israel, our supply chain may be disrupted, limiting our ability to manufacture and distribute NUPLAZID or DAYBUE for commercial sales and our product candidates for our clinical trials and research and development operations. Additionally, if NUPLAZID is approved for commercial sale in jurisdictions outside the U.S., we will need to contract with a third party to manufacture such products for commercial sale in the U.S. and/or in such other jurisdictions. We may not be able to enter into such contracts in a timely manner or on acceptable terms, if at all.

Even though we have agreements with third parties for the manufacture of NUPLAZID and DAYBUE, the FDA may not approve the facilities of such manufacturers, the manufacturers may not perform as agreed, or the manufacturers may terminate their agreements with us. Presently, we have agreements with Patheon for the manufacture of NUPLAZID 10 mg table, with Patheon and another manufacturer for the manufacture of 34 mg capsule drug product and with Siegfried for the manufacture of NUPLAZID API for commercial use. 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 NUPLAZID, DAYBUE or any other product candidates. While we believe that there will be alternative sources available to manufacture NUPLAZID, DAYBUE and any other 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.

The manufacturers of NUPLAZID, DAYBUE and any other product candidates, including Patheon and Siegfried, are obliged to operate in accordance with FDA-mandated 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 NUPLAZID and DAYBUE and any other 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. If any of our third-party manufacturers are unable to successfully manufacture material that conforms to our specifications and the FDA's strict regulatory requirements, or pass regulatory inspection, they will not be able to secure or maintain approval for the manufacturing facilities. 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 NUPLAZID, DAYBUE and any other product candidate that receives regulatory approval, negatively impact our commercialization of NUPLAZID or DAYBUE, 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 fines, injunctions, civil penalties, failure of the government to grant pre-market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of products, operating restrictions, and criminal prosecutions.

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 NUPLAZID, DAYBUE or any other 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 NUPLAZID or DAYBUE in the U.S., or provide pimavanserin, trofinetide or any other product candidates to patients in clinical trials, would be jeopardized. Any delay or interruption in our ability to meet commercial demand for NUPLAZID, DAYBUE 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 NUPLAZID, DAYBUE or any other product candidates and could have a material adverse effect on our business, results of operations, financial condition and prospects.

***If we fail to comply with the obligations in agreements under which we license intellectual property rights from third parties, we could lose license rights to certain of our product candidates.\****

In July 2023, we entered into an expanded license agreement with Neuren under which we have the exclusive worldwide rights to develop and commercialize trofinetide for Rett syndrome and other indications and NNZ-2591 for Rett syndrome and Fragile X syndrome. In January 2022, we entered into a license and collaboration agreement with Stoke to discover, develop and commercialize novel RNA-based medicines for the potential treatment of severe and rare genetic neurodevelopmental diseases of the CNS.

Our agreements with Neuren and Stoke impose, and we expect that future agreements where we in-license intellectual property will impose, various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to bankruptcy-related proceedings, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license.

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, 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, which would have a material adverse effect on our business.



***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 CNS disorders. 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.

### **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, including NUPLAZID and DAYBUE, 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. For a more detailed description of these matters, see 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 NUPLAZID or DAYBUE would have an adverse effect on our results of operations.

With regard to patents, although we have filed numerous patent applications worldwide with respect to pimavanserin, 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 CNS disorders 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 that we have recently initiated 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. If securities analysts or investors 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. For example, some of our patent applications may cover the uses of gene sequences. The patentability of gene sequences and the use of gene sequences has been seriously undermined by recent decisions of the U.S. Supreme Court. 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 product candidates. In addition, U.S. patent laws may change which could prevent or limit us from filing patent applications or patent claims to protect our products and/or technologies or limit the exclusivity periods that are available to patent holders. For example, the America Invents Act (2012) included a number of significant changes to U.S. patent law. These included changes to transition from a "first-to-invent" system to a "first-to-file" system and to the way issued patents are challenged. These changes may favor larger and more established companies that have more resources to devote to patent application filing and prosecution. It is still not clear what, if any, impact the America Invents Act will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend our issued patents.

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

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

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

In both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell NUPLAZID, DAYBUE and any other potential products, as described in greater detail in the Government Regulation section of our Annual Report.

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 approved product, including NUPLAZID and DAYBUE. With respect to pharmaceutical products, the ACA, among other things, expanded and

increased industry rebates for drugs covered by Medicaid and made changes to the coverage requirements under Medicare Part D, Medicare's prescription drug benefits program. There have been legal and political challenges to certain aspects of the ACA. Furthermore, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Moreover, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and additional healthcare reform measures of the Biden administration will impact the ACA and our business.

