

**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 June 30, 2020

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)

3611 Valley Centre Drive, Suite 300  
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 common stock outstanding as of the close of business on July 22, 2020:

<u>Class</u>	<u>Number of Shares Outstanding</u>
Common Stock, \$0.0001 par value	157,680,830

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)

	June 30, 2020 (unaudited)	December 31, 2019
<b>Assets</b>		
Cash and cash equivalents	\$ 310,441	\$ 189,680
Investment securities, available-for-sale	348,110	507,749
Accounts receivable, net	43,785	35,781
Interest and other receivables	2,343	2,093
Inventory	6,210	6,341
Prepaid expenses	24,846	18,606
Total current assets	<u>735,735</u>	<u>760,250</u>
Property and equipment, net	6,687	3,180
Operating lease right-of-use assets	7,880	9,524
Intangible assets, net	1,846	2,585
Restricted cash	5,770	4,787
Other assets	1,731	2,857
Total assets	<u>\$ 759,649</u>	<u>\$ 783,183</u>
<b>Liabilities and stockholders' equity</b>		
Accounts payable	\$ 6,466	\$ 7,222
Accrued liabilities	79,956	67,604
Total current liabilities	<u>86,422</u>	<u>74,826</u>
Operating lease liabilities	5,669	6,361
Other long-term liabilities	4,545	2,861
Total liabilities	<u>96,636</u>	<u>84,048</u>
Commitments and contingencies (Note 9)		
<b>Stockholders' equity:</b>		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized at June 30, 2020 and December 31, 2019; no shares issued and outstanding at June 30, 2020 and December 31, 2019	—	—
Common stock, \$0.0001 par value; 225,000,000 shares authorized at June 30, 2020 and December 31, 2019; 157,383,379 shares and 155,275,300 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	15	15
Additional paid-in capital	2,495,804	2,402,945
Accumulated deficit	(1,834,286)	(1,704,122)
Accumulated other comprehensive income	1,480	297
Total stockholders' equity	<u>663,013</u>	<u>699,135</u>
Total liabilities and stockholders' equity	<u>\$ 759,649</u>	<u>\$ 783,183</u>

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 June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
<b>Revenues</b>				
Product sales, net	\$ 110,103	\$ 83,205	\$ 200,171	\$ 146,164
Total revenues	110,103	83,205	200,171	146,164
<b>Operating expenses</b>				
Cost of product sales	2,899	2,958	5,698	5,908
License fees and royalties	2,575	2,037	4,750	3,667
Research and development	64,295	67,320	136,931	120,243
Selling, general and administrative	84,344	67,981	186,317	161,071
Total operating expenses	154,113	140,296	333,696	290,889
Loss from operations	(44,010)	(57,091)	(133,525)	(144,725)
Interest income, net	1,825	2,527	4,814	5,461
Other income (expense)	437	(12)	(1,060)	(241)
Loss before income taxes	(41,748)	(54,576)	(129,771)	(139,505)
Income tax expense	393	365	393	740
Net loss	\$ (42,141)	\$ (54,941)	\$ (130,164)	\$ (140,245)
Net loss per common share, basic and diluted	\$ (0.27)	\$ (0.38)	\$ (0.83)	\$ (0.97)
Weighted average common shares outstanding, basic and diluted	156,535	144,314	155,951	144,148

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 June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Net loss	\$ (42,141)	\$ (54,941)	\$ (130,164)	\$ (140,245)
Other comprehensive income (loss):				
Unrealized (loss) gain on investment securities	(43)	348	1,183	925
Foreign currency translation adjustments	(2)	(1)	—	1
Comprehensive loss	<u>\$ (42,186)</u>	<u>\$ (54,594)</u>	<u>\$ (128,981)</u>	<u>\$ (139,319)</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)

	<u>Six Months Ended June 30,</u>	
	<u>2020</u>	<u>2019</u>
<b>Cash flows from operating activities</b>		
Net loss	\$ (130,164)	\$ (140,245)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	41,855	40,305
Amortization of premiums and accretion of discounts on investment securities	481	(1,995)
Amortization of intangible assets	739	739
Loss on strategic investment	1,060	241
Depreciation	648	741
Changes in operating assets and liabilities:		
Accounts receivable, net	(8,004)	(5,691)
Interest and other receivables	(250)	758
Inventory	(20)	273
Prepaid expenses	(6,240)	2,220
Operating lease right-of-use assets	2,025	1,133
Other assets	66	70
Accounts payable	(756)	1,483
Accrued liabilities	11,853	(1,576)
Operating lease liabilities	(862)	(1,077)
Long-term liabilities	1,684	49
Net cash used in operating activities	<u>(85,885)</u>	<u>(102,572)</u>
<b>Cash flows from investing activities</b>		
Purchases of investment securities	(100,813)	(176,677)
Maturities of investment securities	261,153	210,904
Purchases of property and equipment	(3,867)	(842)
Net cash provided by investing activities	<u>156,473</u>	<u>33,385</u>
<b>Cash flows from financing activities</b>		
Proceeds from issuance of common stock, net of issuance costs	51,155	8,822
Net cash provided by financing activities	<u>51,155</u>	<u>8,822</u>
Effect of exchange rate changes on cash	1	—
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>121,744</u>	<u>(60,365)</u>
<b>Cash, cash equivalents and restricted cash</b>		
Beginning of period	194,467	139,584
End of period	<u>\$ 316,211</u>	<u>\$ 79,219</u>
<b>Supplemental disclosure of noncash information:</b>		
Property and equipment purchases in accounts payable and accrued liabilities	\$ 288	\$ 17

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)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
<b>Total stockholders' equity, beginning balances</b>	<u>\$ 638,382</u>	<u>\$ 418,356</u>	<u>\$ 699,135</u>	<u>\$ 479,079</u>
<b>Common stock:</b>				
Beginning balance	15	14	15	14
Ending balance	<u>15</u>	<u>14</u>	<u>15</u>	<u>14</u>
<b>Additional paid-in capital:</b>				
Beginning balance	2,428,987	1,972,302	2,402,945	1,948,300
Issuance of common stock from exercise of stock options and units	43,431	2,447	47,185	6,623
Issuance of common stock pursuant to employee stock purchase plan	3,970	2,199	3,970	2,199
Stock-based compensation	19,416	20,506	41,704	40,332
Ending balance	<u>2,495,804</u>	<u>1,997,454</u>	<u>2,495,804</u>	<u>1,997,454</u>
<b>Accumulated deficit:</b>				
Beginning balance	(1,792,145)	(1,554,167)	(1,704,122)	(1,468,863)
Net loss	(42,141)	(54,941)	(130,164)	(140,245)
Ending balance	<u>(1,834,286)</u>	<u>(1,609,108)</u>	<u>(1,834,286)</u>	<u>(1,609,108)</u>
<b>Other comprehensive income (loss):</b>				
Beginning balance	1,525	207	297	(372)
Other comprehensive (loss) income	(45)	347	1,183	926
Ending balance	<u>1,480</u>	<u>554</u>	<u>1,480</u>	<u>554</u>
<b>Total stockholders' equity, ending balances</b>	<u>\$ 663,013</u>	<u>\$ 388,914</u>	<u>\$ 663,013</u>	<u>\$ 388,914</u>

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 disorders. The Company was originally incorporated in Vermont in 1993 as Receptor Technologies, Inc. and reincorporated in Delaware in 1997.

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 (“PD Psychosis”). NUPLAZID became available for prescription in the United States in May 2016.

**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, 2019 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 from those estimates.

*Risk and Uncertainties*

The global pandemic resulting from the disease known as COVID-19, caused by a novel strain of coronavirus, SARS-CoV-2, has caused national and global economic and financial market disruptions and has impacted the Company’s business, including by causing the vast majority of the Company’s workforce to work remotely since March 2020. Although the Company did not see a material impact on its net revenue in the first half of 2020 due to the COVID-19 pandemic, the Company cannot predict the duration or magnitude of the pandemic or the full impact that it may have on the Company’s financial condition, operations, suppliers, and workforce.

During the six months ended June 30, 2020, there have been no changes to the Company’s significant accounting policies as described in its Annual Report on Form 10-K for the fiscal year ended December 31, 2019, except as described below and in Note 6, *investments*.

*Cash, Cash Equivalents and Restricted Cash*

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

	<u>Six Months Ended June 30, 2020</u>		<u>Six Months Ended June 30, 2019</u>	
	<u>Beginning of period</u>	<u>End of period</u>	<u>Beginning of period</u>	<u>End of period</u>
Cash and cash equivalents	\$ 189,680	\$ 310,441	\$ 134,758	\$ 74,432
Restricted cash	4,787	5,770	4,826	4,787
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	<u>\$ 194,467</u>	<u>\$ 316,211</u>	<u>\$ 139,584</u>	<u>\$ 79,219</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. As described further in Note 10, *Recent Accounting Pronouncements*, the Company adopted Financial Accounting Standards Board (“FASB”) Accounting Standards Codification 326-20, *Financial Instruments – Credit Losses* (“ASC 326-20”) as of January 1, 2020. The Company estimated the current expected credit losses of its accounts receivable by assessing the risk of loss and available relevant information about the collectability, including historical credit losses, existing contractual payment terms, actual payment patterns of its customers, individual customer circumstances, and reasonable and supportable forecast of economic conditions expected to exist throughout the contractual life of the receivable. Based on its assessment, as of June 30, 2020 the Company determined that an allowance for credit loss was not required.

Although the Company has not historically experienced significant credit losses, the Company’s exposure may increase due to uncertainties associated with the global economic recession and other disruptions resulting from the COVID-19 pandemic.

## 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 FDA approval of NUPLAZID in April 2016, the Company made a one-time milestone payment of \$8.0 million pursuant to its 2006 license agreement with the Ipsen Group in which the Company licensed certain intellectual property rights that complement its patent portfolio for its serotonin platform, including NUPLAZID. The Company capitalized the \$8.0 million payment as an intangible asset and is amortizing the asset on a straight-line basis over the estimated useful life of the licensed patents through the second half of 2021. The Company recorded amortization expense related to its intangible asset of \$0.4 million and \$0.7 million for each of the three and six months ended June 30, 2020 and 2019, respectively. As of June 30, 2020, estimated future amortization expense related to the Company’s intangible asset was \$0.7 million for the remainder of 2020 and \$1.1 million for 2021.

Royalties incurred in connection with the Company’s license agreement with the Ipsen Group, as disclosed in Note 9, *Commitments and Contingencies*, are expensed to license fees and royalties as revenue from product sales is recognized.

## 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, restricted stock units, and warrants 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 June 30, 2020 and 2019, stock options, employee stock purchase plan rights, restricted stock units, and warrants totaling approximately 19,930,000 shares and 23,389,000 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 condensed consolidated statements of operations for the periods presented (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Cost of product sales	\$ 743	\$ 803	\$ 1,592	\$ 1,798
Research and development	7,235	7,901	15,692	15,781
Selling, general and administrative	11,529	11,718	24,571	22,726
	<u>\$ 19,507</u>	<u>\$ 20,422</u>	<u>\$ 41,855</u>	<u>\$ 40,305</u>

## 5. Balance Sheet Details

Inventory consisted of the following (in thousands):

	June 30, 2020	December 31, 2019
Raw material	\$ 2,677	\$ 3,175
Work in process	1,173	1,685
Finished goods	2,360	1,481
	<u>\$ 6,210</u>	<u>\$ 6,341</u>

Accrued liabilities consisted of the following (in thousands):

	June 30, 2020	December 31, 2019
Accrued compensation and benefits	\$ 20,005	\$ 21,080
Accrued consulting and professional fees	19,611	13,691
Accrued research and development services	19,355	14,273
Accrued sales allowances	12,884	11,326
Current portion of lease liabilities	2,653	3,434
Accrued royalties	2,214	1,971
Other	3,234	1,829
	<u>\$ 79,956</u>	<u>\$ 67,604</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):

	June 30, 2020			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury notes	\$ 185,739	\$ 656	\$ —	\$ 186,395
Government sponsored enterprise securities	38,445	111	—	38,556
Corporate debt securities	90,142	567	(1)	90,708
Commercial paper	32,317	134	—	32,451
	<u>\$ 346,643</u>	<u>\$ 1,468</u>	<u>\$ (1)</u>	<u>\$ 348,110</u>

  

	December 31, 2019			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury notes	\$ 228,609	\$ 7	\$ (13)	\$ 228,603
Government sponsored enterprise securities	88,920	5	(30)	88,895
Corporate debt securities	87,785	262	(8)	88,039
Commercial paper	102,151	61	—	102,212
	<u>\$ 507,465</u>	<u>\$ 335</u>	<u>\$ (51)</u>	<u>\$ 507,749</u>

The Company has classified all of its available-for-sale investment securities, including those with maturities beyond one year, 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. As of June 30, 2020, all of the Company's available-for-sale investment securities have contractual maturity dates of less than one year. As of December 31, 2019, the Company held \$24.3 million of available-for-sale investment securities with contractual maturity dates of more than one year and less than two years. The Company has classified all equity securities as other assets on its condensed consolidated balance sheets.

At June 30, 2020 and December 31, 2019, the Company had one and 20 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 June 30, 2020 and December 31, 2019, 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>June 30, 2020</b>						
Corporate debt securities	\$ —	\$ —	\$ 4,003	\$ (1)	\$ 4,003	\$ (1)
Total	\$ —	\$ —	\$ 4,003	\$ (1)	\$ 4,003	\$ (1)
	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, 2019:</b>						
U.S. Treasury notes	\$ 148,397	\$ (13)	\$ —	\$ —	\$ 148,397	\$ (13)
Government sponsored enterprise securities	61,103	(30)	—	—	61,103	(30)
Corporate debt securities	11,334	(8)	—	—	11,334	(8)
Total	\$ 220,834	\$ (51)	\$ —	\$ —	\$ 220,834	\$ (51)

As described further in Note 10, *Recent Accounting Pronouncements* the Company adopted FASB Accounting Standards Codification 326-30, *Financial Instruments – Credit Losses* (“ASC 326-30”) as of January 1, 2020. ASC 326-30 requires the Company to determine whether a decline in the fair value below the amortized cost basis of available-for-sale securities is due to credit-related factors. 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.

The Company does not intend to sell the investment in unrealized loss position and it is unlikely that the Company will be required to sell the investment before the recovery of its amortized cost basis. Based on its evaluation, the Company determined its year-to-date credit losses related to its available-for-sale securities were immaterial at June 30, 2020.

Although the Company has not historically experienced significant losses on its investments, the Company’s exposure may increase due to uncertainties associated with the global economic recession and other disruptions resulting from the COVID-19 pandemic.

## 7. Fair Value Measurements

The Company’s investments include cash equivalents, available-for-sale investment securities consisting of money market funds, U.S. Treasury notes, and high quality, marketable debt instruments of corporations 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 A3/A- 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 June 30, 2020 and December 31, 2019.

The Company does not hold any securities classified as Level 3, which are securities valued using unobservable inputs. The Company has not transferred any investment securities between the classification levels.

The recurring fair value measurements of the Company's cash equivalents, available-for-sale investment securities and equity securities at June 30, 2020 and December 31, 2019 consisted of the following (in thousands):

	June 30, 2020	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)
Money market fund	\$ 282,247	\$ 282,247	\$ —	\$ —
U.S. Treasury notes	186,395	186,395	—	—
Equity securities	1,247	1,247	—	—
Government sponsored enterprise securities	38,556	—	38,556	—
Corporate debt securities	90,708	—	90,708	—
Commercial paper	32,451	—	32,451	—
	<u>\$ 631,604</u>	<u>\$ 469,889</u>	<u>\$ 161,715</u>	<u>\$ —</u>

	December 31, 2019	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)
Money market fund	\$ 98,084	\$ 98,084	\$ —	\$ —
U.S. Treasury notes	228,603	228,603	—	—
Equity securities	2,307	2,307	—	—
Government sponsored enterprise securities	103,878	—	103,878	—
Corporate debt securities	88,039	—	88,039	—
Commercial paper	102,212	—	102,212	—
	<u>\$ 623,123</u>	<u>\$ 328,994</u>	<u>\$ 294,129</u>	<u>\$ —</u>

## 8. Stockholders' Equity

### Public Offerings

In September 2019, the Company raised net proceeds of approximately \$271.5 million from the sale of 7,187,500 shares of its common stock in a follow-on public offering, including 937,500 shares sold pursuant to the exercise in full of the underwriters' option to purchase additional shares.

In November 2018, the Company raised net proceeds of approximately \$298.5 million from the sale of 18,602,941 shares of its common stock in a follow-on public offering, including 2,426,470 shares sold pursuant to the exercise in full of the underwriters' option to purchase additional shares.

In August 2016, the Company raised net proceeds of approximately \$215.9 million from the sale of 6,969,696 shares of its common stock in a follow-on public offering, including 909,090 shares sold pursuant to the exercise in full of the underwriters' option to purchase additional shares.

In January 2016, the Company raised net proceeds of approximately \$281.6 million from the sale of 10,344,827 shares of its common stock in a follow-on public offering. In connection with the January 2016 offering, the Company entered into a registration rights agreement (the "Registration Rights Agreement") with 667, L.P., Baker Brothers Life Sciences, L.P. and 14159, L.P. (the "Baker Entities"), all of which are existing stockholders of the Company and are affiliated with two of its directors, Julian C. Baker and Dr. Stephen R. Biggar. Under the Registration Rights Agreement, the Company agreed that, if the Baker Entities demand that the Company register their shares of its common stock for resale under the Securities Act of 1933, as amended (the "Securities Act"), the Company would be obligated to effect such registration. The Company's registration obligations under the Registration Rights Agreement cover all shares of its common stock now held or later acquired by the Baker Entities (including approximately \$75.0 million, \$43.0 million, \$200.0 million, and \$62.5 million of shares that the Baker Entities purchased at the public offering price in the January 2016, August 2016, November 2018, and September 2019 offerings, respectively), will continue in effect for up to 10 years, and include the Company's obligation to facilitate certain underwritten public offerings of its common stock by the Baker Entities in the future. The Company has agreed to bear all expenses incurred by it in effecting any registration pursuant to the Registration Rights Agreement as well as the legal expenses of the Baker Entities of up to \$50,000 per underwritten public offering effected pursuant to the Registration Rights Agreement. On May 3, 2019, pursuant to the Registration Rights Agreement, the Company filed a registration statement covering all shares owned by the Baker Entities as of April 29, 2019.

### ***Private Equity Financings***

In December 2012, the Company raised net proceeds of \$80.5 million through the sale of 19,000,000 shares of its common stock at a price of \$4.43 per share and the sale of warrants to purchase 500,000 shares of its common stock at a price of \$4.42 per warrant share in a private equity financing. The warrants have an exercise price of \$0.01 per share. In accordance with authoritative accounting guidance, the warrants' value of \$2.2 million was determined on the date of grant using the Black-Scholes model and recorded as a component of stockholders' equity within additional paid-in capital. Per their terms, the warrants to purchase 500,000 shares of common stock, of which 493,145 remained outstanding at June 30, 2020, may not be exercised if the holder's ownership of the Company's common stock would exceed 19.99 percent following such exercise.

## **9. Commitments and Contingencies**

### ***Royalty Payments***

Pursuant to the terms of its 2006 license agreement with the Ipsen Group, the Company is required to make royalty payments of two percent of net sales of NUPLAZID. This obligation terminates in 2021.

### ***License Agreements***

The Company has entered into various collaboration and licensing 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 June 30, 2020, the Company may be required to make milestone payments up to \$1.1 billion.

In May 2018, the Company signed an Exclusivity Deed (the "Deed") with Neuren Pharmaceuticals Limited ("Neuren") that provided for exclusive negotiations for a period of three months from the date of the Deed. Under the terms of the Deed, the Company paid \$3.1 million to purchase 1,330,000 shares of Neuren and paid \$0.9 million for the exclusive right to negotiate a deal with Neuren, which was recorded in selling, general and administrative expenses in the second quarter of 2018. At June 30, 2020, the Company continues to hold the equity securities as a strategic investment in which the Company does not have a controlling interest or significant influence. Publicly held equity securities are measured using quoted prices in their respective active markets with changes recorded through other expense on the condensed consolidated statements of operations. Net gain on strategic investments recognized in other expense in the condensed consolidated statements of operations was \$0.4 million for the three months ended June 30, 2020. Net loss on strategic investments recognized in other expense in the condensed consolidated statements of operations was \$12,000 for the three months ended June 30, 2019, and \$1.1 million and \$0.2 million for the six months ended June 30, 2020 and 2019, respectively. The aggregate carrying amount of the Company's strategic equity investment was \$1.2 million and \$2.3 million included in other assets on its condensed consolidated balance sheets at June 30, 2020 and December 31, 2019, respectively.

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 may 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 March 2020, the Company entered into a license agreement and research collaboration with Vanderbilt University and obtained exclusive worldwide rights to develop and commercialize novel drug candidates targeting positive allosteric modulators of the muscarinic M1 receptor (the M1 PAM program) with the potential to treat a range of central nervous system disorders. Under the terms of the agreement, the Company paid Vanderbilt University an upfront license fee of \$10.0 million and may be required to pay up to \$515.0 million in milestone payments based on the achievement of certain clinical and commercial development and annual net sales milestones. In addition, the Company may be required to pay Vanderbilt University tiered royalties based on net sales. Furthermore, the Company is required to spend a minimum annual amount in development and the pursuit of regulatory approval for the M1 PAM compounds over the first three years of the license agreement. Such amounts are not material to the Company. 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 first quarter of 2020 as there is no future alternative use for the assets.

#### ***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***

Between July 19 and August 3, 2018, following negative publicity about NUPLAZID, three purported company stockholders filed putative securities class action complaints (captioned *Staublein v. ACADIA Pharmaceuticals, Inc.*, Case No. 18-cv-01647, *Stone v. ACADIA Pharmaceuticals Inc.*, Case No. 18-cv-01672, and *Barglow v. ACADIA Pharmaceuticals Inc.*, Case No. 18-cv-01812) in the U.S. District Court for the Southern District of California against the Company and certain of its current and former executive officers. Thereafter, several putative lead plaintiffs filed motions to consolidate the cases and to appoint a lead plaintiff. On January 3, 2019, the Court consolidated the cases under the caption *In re ACADIA Pharmaceuticals Inc. Securities Litigation*, Case No. 18-cv-01647, and took the lead plaintiff motions under submission. On February 26, 2019, the Court appointed a lead plaintiff and lead counsel. Lead plaintiff filed a consolidated complaint on April 15, 2019. The consolidated complaint generally alleges that defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by making materially false and misleading statements regarding the Company's business, operations, and prospects by failing to disclose that adverse events and safety concerns regarding NUPLAZID threatened initial and continuing FDA approval, and by failing to disclose that the Company engaged in business practices likely to attract regulatory scrutiny. The consolidated complaint seeks unspecified monetary damages and other relief. Defendants filed a motion to dismiss the consolidated complaint on June 7, 2019. On June 1, 2020, the Court granted the motion in part and gave lead plaintiff leave to file an amended complaint. On July 16, 2020, lead plaintiff filed the amended complaint.