Other legislative changes have been proposed and adopted in the U.S. since the ACA. 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. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to certain providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, Congress is considering additional health reform measures as part of the budget reconciliation process.

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 NUPLAZID, DAYBUE or any other product for which we obtain regulatory approval, reduce product utilization and adversely affect our business and results of operations. There have been several recent U.S. presidential executive orders, Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. For example, in July 2021, the Biden administration released an executive order that included multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the Department of Health and Human Services (HHS) released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform. The plan sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. These provisions will take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare and Medicaid Services ("CMS") Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. 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.

The implementation of cost-containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize NUPLAZID, DAYBUE or any other products for which we may receive regulatory approval.

***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: state 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 laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal 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/or the registration of pharmaceutical sales representatives; and state 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 NUPLAZID, DAYBUE and any other product candidates that may be approved, 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 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. In addition, the approval and commercialization of NUPLAZID, DAYBUE or any other product candidates that may be approved, outside the U.S. will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

***We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our 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, processing) 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. 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 civil penalties of up to \$7,500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA may increase compliance costs and potential liability with respect to other personal data we may maintain about California residents. In addition, the California Privacy Rights Act of 2020 (CPRA), which became operative January 1, 2023, expands the CCPA's requirements, including applying to personal information of business representatives and employees and establishing a new regulatory agency to implement and enforce the law. Other states, such as Virginia and Colorado, have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. While these states, like the CCPA, also exempt some data processed in the context of clinical

trials, these developments further complicate compliance efforts and increase legal risk and compliance costs for us and the third parties upon whom we rely.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the EU GDPR, UK GDPR, Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or LGPD) (Law No. 13,709/2018), and China's Personal Information Protection Law (PIPL) impose strict requirements for processing personal data. For example, 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 may adopt similarly stringent interpretations of their 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 and UK's standard contractual clauses, 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 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 EU 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.

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 such obligations in the future. We may also be bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We may publish privacy policies, marketing materials, and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

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

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely on may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely 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); additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data. 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., 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, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price (AMP), for single source and innovator multiple source drugs, beginning 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, there can be no assurance that we will 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 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 NUPLAZID or DAYBUE for any "off-label" uses.\****

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 or patient population that is not described in the product's FDA-approved label in the U.S. or for uses in other jurisdictions that differ from those approved by the applicable regulatory agencies. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician'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 other regulatory agencies with respect to our promotion of NUPLAZID, DAYBUE and any other products we may market, but we cannot be sure that the FDA or other regulatory agencies will agree that we have not violated their restrictions. As a result, we may be subject to criminal and civil liability. In addition, our management's attention could be diverted to handle any such alleged violations. 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 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.

***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, 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, which is 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, including beginning on December 22, 2018 and ending on January 25, 2019, 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. If repeated or prolonged government shutdowns occur, it 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 NUPLAZID, DAYBUE and any other products derived from our product candidates, which could delay the development 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 authorities in other countries. Neither we nor our collaborators can market a pharmaceutical product, including NUPLAZID and DAYBUE, in the U.S. until it has completed rigorous preclinical testing and clinical trials and an extensive regulatory clearance process implemented by the FDA. Satisfaction of regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product, and requires substantial resources. Even if regulatory approval is obtained, the FDA and other regulatory agencies 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.

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. 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 may be delayed or suspended, which may delay or impede our ability to generate product revenues.

***If our competitors develop and market products that are more effective than NUPLAZID, DAYBUE or our other product candidates, they may reduce or eliminate our commercial opportunity.\****

Competition in the pharmaceutical and biotechnology industries is intense and expected to increase. We face competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, both in the U.S. and abroad. Some of these competitors have products or are pursuing the development of drugs that target the same diseases and conditions that are the focus of our drug development programs.

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. Pimavanserin for the treatment of negative symptoms of schizophrenia, if approved for that indication, would compete with off-label use of Vraylar, marketed by Allergan, Rexulti, marketed by Otsuka Pharmaceutical Co., Ltd., Latuda, marketed by Sunovion Pharmaceuticals Inc., Caplyta, marketed by IntraCellular Therapeutics and various generic drugs, including quetiapine, clozapine, risperidone, aripiprazole, and olanzapine. In addition, DAYBUE will 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. In

addition, Anavex has a product, Anavex 2-73 in development for the potential treatment of Rett syndrome. Several academic institutions and pharmaceutical companies are currently conducting clinical trials for the treatment of various symptoms of Rett syndrome.