On February 7, 2020, a purported company stockholder filed a derivative complaint (captioned *Barney v. Davis et al.*, Case No. 20-cv-0238) in the U.S. District Court for the Southern District of California against the Company's directors and certain of its current and former executive officers. The complaint asserts claims for breach of fiduciary duty, waste of corporate assets, and unjust enrichment arising from allegations similar to those in the federal securities class action described above. On February 19, 2020, the Court granted the parties' stipulation to stay the derivative action pending a ruling on the motion to dismiss in the federal securities class action. On July 16, 2020, the parties filed a joint motion to continue to stay the derivative action until the defendants answer, or the case is dismissed with prejudice and all appeals are exhausted, or any party gives 15 days' written notice that it no longer consents to the voluntary stay. The Court stayed the action on July 22, 2020.

On June 23, 2020, a purported company stockholder filed a derivative complaint (captioned *Lazarus v. Davis et al.*, Case No. 20-cv-0843) in the U.S. District Court for the District of Delaware against the Company's directors and certain of its current and former executive officers. The complaint asserts claims for contribution, breach of fiduciary duty, waste of corporate assets, and unjust enrichment arising from allegations similar to those in the federal securities class action described above.

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.

Management currently believes that none of the foregoing claims or actions pending against the Company as of June 30, 2020 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.

### Government Investigation

In September 2018, the Company received a civil investigative demand ("CID") from the Department of Justice ("DOJ") requesting certain documents and information related to the Company's sales and marketing of NUPLAZID. The Company is cooperating with the DOJ's request. Responding to the CID will require considerable resources and no assurance can be given as to the timing or outcome of the DOJ's investigation.

### 10. Recent Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-13, *Financial Instruments—Credit Losses: Measurement of Credit Losses on Financial Instruments*, which changes the impairment model for most financial assets and certain other instruments. For trade receivables and other instruments, entities will be required to use a new forward-looking expected loss model that generally will result in the earlier recognition of allowances for losses. For available-for-sale debt securities with unrealized losses, the losses will be recognized as allowances rather than as reductions in the amortized cost of the securities. This guidance is effective for annual reporting periods beginning after December 15, 2019, including interim periods within those years, with early adoption permitted only as of annual reporting periods beginning after December 15, 2018.

In April 2019, the FASB issued ASU 2019-04, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments*, which, among other things, provides entities with practical expedients and policy elections related to the presentation and disclosure of accrued interest and the related allowance for credit losses and clarifies how to disclose line-of-credit arrangements that are converted to term loans in the vintage table disclosure. ASU 2019-04 has the same effective date as the new credit impairment standard for entities that have not yet adopted the standard. For entities that early adopted the new credit impairment standard, ASU 2019-04 is effective for fiscal years beginning after December 15, 2019 and interim periods therein. Entities that early adopted the new credit impairment standard may early adopt ASU 2019-04.

The Company adopted the above standards on January 1, 2020. The adoption of the new standards did not have a material impact on the Company's consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12 Income Taxes (Topic 740), *Simplifying the Accounting for Income Taxes*. The Board issued this Update as part of its Simplification Initiative to improve areas of GAAP and reduce cost and complexity while maintaining usefulness. The main provision that impacts the Company is the removal of the exception to the incremental approach of intra-period tax allocation when there is a loss from continuing operations and income or gain from other items (for example, discontinued operations and other comprehensive income). ASU 2019-12 is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2020. Early adoption is permitted, including adoption in an interim period. The Company has elected to early adopt ASU 2019-12 as of the beginning of 2020, however, there is no cumulative effect to be recognized with the early adoption and no material impact on the Company's consolidated financial statements.

### 11. Leases

The Company leases facilities and certain equipment under noncancelable operating leases with remaining lease terms of 1.5 year to 5.6 years, one of which includes an option to extend the lease for one five-year term. This optional period was 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 option.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating lease cost	\$ 1,428	\$ 1,271	\$ 2,915	\$ 2,546

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Cash paid for amounts included in the measurement of lease liabilities:				
Operating cash flows from operating leases	\$ 1,291	\$ 1,228	\$ 2,582	\$ 2,357
Right-of-use assets obtained in exchange for operating lease obligations:	105	200	381	11,951

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

	June 30, 2020	December 31, 2019
<b>Operating lease liabilities</b>		
Current portion included in accrued liabilities	\$ 2,653	\$ 3,434
Operating lease liabilities	5,669	6,361
Total operating lease liabilities	<u>\$ 8,322</u>	<u>\$ 9,795</u>

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

	Operating Leases
Remainder of 2020	\$ 1,390
Years ending December 31,	
2021	2,735
2022	2,210
2023	1,369
2024	1,114
Thereafter	1,011
Total lease payments	9,829
Less:	
Imputed interest	(1,507)
Total operating lease liabilities	<u>\$ 8,322</u>

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 June 30, 2020, the weighted average remaining lease term is 4.8 years and the weighted average discount rate used to determine the operating lease liability was 8.0%.

In the fourth quarter of 2018, the Company entered into an agreement to lease approximately 67,020 square feet 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 approximately 30,608 square feet of additional 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 67,020 square feet of corporate office space to \$51.4 million. As of June 30, 2020, the lease had not yet commenced. This operating lease is expected to commence in the third quarter of 2020. In connection with this lease and its amendment agreements, the Company established a letter of credit for \$3.1 million, which has automatic annual extensions and is fully secured by restricted cash.

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

The following discussion and analysis of our 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 on Form 10-Q, or this Quarterly Report, and the audited financial statements and notes thereto as of and for the year ended December 31, 2019 included with our Annual Report on Form 10-K, or our Annual Report, filed with the Securities and Exchange Commission, or 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® (pimavanserin) and other drug candidates, the potential market opportunities for pimavanserin and other drug candidates, our strategy for the commercialization of NUPLAZID, our plans for exploring and developing pimavanserin for indications other than in Parkinson’s disease psychosis, 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 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, the potential or expected impact of the global COVID-19 pandemic on our business, 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**

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

On March 11, 2020, the World Health Organization declared a pandemic resulting from the disease known as COVID-19 caused by a novel strain of coronavirus, SARS-CoV-2. In an effort to contain COVID-19 or slow its spread, governments around the world have enacted various measures, including orders to close all businesses not deemed “essential,” isolate residents to their homes or places of residence, and practice social distancing when engaging in essential activities. In certain countries, and in certain states within the U.S., such orders have been lifted, although recent trends in COVID-19 infections have led to the reinstatement of such orders in various jurisdictions. Certain states in the United States, such as New York, have imposed quarantine requirements on residents of other states travelling to such states, and on July 1, 2020, the European Union banned entry by nonessential travelers from the United States. Additionally, as a result of the pandemic, there have been changes in the practice of medical care and medical education. For example, a significant number of health care providers are conducting patient visits through telemedicine and enrollment in clinical trials is being assessed based on local COVID-19 conditions and regional regulatory guidance. In addition, in many regions within the U.S. the ability of our sales force to call upon medical clinics, hospitals, long-term care facilities and skilled nursing facilities has been restricted or converted to remote access, and many medical congresses, an important means for medical education, have been cancelled or are being conducted virtually.

In an effort to protect the health and safety of our employees and our stakeholders, we adopted recommended policies applicable to office-based employees such as working from home, limiting employees to essential on site work only, and suspending all business travel. For our field-based commercial and medical affairs personnel, we have instituted a protocol to assess the safety of employees to conduct in-person interactions on a localized basis in accordance with applicable regulatory guidance and local policies.

Since the beginning of the pandemic, we have been able to provide an uninterrupted supply of NUPLAZID to patients. We are monitoring our supply chain closely and do not anticipate disruptions in our ability to continue delivering NUPLAZID to patients.

Although we did not see a significant impact on NUPLAZID net sales in the first half of 2020, the duration and ultimate effect of the COVID-19 pandemic on our business, results of operations, financial condition and prospects are difficult to assess or predict at this time. For example, we have re-initiated enrollment in clinical studies that were temporarily paused due to COVID-19 on a study-by-study and site-by-site basis. It is possible that future enrollment in these studies, or enrollment in future studies, could be impacted due to COVID-19. We are continuing to actively monitor the situation and may take further actions affecting our business operations as we deem necessary and in the best interests of our employees, customers, partners, suppliers, and stakeholders, or as required by federal, state, or local authorities.

## Background

We are a biopharmaceutical company focused on the development and commercialization of innovative medicines to address unmet medical needs in central nervous system disorders. We have a portfolio of product opportunities led by our novel drug, NUPLAZID (pimavanserin), which was approved by the U.S. Food and Drug Administration (FDA), in April 2016 for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis, or PD Psychosis. We hold worldwide commercialization rights to pimavanserin. NUPLAZID is available in 34 mg capsule and 10 mg tablet.

We believe that pimavanserin has the potential to address important unmet medical needs in neurological and psychiatric disorders in addition to PD Psychosis and we plan to continue to study the use of pimavanserin in multiple disease states. For example, we believe dementia-related psychosis (DRP), represents one of our most important opportunities for further exploration. In June 2020, we submitted a supplemental New Drug Application (sNDA) for NUPLAZID for the treatment of hallucinations and delusions associated with DRP. In July 2020 the FDA notified us of acceptance of our sNDA with a PDUFA date of April 3, 2021. The FDA advised us that it has not identified any potential review issues at this point in their evaluation and at this time they are not planning to hold an Advisory Committee meeting. The sNDA is supported by results from the pivotal Phase 3 HARMONY study, which met its primary endpoint, demonstrating that pimavanserin significantly reduced the risk of relapse of psychosis by 2.8 fold compared to placebo (hazard ratio = 0.353; one-sided  $p=0.0023$ ). The sNDA also includes positive efficacy results from two additional placebo-controlled studies, both of which met their respective primary endpoints: the Phase 2 (-019) study in patients with Alzheimer's disease psychosis and the Phase 3 (-020) study in patients with Parkinson's disease psychosis. The sNDA includes a large safety database from completed and ongoing studies representing over 1,500 patients with neurodegenerative disease. An estimated 8.0 million people in the United States are living with dementia, and studies suggest that approximately 30% of dementia patients, or 2.4 million people, have psychosis, commonly consisting of delusions and hallucinations. Approximately 1.2 million patients in the United States are currently treated for DRP and, of those treated, approximately two-thirds are treated with off-label anti-psychotics. In the fourth quarter of 2017, the FDA granted Breakthrough Therapy Designation for pimavanserin for the treatment of DRP.

In October 2018, we announced positive top-line results from CLARITY, a Phase 2 study evaluating pimavanserin for adjunctive treatment in 207 patients with major depressive disorder (MDD). In July 2020, we announced that our Phase 3 CLARITY study, which combined the two identical, double-blind, placebo-controlled studies (CLARITY-2 and CLARITY-3) in 298 patients, did not achieve statistical significance on the primary endpoint. At this time we do not plan on initiating any additional Phase 3 studies to evaluate pimavanserin for the adjunctive MDD indication.

Schizophrenia remains a disease with high unmet need, and we are currently exploring the utility of pimavanserin in this area. In the fourth quarter of 2016, we initiated our ADVANCE study, a Phase 2 study that evaluated pimavanserin for the negative symptoms of schizophrenia, for which there are currently no FDA-approved therapies. Negative symptoms of schizophrenia have been associated with poor long-term outcomes and disability even when the positive symptoms are well controlled, representing a high unmet need. In November 2019, we announced positive top-line results from our ADVANCE study that evaluated the efficacy of pimavanserin compared to placebo in 403 patients with predominantly negative symptoms of schizophrenia who have achieved adequate control of positive symptoms with their existing antipsychotic treatment. Pimavanserin demonstrated a statistically significant improvement on the study's primary endpoint, the change from baseline to week 26 on the Negative Symptom Assessment-16 (NSA-16) total score compared to placebo ( $p=0.043$ ). A greater improvement in the NSA-16 total score compared to placebo was observed in patients who received the highest pimavanserin dose of 34 mg ( $n=107$ ; unadjusted  $p=0.0065$ ). 53.8% of patients who were randomized to receive pimavanserin completed the trial on 34 mg, 44.7% on 20 mg, and 1.5% on 10 mg. In the study, pimavanserin did not separate from placebo on the key secondary endpoint, the Personal and Social Performance (PSP), scale. In the third quarter of 2020, we initiated a second pivotal study, ADVANCE-2. The Phase 3 study will evaluate the efficacy of pimavanserin 34 mg once daily compared to placebo in approximately 386 patients with predominantly negative symptoms of schizophrenia who have achieved adequate control of positive symptoms with their existing antipsychotic treatment.

In August 2018, we acquired an exclusive North American license to develop and commercialize trofinetide 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. 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, disorganized breathing patterns, scoliosis and sleep disturbances. Trofinetide is a novel synthetic analog of the amino-terminal tripeptide of insulin-like growth factor 1 (IGF-1), designed to treat the core symptoms of Rett syndrome by reducing neuroinflammation and supporting synaptic function. Trofinetide has been granted FDA Fast Track Status and an Orphan Drug Designation in the U.S. and an Orphan Designation in Europe, as well as Rare Pediatric Disease designation in the U.S. Currently, there are no approved medicines for the treatment of Rett syndrome. In October 2019, we initiated the Phase 3 LAVENDER randomized, double-blind placebo-controlled study evaluating trofinetide in girls and young women 5-20 years of age with Rett syndrome. We expect results from our LAVENDER study in the second half of 2021, but we are unable to predict with certainty how the pandemic might affect the timing for completion of the study.

In March 2020, we acquired an exclusive worldwide license to develop and commercialize novel drug candidates targeting positive allosteric modulators (PAMs) of the muscarinic M1 receptor with the potential to treat a range of central nervous system (CNS) disorders, from Vanderbilt University. Under the agreement, we obtained exclusive worldwide rights to certain highly selective M1 PAMs, which represent a promising approach for improving cognitive function and other neuropsychiatric symptoms in patients suffering from CNS disorders. The agreement includes a portfolio of candidates, with molecules at various stages of testing, including a lead compound in early Phase 1 testing, several additional compounds in pre-clinical development as well as any additional compounds generated in an ongoing discovery program.

We have incurred substantial operating losses since our inception due in large part to expenditures for our research and development activities and more recently for our sales and marketing activities related to the commercialization of NUPLAZID. As of June 30, 2020, we had an accumulated deficit of \$1.8 billion. We expect to continue to incur operating losses for the next few years as we advance our programs and incur significant development and commercialization costs.

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

## **Financial Operations Overview**

### ***Product Revenues***

Net product sales consist of sales of NUPLAZID, our first and only commercial product to date. The FDA approved NUPLAZID in April 2016 and we launched the product in the United States in May 2016.

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

Cost of product sales consists of third-party manufacturing costs, freight, and indirect overhead costs associated with sales of NUPLAZID. 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.

### ***License Fees and Royalties***

License fees and royalties consist of milestone payments expensed or capitalized and subsequently amortized under our 2006 license agreement with the Ipsen Group. License fees and royalties also include royalties of two percent due to the Ipsen Group based upon net sales of NUPLAZID.

### ***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 primarily focused on NUPLAZID (pimavanserin) which was approved by the FDA for the treatment of hallucinations and delusions associated with PD Psychosis in April 2016. We currently are responsible for all costs incurred in the ongoing development of pimavanserin and we expect to continue to make substantial investments in clinical studies of pimavanserin for indications other than PD Psychosis, including schizophrenia. While the FDA notified us of acceptance of our sNDA with a filing date of August 2, 2020 and a PDUFA action date of April 3, 2021, at this time, due to the risks in the regulatory and approval processes, we are unable to estimate with any certainty the costs we will incur for the continued development activities of DRP, including work necessary to support the review of the sNDA. Additionally, in connection with the FDA approval of NUPLAZID, we committed to conduct post-marketing studies, including a randomized, placebo-controlled withdrawal study in patients treated with NUPLAZID and 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. We will be responsible for all costs incurred for these post-marketing studies. We expect to incur increased research and development expenses as a result of our development of trofinetide under the exclusive North American license granted to us by Neuren, including the costs of the Phase 3 LAVENDER study and a long term extension study. We currently are responsible for all costs incurred in the development of trofinetide, as well as milestone payments subject to achievement of development milestones. We expect to incur increased research and development expenses as a result of our recently executed exclusive worldwide license agreement for the M1 PAM program and the research collaboration with Vanderbilt University. We currently are responsible for all costs incurred in the development of the M1 PAM program as well as milestone payments subject to achievement of development milestones.

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 and trofinetide. 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 programs. The following table summarizes our research and development expenses for the three and six months ended June 30, 2020 and 2019 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Costs of external service providers:				
NUPLAZID (pimavanserin)	\$ 27,509	\$ 34,368	\$ 56,503	\$ 63,722
Trofinetide	11,487	11,356	21,120	14,165
Other programs	3,619	1,484	15,239	2,008
Subtotal	42,615	47,208	92,862	79,895
Internal costs	14,445	12,211	28,377	24,567
Stock-based compensation	7,235	7,901	15,692	15,781
Total research and development	\$ 64,295	\$ 67,320	\$ 136,931	\$ 120,243

Although NUPLAZID was approved by the FDA for the treatment of hallucinations and delusions associated with PD Psychosis, at this time, due to the risks inherent in clinical development, we are unable to estimate with certainty the costs we will incur for the ongoing development of pimavanserin in additional indications, including those within schizophrenia, and the development of trofinetide and the M1 PAM program. Due to these same factors, we are unable to determine with any 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 in additional indications other than PD Psychosis, 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 to increase and continue to be substantial as we conduct studies pursuant to our post-marketing commitments and pursue the development of pimavanserin in additional indications other than PD Psychosis, including our studies within schizophrenia and the development of trofinetide in Rett syndrome and the development of the M1 PAM program. 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, 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. We expect our selling, general and administrative expenses to increase in future periods to support commercial activities associated with NUPLAZID and our further development of pimavanserin in additional indications other than PD Psychosis.

## 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. Other than the adoption of ASU 2016-13, *Financial Instruments—Credit Losses: Measurement of Credit Losses on Financial Instruments* and ASU 2019-04, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments* as described in Item 1 of Part I, "Notes to Condensed Consolidated Financial Statements — Note 2 — Presentation and Significant Accounting Policies and Note 6 — Investments" of this quarterly report, there have been no significant changes to our critical accounting policies and estimates since December 31, 2019. 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 the extent to which we generate revenue from product sales, our development of pimavanserin in additional indications other than PD Psychosis, our development of trofinetide and the M1 PAM program, and the progress and timing of expenditures related to studies 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 of COVID-19 pandemic may have on our business, results of operations, financial condition and prospects, including with respect to our financial results for the remainder of fiscal 2020. 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 June 30, 2020 and 2019*

#### *Product Sales, Net*

Net product sales, comprised of NUPLAZID, were \$110.1 million and \$83.2 million for the three months ended June 30, 2020 and 2019, respectively. The increase in net product sales of \$26.9 million was primarily due to growth in NUPLAZID unit sales of approximately 17% in the three months ended June 30, 2020 as compared to the same period in 2019. Also contributing to the increase was a higher average gross selling price of NUPLAZID in 2020 compared to 2019.

#### *Cost of Product Sales*

Cost of product sales was \$2.9 million and \$3.0 million for the three months ended June 30, 2020 and 2019, respectively, or approximately 3% and 4% of net product sales, respectively. The cost of product sales as a percentage of net sales decreased during the three months ended June 30, 2020 as compared to the same period in 2019 due primarily to a higher average selling price for NUPLAZID in the current period and a lower per unit cost.

#### *License Fees and Royalties*

License fees and royalties were \$2.6 million and \$2.0 million for the three months ended June 30, 2020 and 2019, respectively, and included royalties due to the Ipsen Group of two percent of net sales of NUPLAZID and amortization related to the milestone paid to the Ipsen Group upon FDA approval of NUPLAZID in 2016. The increase in license fees and royalties during the three months ended June 30, 2020 as compared to the same period in 2019 was primarily due to the increase in net sales during the current period.

#### *Research and Development Expenses*

Research and development expenses decreased to \$64.3 million for the three months ended June 30, 2020, including \$7.2 million in stock-based compensation expense, from \$67.3 million for the three months ended June 30, 2019, including \$7.9 million in stock-based compensation expense. The decrease in research and development expenses was due to a decrease of \$4.6 million in external costs, offset by an increase of \$1.6 million in personnel and related costs. The decrease in external costs was primarily due to lower costs associated with development of pimavanserin for the treatment of schizophrenia and DRP.

### *Selling, General and Administrative Expenses*

Selling, general and administrative expenses increased to \$84.3 million for the three months ended June 30, 2020, including \$11.5 million in stock-based compensation expense, from \$68.0 million for the three months ended June 30, 2019, including \$11.7 million in stock-based compensation expense. The increase in selling, general and administrative expenses was mainly due to an increase of \$11.0 million in external service costs as well as an increase of \$5.3 million in personnel and related costs. The increase in external service costs was primarily attributable to increased advertising and promotion expenses, including our direct-to-consumer advertising campaign. The increase in personnel and related costs was due to increased headcount in our commercial and administrative support team during the three months ended June 30, 2020 as compared to the same period of 2019.

### *Comparison of the Six Months Ended June 30, 2020 and 2019*

#### *Product Sales, Net*

Net product sales, comprised of NUPLAZID, were \$200.2 million and \$146.2 million for the six months ended June 30, 2020 and 2019, respectively. The increase in net product sales of \$54.0 million was primarily due to growth in NUPLAZID unit sales of approximately 24% in the six months ended June 30, 2020 as compared to the same period in 2019. Also contributing to the increase was a higher average gross selling price of NUPLAZID in 2020 compared to 2019.

The following table provides a summary of activity with respect to our sales allowances and accruals for the six months ended June 30, 2020 (in thousands):

	<b>Distribution Fees, Discounts &amp; Chargebacks</b>	<b>Co-Pay Assistance</b>	<b>Rebates, Data Fees &amp; Returns</b>	<b>Total</b>
Balance as of December 31, 2019	\$ 2,576	\$ 316	\$ 11,326	\$ 14,218
Provision related to current period sales	22,203	943	26,721	49,867
Credits/payments for current period sales	(19,213)	(762)	(16,297)	(36,272)
Credits/payments for prior period sales	(2,576)	(316)	(8,866)	(11,758)
Balance as of June 30, 2020	<u>\$ 2,990</u>	<u>\$ 181</u>	<u>\$ 12,884</u>	<u>\$ 16,055</u>

#### *Cost of Product Sales*

Cost of product sales was \$5.7 million and \$5.9 million for the six months ended June 30, 2020 and 2019, respectively, or approximately 3% and 4% of net product sales, respectively. The cost of product sales as a percentage of net sales decreased during the six months ended June 30, 2020 as compared to the same period in 2019 due primarily to a higher average selling price for NUPLAZID in the current period.

#### *License Fees and Royalties*

License fees and royalties were \$4.8 million and \$3.7 million for the six months ended June 30, 2020 and 2019, respectively, and included royalties due to the Ipsen Group of two percent of net sales of NUPLAZID and amortization related to the milestone paid to the Ipsen Group upon FDA approval of NUPLAZID in 2016. The increase in license fees and royalties during the six months ended June 30, 2020 as compared to the same period in 2019 was primarily due to the increase in net sales during the current period.