Many of our competitors and their collaborators have significantly greater experience than we do in the following:

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

In addition, many of our competitors and their collaborators have substantially greater capital and research and development resources, manufacturing, sales and marketing capabilities, 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 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 NUPLAZID, DAYBUE or any other product for which we obtain regulatory approval, or development or commercialization of our product candidates.\****

We face an inherent risk of product liability as a result of the commercial sales of NUPLAZID and DAYBUE in the U.S. and the clinical testing of our product candidates, and will face an even greater risk following commercial launch of NUPLAZID in additional jurisdictions, if approved, or if we engage in the clinical testing of new product candidates or commercialize any additional products. For example, we may be sued if NUPLAZID, DAYBUE or any other product we develop allegedly causes injury or is 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. 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 that we may develop;
- 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; and
- a decline in our stock price.

Although we currently have product liability insurance that covers our clinical trials and the commercialization of NUPLAZID and DAYBUE, we may need to increase and expand this coverage, including if we commence larger scale trials and if other 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 upon which we rely, 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 upon which we rely, process, collect, receive, store, use, transmit, transfer, make accessible, protect, secure, dispose of, disclose and share proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property, and trade secrets.

Cyberattacks, malicious internet-based activity, online and offline fraud and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. 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,” 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 upon which we rely 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 upon which we rely are subject to a variety of evolving threats, including but not limited to, social engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), 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, 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, loss of 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 become more common and has increased risks to our information technology systems and data, as more of 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 information 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 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, in May 2021, a key drug supplier notified us of a ransomware attack on our supplier’s systems; however, to date we found no indication that our personal data was exposed.

Any of the previously identified or similar threats could cause 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 upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our products.

We may expend significant resources, 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 information. 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 to detect and remediate vulnerabilities, but we may be unable in the future to detect vulnerabilities in our information technology systems (including our products) because such threats and techniques change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. These vulnerabilities pose material risks to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) 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 information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may 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 information 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.

## **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 3, 2023 to September 30, 2023, the closing price of our common stock has ranged from a low of \$16.32 per share to a high of \$33.47 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 NUPLAZID in the U.S. for the treatment of hallucinations and delusions associated with PDP and DAYBUE in the U.S. for the treatment of Rett syndrome;
- the status and cost of development and commercialization of our product candidates, 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 or products;

- the status and cost of development and commercialization of pimavanserin for indications other than in PDP, including ADP, and in jurisdictions other than the U.S.;
- any other communications or guidance from the FDA or other regulatory authorities that pertain to NUPLAZID, DAYBUE or our product candidates;
- the status and cost of our post-marketing commitments for NUPLAZID;
- 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, including, for example, recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures, the ongoing conflict between Ukraine and Russia and related sanctions and the ongoing conflict in Israel; 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 often been brought against that company. For example, we, and certain of our current and former officers and directors, are subject to numerous lawsuits related to prior statements about NUPLAZID and our sNDA seeking approval of pimavanserin for the treatment of hallucinations and delusions associated with DRP, as described in "Legal Proceedings". If we are not successful in defense of these claims, we may have to make significant payments to, or other settlements with, our stockholders and their attorneys. Even if such claims are not successful, the litigation has resulted in additional costs in the past and could result in further substantial costs and diversion of our management's attention and resources in the future, which could have a material adverse effect on our business, operating results or financial condition.

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

A significant number of shares of our common stock are held by a small number of stockholders. Sales of a significant number of shares of our common stock, or the expectation that such sales may occur, could significantly reduce the market price of our common stock. In connection with our March 2014 public offering of common stock, we agreed to provide resale registration rights for the shares of our common stock held by entities affiliated with one of our principal stockholders and two of our directors, Julian C. Baker and Dr. Stephen R. Biggar, which we refer to as the Baker Entities. In connection with our January 2016 public offering of common stock, we entered into a formal registration rights agreement with the Baker Entities to provide for these rights. Under the registration rights agreement, we have 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, we would be obligated to effect such registration. On May 25, 2022, we filed a registration statement covering the sale of up to 42,393,855 shares of our common stock, which includes 489,269

shares of our common stock issuable upon the exercise of warrants that were owned by the Baker Entities as of May 16, 2022, and which represented approximately 26 percent of our outstanding shares at the time. Our registration obligations under this registration rights agreement, which cover all shares 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 of our common stock by the Baker Entities in the future. If the Baker Entities sell a large number of our shares, or the market perceives that the Baker Entities intend to sell a large number of our shares, this could adversely affect the market price of our common stock. We also may elect to sell from time to time an indeterminate number of shares on our own behalf pursuant to a registration statement or in a private placement. Our stock price may decline as a result of the sale of the 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<sup>2/3</sup>% stockholder approval; and
- provide for a board of directors with staggered terms.

We are also subject to provisions of the Delaware corporation law 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.