#### *Research and Development Expenses*

Research and development expenses increased to \$136.9 million for the six months ended June 30, 2020, including \$15.7 million in stock-based compensation expense, from \$120.2 million for the six months ended June 30, 2019, including \$15.8 million in stock-based compensation expense. The increase in research and development expenses was due to an increase of \$13.0 million in external costs and an increase of \$3.7 million in personnel and related costs. The increase in external costs was primarily due to an upfront payment of \$10.0 million to Vanderbilt University for the license agreement and research collaboration to develop and commercialize M1 PAM program and increased development costs of \$7.0 million associated with trofinetide, offset by lower costs associated with development of pimavanserin for the treatments of schizophrenia and DRP.

## *Selling, General and Administrative Expenses*

Selling, general and administrative expenses increased to \$186.3 million for the six months ended June 30, 2020, including \$24.6 million in stock-based compensation expense, from \$161.1 million for the six months ended June 30, 2019, including \$22.7 million in stock-based compensation expense. The increase in selling, general and administrative expenses was mainly due to an increase of \$14.3 million in personnel and related costs, including an increase of \$1.9 million in stock-based compensation expense and an increase of \$10.9 million in external costs. The increase in personnel and related costs was due to increased headcount in our commercial and administrative support team during the six months ended June 30, 2020 as compared to the same period of 2019. The increase in external costs was primarily a result of increased medical affairs costs, including Phase IV studies.

## **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, since 2016, with revenues from sales of NUPLAZID. In September 2019, we raised net proceeds of approximately \$271.5 million in a follow-on public offering of our common stock. In November 2018, we raised net proceeds of approximately \$298.5 million in a follow-on public offering of our common stock. In January and August 2016, we raised total net proceeds of approximately \$497.5 million in follow-on public offerings of our common stock, and in 2014 we raised net proceeds of \$196.8 million in a public offering of our common stock. We anticipate that the level of cash used in our operations will increase in future periods in order to fund our ongoing and planned commercial activities for NUPLAZID, our ongoing and planned development activities for pimavanserin in additional indications other than PD Psychosis, studies to be conducted pursuant to our post-marketing commitments and our ongoing and planned development activities for trofinetide for the treatment of Rett syndrome and for various M1 PAM compounds under the agreement with Vanderbilt University. We expect that our cash, cash equivalents, and investment securities will be sufficient to fund our planned operations through at least the next twelve months.

We may require significant 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 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, ongoing and planned commercial activities for NUPLAZID;
- the costs of our development activities for trofinetide;
- the costs of our development activities for the M1 PAM program;
- the costs of maintaining and developing our sales and marketing capabilities for NUPLAZID;
- the costs of establishing, or contracting for, sales and marketing capabilities for other product candidates;
- the amount of U.S. product sales from NUPLAZID;
- the costs of preparing applications for regulatory approvals for NUPLAZID in jurisdictions other than the United States, and in additional indications other than PD Psychosis and for other product candidates, as well as the costs required to support review of such applications;
- the costs of manufacturing and distributing NUPLAZID for commercial use in the United States;
- our ability to obtain regulatory approval for, and subsequently generate product sales from, NUPLAZID in jurisdictions other than the United States or in additional indications other than PD Psychosis, or from trofinetide, the M1 PAM program and 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 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.

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, strategic collaborations, 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, due to the COVID-19 pandemic and actions taken to slow its spread, 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 adequate funds are not available when needed, we will be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts. We also may be required to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Additional funding, if obtained, may significantly dilute existing stockholders and could negatively impact the price of our stock.

We have invested a substantial portion of our available cash in money market funds, U.S. treasury notes, and high quality, marketable debt instruments of corporations 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 A3/A- 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.

At June 30, 2020, we had \$658.6 million in cash, cash equivalents, and investment securities, compared to \$697.4 million at December 31, 2019. This \$38.8 million decrease was primarily due to cash used in operating activities. Net cash used in operating activities decreased to \$85.9 million for the six months ended June 30, 2020 compared to \$102.6 million for the six months ended June 30, 2019. This decrease in cash used in operations was primarily due to an increase in our net revenues, offset by additional clinical study activities and sales and marketing costs.

Net cash provided by investing activities totaled \$156.5 million for the six months ended June 30, 2020 compared to net cash provided by investing activities of \$33.4 million for the six months ended June 30, 2019. The increase in net cash provided by investing activities for the six months ended June 30, 2020 compared to the six months ended June 30, 2019 was primarily due to increased net maturities of investment securities.

Net cash provided by financing activities increased to \$51.2 million for the six months ended June 30, 2020 compared to \$8.8 million for the six months ended June 30, 2019. This increase in net cash provided by financing activities for the six months ended June 30, 2020 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**

See Item 1 of Part I, "Notes to Condensed Consolidated Financial Statements — Note 10 — Recent Accounting Pronouncements".

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

#### ***Interest Rate Risk***

We invest our excess cash in investment-grade, interest-bearing securities. The primary objective of our investment activities is to preserve principal and liquidity. To achieve this objective, we invest in money market funds, U.S. Treasury notes, and high quality marketable debt instruments of corporations and government sponsored enterprises with contractual maturity dates of generally less than two years. All investment securities have a credit rating of at least A3/A- 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 June 30, 2020, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

### **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 June 30, 2020, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of June 30, 2020.

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

## **PART II. OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

Between July 19 and August 3, 2018, following negative publicity about NUPLAZID, three purported company stockholders filed putative securities class action complaints (captioned Staublein v. ACADIA Pharmaceuticals, Inc., Case No. 18-cv-01647, Stone v. ACADIA Pharmaceuticals Inc., Case No. 18-cv-01672, and Barglow v. ACADIA Pharmaceuticals Inc., Case No. 18-cv-01812) in the U.S. District Court for the Southern District of California against us and certain of our current and former executive officers. Thereafter, several putative lead plaintiffs filed motions to consolidate the cases and to appoint a lead plaintiff. On January 3, 2019, the Court consolidated the cases under the caption In re ACADIA Pharmaceuticals Inc. Securities Litigation, Case No. 18-cv-01647, and took the lead plaintiff motions under submission. On February 26, 2019, the Court appointed a lead plaintiff and lead counsel. Lead plaintiff filed a consolidated complaint on April 15, 2019. The consolidated complaint generally alleges that defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by making materially false and misleading statements regarding our business, operations, and prospects by failing to disclose that adverse events and safety concerns regarding NUPLAZID threatened initial and continuing FDA approval, and by failing to disclose that we engaged in business practices likely to attract regulatory scrutiny. The consolidated complaint seeks unspecified monetary damages and other relief. Defendants filed a motion to dismiss the consolidated complaint on June 7, 2019. On June 1, 2020, the Court granted the motion in part and gave lead plaintiff leave to file an amended complaint. On July 16, 2020, lead plaintiff filed the amended complaint.

On February 7, 2020, a purported company stockholder filed a derivative complaint (captioned Barney v. Davis et al., Case No. 20-cv-0238) in the U.S. District Court for the Southern District of California against our directors and certain of our current and former executive officers. The complaint asserts claims for breach of fiduciary duty, waste of corporate assets, and unjust enrichment arising from allegations similar to those in the federal securities class action described above. On February 19, 2020, the Court granted the parties' stipulation to stay the derivative action pending a ruling on the motion to dismiss in the federal securities class action. On July 16, 2020, the parties filed a joint motion to continue to stay the derivative action until the defendants answer, or the case is dismissed with prejudice and all appeals are exhausted, or any party gives 15 days' written notice that it no longer consents to the voluntary stay. The Court stayed the action on July 22, 2020.

On June 23, 2020, a purported company stockholder filed a derivative complaint (captioned Lazarus v. Davis et al., Case No. 20-cv-0843) in the U.S. District Court for the District of Delaware against our directors and certain of our current and former executive officers. The complaint asserts claims for contribution, breach of fiduciary duty, waste of corporate assets, and unjust enrichment arising from allegations similar to those in the federal securities class action described above.

On July 24, 2020, we 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, we 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 our Orange Book-listed patents covering NUPLAZID.

We currently believe that none of the foregoing claims or actions pending against us as of June 30, 2020 is likely to have, individually or in the aggregate, a material adverse effect on our business, liquidity, financial position, or results of operations. Given the unpredictability inherent in litigation, however, we cannot predict the outcome of these matters. We are unable to estimate possible losses or ranges of losses that may result from these matters, and therefore we have not accrued any amounts in connection with these matters other than attorneys' fees incurred to date.

## **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.*

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

***Our prospects are highly dependent on the successful commercialization of NUPLAZID. To the extent NUPLAZID is not commercially successful, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.\****

NUPLAZID is our only drug that has been approved for sale and it has only been approved for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis, or PD Psychosis, in the United States since April 2016. We are currently focusing most of our activities and resources on NUPLAZID, because we believe that our prospects are highly dependent on, and the vast majority of the value of our company relates to, our ability to successfully commercialize NUPLAZID in the United States.

Successful commercialization of NUPLAZID is subject to many risks, and there is no guarantee that we will be able to successfully commercialize NUPLAZID for additional approved indications beyond PD Psychosis. 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 will need to further expand and develop the team in order to successfully commercialize NUPLAZID for additional indication. Even if we are successful in developing our commercial team, there are many factors that could cause the commercialization of NUPLAZID to be unsuccessful, including a number of factors that are outside our control. Because no drug has previously been approved by the FDA for the treatment of hallucinations and delusions associated with PD Psychosis, it is especially difficult to estimate NUPLAZID's market potential for its approved indication and potential additional indications. The commercial success of NUPLAZID currently depends on the extent to which patients and physicians recognize and diagnose PD Psychosis and accept and adopt NUPLAZID as a treatment for hallucinations and delusions associated with PD Psychosis, and we do not know whether our or others' estimates in this regard will be accurate. For example, if the patient population suffering from hallucinations and delusions associated with PD Psychosis is smaller than we estimate or if physicians are unwilling to prescribe or patients are unwilling to take NUPLAZID, perceived safety issues, or for other reasons, the commercial potential of NUPLAZID will be limited. We have limited information about how physicians, patients and payors have responded and will respond to the pricing of NUPLAZID. 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 or reimbursement is inadequate to cover a significant portion of the cost. Additionally, any negative publicity related to NUPLAZID, or negative development for NUPLAZID in our post-marketing commitments, in clinical development in additional indications, or in regulatory processes in other jurisdictions, may adversely impact the commercial results and potential of NUPLAZID. Thus, significant uncertainty remains regarding the commercial potential of NUPLAZID.

In addition, our business could be adversely affected by the effects of public health threats, including the ongoing COVID-19 pandemic. Although we did not see a material impact on our net sales of NUPLAZID for the six months ended June 30, 2020, in light of the lengthy duration of the pandemic, we continue to expect that sales of NUPLAZID may be negatively impacted by changes in commercial practices resulting from COVID-19, such as the transition to telemedicine, possible decreases in initial diagnoses, and decreased access to certain market segments. Accordingly, in May 2020 we reduced our revenue guidance for 2020 to reflect this expectation. The ultimate effects of COVID-19, and the duration thereof, are difficult to assess or predict at this time and no assurances can be given that the pandemic will not have a significant impact on our business, results of operations, financial condition and prospects.

If the commercialization of NUPLAZID is less successful than expected or perceived as disappointing, our stock price could decline significantly and the long-term success of the product and our company could be harmed.

***If we do not obtain regulatory approval of pimavanserin for other additional indications in the United States, or for any indication in foreign jurisdictions, or regulatory approval of trofinetide for Rett syndrome, we will not be able to market pimavanserin for other indications or in other jurisdictions or market trofinetide at all, 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 PD Psychosis, 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 PD Psychosis does not ensure that foreign jurisdictions will also approve NUPLAZID for that indication, nor does it ensure that NUPLAZID will be approved by the FDA for any other indication. In September 2019, we announced that our Phase 3 HARMONY study, a double-blind, placebo-controlled relapse prevention trial evaluating pimavanserin for the treatment of dementia-related psychosis, would be stopped early for positive efficacy as it met the primary endpoint, demonstrating a highly statistically significant longer time to relapse of psychosis with pimavanserin compared to placebo in a planned interim efficacy analysis. In December 2019, we announced top-line results from the HARMONY study in a presentation at the 12th CTAD Meeting. Pimavanserin was well-tolerated in the study and met the primary endpoint of the study by significantly reducing the risk of relapse of psychosis by 2.8 fold compared to placebo (HR = 0.353; one-sided p=0.0023). We submitted a sNDA to the FDA for the treatment of dementia-related psychosis on June 3, 2020. In July 2020 the FDA notified us of acceptance of our sNDA with a filing date of August 2, 2020 and a PDUFA action date of April 3, 2021. The FDA advised us that it has not identified any potential review issues at this point in their evaluation and at this time they are not planning to hold an Advisory Committee meeting. We initiated a Phase 3 program for pimavanserin as an adjunctive treatment for major depressive disorder 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 the broader adjunctive MDD indication.

We initiated the Phase 3 LAVENDER study of trofinetide for Rett syndrome in October 2019. We initiated the Phase 3 ADVANCE-2 study of pimavanserin for the treatment of the negative symptoms of schizophrenia in August 2020. There is no guarantee that our ongoing studies will be successful, or that the FDA or any regulatory authority in foreign jurisdictions will approve pimavanserin or trofinetide for any of those indications. In particular, our sNDA for pimavanserin in dementia-related psychosis is subject to FDA review to determine whether the sNDA is adequate to support approval of pimavanserin for that indication. The FDA retains complete discretion in deciding whether or not to approve a sNDA and there is no guarantee that pimavanserin will be approved for the treatment of dementia-related psychosis.

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 United States 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 or to submit trofinetide for approval for Rett syndrome. 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 PD Psychosis. In addition, strategic considerations need to be taken into account when determining whether and when to submit NUPLAZID for approval in other jurisdictions. For example, in the fourth quarter of 2016, the European Medicines Agency, or EMA, approved our proposed pediatric investigation plan related to our planned submission of a marketing authorization application, or MAA, for NUPLAZID for the treatment of PD Psychosis in Europe. However, in light of our continuing clinical development of pimavanserin in indications other than in PD Psychosis, and the time-limited data exclusivity currently granted by the EMA that commences on first approval of a product in Europe, we deferred submission of the MAA and we do not yet have a revised estimate of when we will make that filing. If we do not receive marketing approval for NUPLAZID for any other indication or from any regulatory agency outside of the United States or any marketing approval for trofinetide, we will never be able to commercialize NUPLAZID for any other indication in the United States or for any indication in any other jurisdiction or be able to commercialize trofinetide at all. 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

***Even though the FDA has granted approval of NUPLAZID for the treatment of hallucinations and delusions associated with PD Psychosis, the terms of the approval may limit its commercial potential. Additionally, NUPLAZID is still subject to substantial, ongoing regulatory requirements.***

Even though the FDA has granted approval of NUPLAZID, the scope and terms of the approval 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 PD Psychosis. The label for NUPLAZID also contains a “boxed” warning that elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death, and that NUPLAZID is not approved for the treatment of patients with dementia-related psychosis unrelated to the hallucinations and delusions associated with PD Psychosis. This “boxed” warning may discourage physicians from prescribing NUPLAZID to patients diagnosed with PD Psychosis, including those with dementia.

In connection with the FDA approval, we committed to conduct the following post-marketing studies: (i) a randomized, placebo-controlled withdrawal study in patients treated with NUPLAZID, (ii) studies to collect additional data to add to the NUPLAZID safety database from an aggregate of at least 500 predominantly frail and elderly subjects on NUPLAZID in one or more randomized, placebo-controlled studies of eight or more weeks duration, (iii) a drug-drug interaction study with NUPLAZID and a strong CYP3A4 inducer, and (iv) re-analysis of tissue samples from certain previously conducted pre-clinical studies. We have completed the (iii) drug-drug interaction study with NUPLAZID and a strong CYP3A4 inducer and (iv) the re-analysis of tissue samples. We have received FDA approval of a sNDA for labeling revisions related to the completed CYP3A4 study. If we fail to comply with our remaining post-marketing commitments, or if the results of the post-marketing studies, or any other ongoing or planned clinical studies of NUPLAZID, are negative, the FDA could decide to withdraw approval, add warnings or narrow the approved indication in the product label.

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 current good manufacturing processes, good clinical practices, international council for harmonization guidelines and good laboratory practices, 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 has only been studied in a limited number of patients and in limited populations. As we continue to commercialize NUPLAZID, it is becoming available to a much larger number of patients and in broader populations, and we do not know whether the results of NUPLAZID use in such larger number of patients and broader populations will be consistent with the results from our clinical studies.***

Prior to commencing our commercial launch of NUPLAZID in May 2016, NUPLAZID was administered only to a limited number of patients and in limited populations in clinical studies, including our successful pivotal -020 Phase 3 trial with NUPLAZID for the treatment of PD Psychosis. We do not know whether the results, when broader populations are exposed to NUPLAZID, including results related to safety and efficacy, will be consistent with the results from the clinical studies of NUPLAZID that served as the basis for its approval. New data relating to NUPLAZID, including from adverse event reports and post-marketing studies in the United States, 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 from the market. The FDA and regulatory authorities in other jurisdictions may also consider the new data in reviewing NUPLAZID marketing applications for indications other than in PD Psychosis 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 currently market and sell NUPLAZID, our only commercial product, and rely on a limited network of third-party distributors and pharmacies. If we are unable to continue to effectively commercialize NUPLAZID, we may not be able to generate adequate product revenues.***

NUPLAZID is our only drug that has been approved for sale by any regulatory body, and it became available for prescription in the United States in May 2016. In order to successfully market NUPLAZID, we must continue to develop our sales, marketing, managerial, compliance, and related capabilities or make arrangements with third parties to perform these services. If we are unable to maintain and develop adequate sales, marketing, and distribution capabilities, whether independently or with third parties, we may not be able to appropriately commercialize NUPLAZID and may not become profitable.

We employ our own internal specialty sales force to commercialize NUPLAZID for the treatment of PD Psychosis as part of our commercialization strategy in the United States. We will need to refine and further develop our sales force as we continue our commercialization efforts, and we will be competing with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. These efforts will continue to be expensive and time-consuming, and we cannot be certain that we will be able to successfully refine and further develop our sales force. In preparation for a potential U.S. launch of pimavanserin in dementia-related psychosis, we will need to increase the U.S. sales force significantly, and expand additional commercial, medical affairs and general and administrative support functions prior to obtaining regulatory approval.

Additionally, our strategy in the United States includes distributing NUPLAZID 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 in the United States, 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. If we are unable to maintain and, if needed, expand, our network of specialty distributors and specialty pharmacies, we would be exposed to substantial distribution risk.

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 specialty distributors and specialty pharmacies, our ability to effectively commercialize NUPLAZID and generate product revenues would be limited.

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

NUPLAZID is the first drug approved by the FDA for the treatment of hallucinations and delusions associated with PD Psychosis. 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 for the treatment of hallucinations and delusions associated with PD Psychosis to neurologists, select psychiatrists, and pharmacists and physicians in long-term care facilities. In addition, we must ensure that consistent and appropriate messages about NUPLAZID 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 effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits of NUPLAZID and its proper administration, our efforts to successfully commercialize NUPLAZID could be put in jeopardy, which would negatively impact our ability to generate product revenues.

***NUPLAZID 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, 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;
- pricing and cost effectiveness, which may be subject to regulatory control;
- effectiveness of our or our collaborators' sales and marketing strategy; and
- our ability to obtain 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 PD Psychosis, 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. 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 PD Psychosis, the rate of diagnosis of PD Psychosis, the prevalence and rate of hallucinations and delusions in patients diagnosed with PD Psychosis, 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 PD Psychosis 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 PD Psychosis. For these reasons, even if PD Psychosis occurs in high rates among patients with Parkinson's disease, it may be underdiagnosed. Even if PD Psychosis is diagnosed, physicians may not prescribe treatment for hallucinations and delusions associated with PD Psychosis, and if they do prescribe treatment, they may prescribe other drugs, even though they are not approved in PD Psychosis, instead of NUPLAZID. In addition, even if NUPLAZID is prescribed for the treatment of hallucinations and delusions associated with PD Psychosis, 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 dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death, and that NUPLAZID is not approved for the treatment of patients with dementia-related psychosis unrelated to the hallucinations and delusions associated with PD Psychosis. There has also been recent 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 U.S. 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 health care 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 PD psychosis. Regardless, perceptions that NUPLAZID is unsafe, even if unfounded, may discourage physicians from prescribing or patients from taking NUPLAZID.

The commercial success of NUPLAZID depends on acceptance by patients and physicians, and there are a number of factors that could skew our or others' estimates about prescribing behaviors and market adoption.

***Our ability to generate product revenues will be diminished if NUPLAZID does not receive coverage from payors or sells for inadequate prices, 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 commercial 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, 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 if coverage is not provided or reimbursement is inadequate to cover a significant portion of its cost.

In addition, the market for NUPLAZID 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 is approved.

In many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. We may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, there may be importation of foreign products that compete with NUPLAZID, and any other products we may market, which could negatively impact our profitability.

Third-party payors, whether foreign or domestic, or 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 at less than an optimized price could impact our revenues and overall success as a company. We have changed, and may continue to change, the price of NUPLAZID from time to time, however, we do not know if the price we have selected, or may select in the future, for NUPLAZID 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. In the United States, 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 assure that other payors also will provide coverage and reimbursement for the product. Therefore, coverage and reimbursement for NUPLAZID 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 to each payor separately, with no assurance that coverage will be obtained. If we are unable to obtain coverage of, and adequate payment levels for, NUPLAZID 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, or any other products we may market, and thereby adversely impact our profitability, results of operations, financial condition, and future success.

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

In both the United States 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, 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, or 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. 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 remain legal and political challenges to certain aspects of the ACA, as well as efforts by the Trump administration to repeal and replace certain aspects of the ACA, and we expect such challenges to continue. Since January 2017, President Trump has signed executive orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been enacted. Legislation enacted in 2017, informally title the Tax Cuts and Jobs Act of 2017, or the 2017 Tax Act, includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and the medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole", and also increases for 2019 the percentage that a drug manufacturer must discount the cost of prescription drugs from 50 percent to 70 percent. Given that the current patient population for NUPLAZID is primarily Medicare beneficiaries, accelerating the closure of the coverage gap and the increase in the discount that must be paid, could have a significant impact on the Company's business in 2020 and beyond. In December 2018, CMS published a new rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of litigation regarding the method CMS uses to determine this risk adjustment. However, on April 27, 2020, the United States Supreme Court reversed a Federal Circuit decision that previously upheld Congress' denial of \$12 billion in "risk corridor" funding. On December 14, 2018, a federal judge in Texas ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the 2017 Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are expected to occur in the fall. It is unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA and our business.

Other legislative changes have been proposed and adopted in the United States 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 percent per fiscal year, which went into effect in April 2013 and, following passage of the BBA, will remain in effect through 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief and Economic Security Act, or CARES Act, which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. 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.