***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.

## General Risk Factors

***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.

***We have incurred, and expect to continue to incur, significant costs as a result of laws and regulations relating to corporate governance and other matters.***

Laws and regulations affecting public companies, including 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), and rules adopted or proposed by the SEC and by The Nasdaq Stock Market, have resulted in, and will continue to result in, significant costs to us as we evaluate the implications of these rules and respond to their requirements. 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. New rules could make it more difficult or more costly for us to obtain certain types of insurance, including 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. We cannot predict or estimate the total amount of the costs we may incur or the timing of such costs to comply with these rules and regulations.

***Adverse securities and credit market conditions may significantly affect our ability to raise capital.***

Historically, turmoil and volatility in the financial markets (including recent volatility as a result of geopolitical and macroeconomic developments such as the ongoing conflict between Ukraine and Russia and related sanctions and the ongoing conflict in Israel) have adversely affected the market capitalizations of many biotechnology companies, and generally made equity and debt financing more difficult to obtain. These events, coupled with other factors, may limit our access to financing in the future. This could have a material adverse effect on our ability to access funding on acceptable terms, or at all, and our stock price may suffer further as a result.

## **ITEM 5. OTHER INFORMATION**

### **Insider Trading Arrangements**

The following officers adopted, modified or terminated a “Rule 10b5-1 trading arrangement” as defined in Item 408 of Regulation S-K, as follows:

- On May 23, 2023, Mark C. Schneyer, Executive Vice President and Chief Financial Officer, adopted a Rule 10b5-1 trading arrangement providing for the sale of up to 28,103 shares of our common stock. The trading arrangement is intended to satisfy the affirmative defense in Rule 10b5-1(c). The duration of the trading arrangement is from August 21, 2023 until July 31, 2024, or earlier if and when all transactions under the trading arrangement are completed.
- On July 19, 2023, Brendan P. Teehan, Executive Vice President, Chief Operating Officer and Head of Commercial, terminated a Rule 10b5-1 trading arrangement providing for the sale of up to 30,000 shares of our common stock. The trading arrangement was intended to satisfy the affirmative defense in Rule 10b5-1(c). The duration of the trading arrangement was until July 31, 2023, or earlier if all transactions under the trading arrangement had been completed. At the time of termination, no shares had been sold under the trading arrangement.

No other officers or directors, as defined in Rule 16a-1(f), adopted, modified, or terminated a “Rule 10b5-1 trading arrangement” or a “non-Rule 10b5-1 trading arrangement,” as defined in Regulation S-K Item 408, during the fiscal quarter.



**ITEM 6. EXHIBITS**

<b>Exhibit Number</b>	<b>Description</b>
3.1	<a href="#"><u>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).</u></a>
3.2	<a href="#"><u>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 24, 2021).</u></a>
3.3	<a href="#"><u>Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed September 12, 2013).</u></a>
4.1	<a href="#"><u>Form of common stock certificate of the Registrant (incorporated by reference to Exhibit 4.1 to Registration Statement No. 333-52492).</u></a>
4.2	<a href="#"><u>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).</u></a>
10.1*	<a href="#"><u>Joint Venture and Licence Agreement, dated July 13, 2023, by and between the Registrant and Neuren Pharmaceuticals Ltd (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed on August 3, 2023).</u></a>
31.1	<a href="#"><u>Certification of Stephen R. Davis, 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.</u></a>
31.2	<a href="#"><u>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.</u></a>
32.1	<a href="#"><u>Certification of Stephen R. Davis, Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u></a>
32.2	<a href="#"><u>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.</u></a>
101	The following financial statements from the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, filed on November 2, 2023, 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 Loss, (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)

\* Pursuant to Item 601(b)(10) of Regulation S-K promulgated by the SEC, certain portions of this exhibit have been redacted (indicated by "[...\*\*\*...]") because the Registrant has determined that the information is not material and is the type that the Registrant treats as private or confidential.

## 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 2, 2023

By: /s/ Mark C. Schneyer

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Mark C. Schneyer

Executive Vice President and Chief Financial Officer

(on behalf of the registrant and as the registrant's Principal Financial Officer)

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

I, Stephen R. Davis, 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 2, 2023

/s/ STEPHEN R. DAVIS  

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**Stephen R. Davis**  
**Chief Executive Officer**  
(Registrant's Principal Executive Officer)

**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 2, 2023

/s/ MARK C. SCHNEYER

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

**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, 2023, as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), I, Stephen R. Davis, 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 2, 2023

/s/ STEPHEN R. DAVIS

**Stephen R. Davis**  
**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.

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**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, 2023, 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 2, 2023

/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.

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