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 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. 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, the Trump administration's budget proposal for fiscal year 2021 includes a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, the Trump administration previously released a "Blueprint," or plan, to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and has implemented others under its existing authority. Although a number of such measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or

administrative measures to control drug costs. Individual states in the United States 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 or any other products for which we may receive regulatory approval. It is also possible that additional governmental action may be taken to address the COVID-19 pandemic. For example, on April 18, 2020, CMS announced that Qualified Health Plan (QHP) issuers under the ACA may suspend activities related to the collection and reporting of quality data that would have otherwise been reported between May and June 2020 given the challenges healthcare providers are facing responding to the COVID-19 pandemic. CMS noted its concern that such activities may divert provider attention from caring for patients, as well as jeopardize the health and safety of QHP issuer staff and survey vendor staff.

***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 sunshine laws and regulations. These laws may impact, among other things, our 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 are subject to patient data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business. 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, or 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, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, and as amended again by the Final HIPAA Omnibus Rule, Modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules Under 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;

- the U.S. Federal Food, Drug and Cosmetic Act, or 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 CMS information related to certain payments and other transfers of value made to physicians (as defined under such law), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- 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; and
- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers, and the European General Data Protection Regulation (EU) 2016/679, or GDPR, which became effective in May 2018 and contains new provisions specifically directed at the processing of health information, higher sanctions and extra-territoriality measures intended to bring non-EU companies under the regulation, including companies like us that conduct clinical trials in the EU; we anticipate that over time we may expand our business operations to include additional operations in the EU and with such expansion, we would be subject to increased governmental regulation in the EU countries in which we might operate, including the GDPR.

Additionally, California recently enacted legislation, which became effective on January 1, 2020, that has been dubbed the first “GDPR-like” law in the United States. Known as the California Consumer Privacy Act, or CCPA, it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. As currently written, the CCPA will likely impact (possibly significantly) our business activities and exemplifies the vulnerability of our business to not only cyber threats but also the evolving regulatory environment related to personal data.

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, 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, or any other product candidates that may be approved, outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

***If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the United States, 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 United States, 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. 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 average manufacturer price, or AMP, and best price, or 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.

***The FDA granted marketing approval of NUPLAZID for the treatment of hallucinations and delusions associated with PD Psychosis, and we could face liability if a regulatory authority determines that we are promoting NUPLAZID 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 United States 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, 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, or 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, including as a result of the civil investigative demand mentioned below, or if we are the subject of a qui tam suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects, and reputation. In September 2018, we received a civil investigative demand, or CID, from the DOJ pursuant to the Federal False Claims Act requesting certain documents and information related to our sales and marketing of NUPLAZID. We are cooperating with the DOJ’s request. Responding to the CID will require considerable resources and no assurance can be given as to the timing or outcome of the DOJ’s investigation.

***We expect our net losses to continue for the next few years and 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 June 30, 2020, we had an accumulated deficit of approximately \$1.8 billion. We expect to incur net losses over the next few years as we invest in the commercialization of NUPLAZID and advance our development programs.

Even though we began commercializing NUPLAZID in the United States in May 2016, we still expect to incur significant expenses and net losses for at least the next few years as we continue our commercialization efforts for NUPLAZID and pursue the further development of NUPLAZID and our product candidates. Substantially all of our revenues since May 2016 were from net product sales of NUPLAZID.

We expect that our revenues over the next few years will be entirely dependent on our ability to generate net product sales of NUPLAZID. To the extent that we cannot generate significant revenues from the sale of NUPLAZID to cover our expenses, including the significant expenses associated with commercializing NUPLAZID and continuing to develop pimavanserin 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, 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 from our commercialization of NUPLAZID, or from other product candidates that may be approved, 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 or successfully develop and commercialize our other product candidate opportunities.\****

We have consumed substantial amounts of capital since our inception. Our cash, cash equivalents, and investment securities totaled \$658.6 million at June 30, 2020. 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, post-marketing studies for NUPLAZID to be conducted over the next several years, ongoing and planned commercial activities for NUPLAZID, and other research and development programs;
- the costs of our development activities for trofinetide;
- the costs of our development activities for the M1 PAM program;
- the costs of maintaining and developing our sales and marketing capabilities for NUPLAZID;
- the costs of establishing, or contracting for, sales and marketing capabilities for other product candidates;
- the amount of U.S. product sales from NUPLAZID;
- the costs of preparing applications for regulatory approvals for NUPLAZID in jurisdictions other than the United States, and in additional indications other than in PD Psychosis, and for other product candidates, as well as the costs required to support review of such applications;
- the costs of manufacturing and distributing NUPLAZID for commercial use in the United States;
- our ability to obtain regulatory approval for, and subsequently generate product sales from, NUPLAZID in jurisdictions other than the United States or in additional indications other than in PD Psychosis, or from trofinetide, the M1 PAM program and 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.

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 the COVID-19 pandemic and actions taken to slow its spread, 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.

***Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, 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. In addition, the COVID-19 pandemic may affect processing times as the FDA reallocates resources to immediate needs such as the review and approval of viral and antibody tests, therapeutic treatments for use by COVID-19 patients and SARS-CoV-2 vaccines.

***There is no guarantee that future studies with pimavanserin will be successful.\****

The historical rate of failures for product candidates in clinical development is extremely high. In November 2012, we announced successful results from the Phase 3 -020 Study of pimavanserin for PD Psychosis. Additionally, in December 2016, we announced positive top-line results from our Phase 2 exploratory study of pimavanserin in patients with AD Psychosis. Even though we successfully completed this Phase 2 exploratory study, or the -019 Study, and the -020 Study, those results may not be predictive of the results of any additional studies that we are currently undertaking or may undertake in the future with pimavanserin, including the post-marketing studies we committed to conduct in connection with FDA approval of NUPLAZID and the ongoing studies of pimavanserin in various indications. We believe that pimavanserin also may have utility in indications other than in PD Psychosis, such as in dementia-related psychosis and schizophrenia. However, prior to the Phase 3 HARMONY study that we initiated in the fourth quarter of 2017, which was stopped early for efficacy in September 2019, we had never tested pimavanserin in clinical studies

where the primary outcome was for the broad indication of dementia-related psychosis, and prior to the Phase 2 CLARITY study in major depressive disorder for which we announced positive top-line results in October 2018, we had never tested pimavanserin in clinical studies in depression. Additionally, prior to the studies in schizophrenia that we initiated in the fourth quarter of 2016, we had only conducted a Phase 2 trial for pimavanserin as a co-therapy treatment in schizophrenia. There is no guarantee that we will have the same level of success with pimavanserin in other studies that we had with the -020 Study, the HARMONY study, the ADVANCE study, and the Phase 2 CLARITY-1 study. For example, in July 2020 we announced top-line results from the Phase 3 CLARITY study evaluating pimavanserin as an adjunctive treatment in major depressive disorder. In this study pimavanserin did not achieve statistical significance on the primary endpoint. Further, there is no guarantee that we will be successful at all in ongoing or future studies for additional indications or in our post-marketing studies, or that future results of studies of NUPLAZID for treatment in PD Psychosis or for other indications will be positive.

If we do not successfully complete additional development of NUPLAZID, we will be unable to market and sell NUPLAZID or products derived from it for indications other than the treatment of hallucinations and delusions associated with PD Psychosis, or to generate related product revenues.

***We are solely responsible for the development and advancement of this program and commercialization of the product.\****

We have full responsibility for the pimavanserin program throughout the world. We expect our research and development costs for continued development of pimavanserin to be substantial. While we currently are undertaking the ongoing development work for pimavanserin, including clinical trials of pimavanserin for indications other than in PD Psychosis and a planned supplemental NDA submission for pimavanserin in dementia-related psychosis, in the event of approval for dementia-related psychosis, we would need to add significant resources, and possibly raise additional capital, in order to further commercialize pimavanserin, and to conduct the necessary sales and marketing activities, and to conduct further development activities. Our current strategy is to continue to commercialize NUPLAZID for the treatment of hallucinations and delusions associated with PD Psychosis in the United States 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 PD Psychosis patients. In preparation for a potential U.S. launch in dementia-related psychosis, we will need to increase the U.S. sales force significantly, and expand additional commercial, medical affairs and general and administrative support functions prior to obtaining regulatory approval for pimavanserin in dementia-related psychosis. In addition, if we are approved to commercialize NUPLAZID in markets outside of the United States, 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 United States 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 PD Psychosis, a failure in a subsequent pimavanserin study for another indication, including our ongoing studies in schizophrenia and our previous studies in depression, or any additional studies that may be required in dementia-related psychosis, 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 PD Psychosis or could lead to it being withdrawn from the market. If we are unable to develop pimavanserin for other indications, we may not be able to maximize the potential of the compound and that could have a material adverse effect on our future revenues and our success as a company.

***Pimavanserin is currently in late-stage development for several additional indications other than in PD Psychosis, and we have initiated Phase 3 development of trofinetide for Rett syndrome. 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. Interim results of clinical trials do not necessarily predict final results, and 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 the fourth quarter of 2017, we initiated a Phase 3 study of pimavanserin in patients with dementia-related psychosis, and in the fourth quarter of 2016 we initiated both a Phase 2 and a Phase 3 study of pimavanserin as a treatment in patients with schizophrenia.

In October 2018, we announced positive top-line results from CLARITY, a Phase 2 study evaluating pimavanserin as an adjunctive treatment for major depressive disorder and in April 2019, we initiated our Phase 3 CLARITY program, consisting of two Phase 3 studies, CLARITY-2 and CLARITY-3, evaluating pimavanserin as an adjunctive treatment for major depressive disorder. In July 2020, we announced that 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. In September 2019, we announced that our Phase 3 HARMONY study, a double-blind, placebo-controlled relapse prevention trial evaluating pimavanserin for the treatment of dementia-related psychosis, would be stopped early for positive efficacy as it met the primary endpoint, demonstrating a highly statistically significant longer time to relapse of psychosis with pimavanserin compared to placebo in a planned interim efficacy analysis.

In December 2019, we announced top-line results from the HARMONY study in a presentation at the 12th CTAD Meeting. Pimavanserin was well-tolerated in the study and met the primary endpoint of the study by significantly reducing the risk of relapse of psychosis by 2.8 fold compared to placebo (HR = 0.353; one-sided p=0.0023). In July 2020 the FDA notified us of acceptance of our sNDA with a PDUFA date of April 3, 2021. We cannot guarantee that the full results of the HARMONY study and other existing clinical data will be sufficient to support the approval of a supplemental NDA, or whether regulatory agencies will require additional clinical trials or information, which could impact the approvability or commercialization timing and prospects of pimavanserin in the dementia-related psychosis indication. In November 2019, we announced positive top-line results from the Phase 2 ADVANCE study evaluating pimavanserin for the negative symptoms of schizophrenia for patients whose positive symptoms were controlled on a stable background antipsychotic treatment. We may plan and conduct additional studies in the future, and have initiated the Phase 3 LAVENDER study of trofinetide in Rett syndrome in October 2019.

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 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 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;
- 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 clinical trials could be disrupted by man-made or natural disasters or public health emergencies. For example, as a result of the COVID-19 pandemic, we temporarily paused enrollment of new patients in our ongoing clinical trials, as well as commencement of new trials. However, we have re-initiated enrollment in clinical trials on a study-by-study and site-by-site basis. It is possible that future enrollment in these studies, or enrollment in future studies, could be impacted due to COVID-19. 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 disputed due to COVID-19 or actions taken to slow its spread, 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.

***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 United States.

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;
- decide to pursue a competitive product developed outside of the collaboration; or
- cannot obtain the necessary regulatory approvals.

We also 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. 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.

***Public health threats, including the current global COVID-19 pandemic, could have an adverse effect on our operations and financial results, or may cause us to modify or suspend our financial guidance.\****

On March 11, 2020, the World Health Organization declared a pandemic resulting from the disease known as COVID-19 caused by a novel strain of coronavirus, SARS-CoV-2. The rapid global spread of COVID-19 has had a major impact on the financial markets, the global economy and the economies of particular countries or regions, and has led to 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 United States 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, we adopted recommended policies applicable to office-based employees as well as our field-based commercial and medical affairs personnel, such as working from home, limiting employees to essential on site work only, and suspending all business travel. The effects and duration of such measures could have a material adverse impact on our business, results of operations, financial condition and prospects. In addition, travel restrictions, quarantines, "work-at-home" and "shelter-in-place" orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, whether related to COVID-19 or other infectious diseases, could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain.

Our sales force has had physical access to hospitals, clinics, long-term care and skilled nursing facilities, healthcare providers and pharmacies curtailed, which may have a material adverse effect on our future sales. While digital tools are available to our field employees to facilitate remote meetings with healthcare providers, we cannot ensure that these methods will be effective. Additionally, patients who are currently using NUPLAZID or who are eligible to use NUPLAZID, 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 have been impacted by the COVID-19 pandemic. We temporarily paused enrollment of new patients in our ongoing clinical trials as well as commencement of new trials, and our data collection and site monitoring activities relating to currently active clinical trials could be delayed or otherwise impeded by travel and access restrictions and diversion of healthcare resources toward treating COVID-19 patients, among other things. However, we have re-initiated enrollment in clinical trials on a study-by-study and site-by-site basis. It is possible that future enrollment in these studies, or enrollment in future studies, could be impacted due to COVID-19.

Although we did not see a material impact on NUPLAZID net sales during the six months ended June 30, 2020, the ultimate effects of COVID-19, and the duration thereof, are difficult to assess or predict at this time and no assurances can be given that the pandemic will not have a significant impact on our business, results of operations, financial condition and prospects. Furthermore, this uncertainty may cause us to retract, suspend or modify our existing financial guidance, and/or negatively affect our ability to provide financial guidance for 2020 and future periods.

***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 contract research organizations, 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 the COVID-19 pandemic 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 contract research organizations 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.

***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, trofinetide 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, trofinetide 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 and our product candidates.

We have contracted with Patheon Pharmaceuticals Inc. and Catalent Pharma Solutions, LLC to manufacture NUPLAZID drug product for commercial use in the United States. Additionally, we have contracted with Siegfried AG to manufacture active pharmaceutical ingredient, or 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 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 over two years of pimavanserin API and over nine months of NUPLAZID finished product on hand to continue our commercial and clinical operations as planned, depending on the length of the COVID-19 pandemic and whether further disruptions occur, 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 restrictions resulting from the COVID-19 outbreak, including staffing shortages, production slowdowns and disruptions in delivery systems, our supply chain may be disrupted, limiting our ability to manufacture and distribute NUPLAZID 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 United States, we will need to contract with a third party to manufacture such products for commercial sale in the United States and/or in such other jurisdictions.

We have contracted with manufacturers to produce clinical supplies of trofinetide to support the development program. If trofinetide or any other product candidate is approved by the FDA or other regulatory agencies for commercial sale, we will need to contract with a third party to manufacture such products for commercial sale in the United States and/or in such other jurisdictions.

Even though we have agreements with Patheon and Catalent for the manufacture of NUPLAZID drug product and with Siegfried for the manufacture of NUPLAZID API for commercial use, and even if we successfully enter into long-term agreements with other manufacturers, 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 only one supplier of API, two suppliers for the 34mg capsule and one supplier for the 10mg tablet of NUPLAZID. 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 or trofinetide or any other product candidates. While we believe that there will be alternative sources available to manufacture NUPLAZID and trofinetide 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 and trofinetide and any other product candidates, including Catalent, Patheon and Siegfried, are obliged to operate in accordance with FDA-mandated current good manufacturing practices, or 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 trofinetide 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 and trofinetide and any other product candidate that receives regulatory approval, negatively impact our commercialization of NUPLAZID, or lead to significant delays in the launch and commercialization of trofinetide or 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 and 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 or trofinetide 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 in the United States, or provide 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 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 or trofinetide or any other product candidates and could have a material adverse effect on our business, results of operations, financial condition and prospects.

***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, including NUPLAZID, or develop our product candidates, including pimavanserin for indications beyond PD Psychosis.***

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 central nervous system 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 commercial activities for NUPLAZID. 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 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.

***We have recently increased the size of our organization, and if we receive approval of NUPLAZID in additional indications, including dementia-related psychosis, we would 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 June 30, 2020, we employed approximately 570 employees. Although we have already added several capabilities, we will need to add additional qualified personnel and resources. 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, maintain, and integrate additional 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 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, as we commercialize NUPLAZID, we will need to support the training and ongoing activities of our sales force and expect to need to expand the size of our employee base for managerial, operational, financial, and other resources. In addition, in anticipation of receiving regulatory approval for pimavanserin for the treatment of dementia-related psychosis, we plan to increase our U.S. sales force and additional functions significantly to support the expected commercial launch in dementia-related psychosis. 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.

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 or our 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.

***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 August 2018, we entered into a license agreement with Neuren, and obtained exclusive North American rights to develop and commercialize trofinetide for Rett syndrome and other indications. In March 2020, we entered into a license agreement with Vanderbilt University, and obtained exclusive worldwide license to develop and commercialize M1 PAM program, and we may enter into additional license agreements in the future.

Our agreements with Neuren and Vanderbilt University 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 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 United States for the treatment of hallucinations and delusions associated with PD Psychosis;
- the impact of the COVID-19 pandemic on our business, including the ability of our field sales force to meet with healthcare providers, visit physician's offices, hospitals and other healthcare facilities (including long-term care and skilled nursing facilities);
- 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 in PD Psychosis and in jurisdictions other than the United States;
- 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; 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 NUPLAZID net sales 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, the 2017 Tax Act enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the 2017 Tax Act may affect us, and certain aspects of the 2017 Tax Act could be repealed or modified in future legislation. For example, the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, modified certain provisions of the 2017 Tax Act. In addition, it is uncertain if and to what extent various states will conform to the 2017 Tax Act or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the 2017 Tax Act or future 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.\****

Our net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the 2017 Tax Act, as modified by the CARES Act, 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 in tax years beginning after December 31, 2020, is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the 2017 Tax Act or the CARES Act. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or 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.

***Changes to U.S. and non-U.S. tax laws or challenges by tax authorities to our intercompany arrangements could materially adversely affect us.\****

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. 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 changes in tax law are enacted, or our licensing of worldwide intellectual property rights for pimavanserin to our Swiss subsidiary is otherwise challenged, this could materially adversely affect 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 central nervous system 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.

***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, or 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.

***Changes or modifications in financial accounting standards, including those related to revenue recognition, may harm our results of operations.***

From time to time, the Financial Accounting Standards Board, or FASB, either alone or jointly with other organizations, promulgates new accounting principles that could have an adverse impact on our financial position, results of operations or reported cash flows. In February 2016, the FASB issued Accounting Standards Update (ASU) No. 2016-02, *Leases (Topic 842)*, which requires a lessee to recognize a lease liability and a right-of-use asset for all leases with lease terms of more than 12 months. We adopted this new standard for the year beginning January 1, 2019. Consequently, all of our operating lease commitments were recognized as lease liabilities, with corresponding right-of-use assets, based on the present value of the remaining minimum rental payments under current leasing standards for existing operating leases. Upon adoption of the standard, we recorded a right-of-use asset and lease liability of approximately \$12.0 million in our condensed consolidated balance sheets. We have elected the standard's package of practical expedients on adoption requiring no reassessment of whether any expired or existing agreements contain a lease, the classification of any expired or existing lease agreements, or initial direct costs for any existing leases. The majority of our leases are facility and equipment leases and are classified as operating leases under current lease guidance. Any difficulties in implementing this standard, or in adopting or implementing any other new accounting standard, and to update or modify our internal controls as needed on a timely basis, could result in our failure to meet our financial reporting obligations, which could result in regulatory discipline and harm investors' confidence in us. Finally, if we were to change our critical accounting estimates, including those related to the recognition of product revenue, our operating results could be significantly affected.

***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 there is the possibility of an earthquake, 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 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 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 June 2020, Aurobindo Pharma Limited ("Aurobindo"), Hetero Labs Limited ("Hetero"), MSN Laboratories Private Ltd. ("MSN Labs"), Teva Pharmaceuticals USA, Inc. ("Teva") and Zydus Pharmaceuticals (USA) Inc. ("Zydus") notified us that they had filed an Abbreviated New Drug Application ("ANDA") with the FDA for generic versions of NUPLAZID, seeking approval prior to the expiration of our patents. On July 24, 2020, we filed complaints against Aurobindo and its affiliate Aurobindo Pharma USA, Inc. and Teva and its affiliate Teva Pharmaceutical Industries Ltd., and on July 30, 2020, we filed complaints against Hetero and its affiliates Hetero Labs Limited Unit-V and Hetero USA Inc., MSN Labs and its affiliate MSN Pharmaceuticals, Inc., and Zydus 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. 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 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 United States 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, or 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 central nervous system 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 United States Patent and Trademark Office, or United States 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 United States PTO and foreign patent agencies in several stages over the lifetime of the patent. The United States 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 United States 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 United States 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, or IPR, and post-grant review, that allow third parties to challenge the validity of an issued patent in front of the United States 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 United States 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, United States 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 United States 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 United States 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 United States 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 United States Supreme Court. The United States 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 United States 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 United States 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 Our Industry**

***We are subject to stringent regulation in connection with the marketing of NUPLAZID 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 United States and by comparable authorities in other countries. Neither we nor our collaborators can market a pharmaceutical product, including NUPLAZID, in the United States 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 United States, 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 United States and, similarly, approval by regulatory authorities outside the United States 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 or our 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 United States 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 hallucinations and delusions associated with PD Psychosis competes with off-label use of antipsychotic drugs, including the generic drugs quetiapine and clozapine. If approved, pimavanserin for the treatment of dementia-related psychosis would compete with off-label use of antipsychotic drugs, including the generic drugs risperidone and quetiapine, and drugs indicated for the treatment of Alzheimer's disease and dementia in patients with Alzheimer's disease, including Aricept, marketed by Eisai Inc. and Pfizer Inc., and Namenda, marketed by Forest Laboratories, LLC, a wholly-owned subsidiary of Actavis. Pimavanserin for the treatment of schizophrenia, if approved for that indication, would compete with Rexulti, marketed by Otsuka Pharmaceutical Co., Ltd., Latuda, marketed by Sunovion Pharmaceuticals Inc., Caplyta, marketed by IntraCellular Therapeutics and generic drugs, including olanzapine, risperidone, aripiprazole and clozapine.

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.

While there are no approved medications for the treatment of Rett syndrome, trofinetide, if approved for Rett syndrome would compete with off label usage of generic prescription medications targeted at individual symptoms of Rett syndrome. These include antipsychotics including risperidone and aripiprazole; antidepressants sertraline and citalopram; and benzodiazepines clonazepam and diazepam. Several academic institutions and pharmaceutical companies are conducting clinical research in Rett syndrome.

***If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of NUPLAZID 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 in the United States 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 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, 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.

***We are dependent on information technology systems, infrastructure and data, which exposes us to data security risks.***

We are dependent upon our own or third-party information technology systems, infrastructure and data, including mobile technologies, to operate our business. The multitude and complexity of our computer systems may make them vulnerable to service interruption or destruction, disruption of data integrity, malicious intrusion, or random attacks. Likewise, data privacy or security incidents or breaches by employees or others may pose a risk that sensitive data, including our intellectual property, trade secrets or personal information of our employees, patients, customers or other business partners may be exposed to unauthorized persons or to the public. Cyber-attacks are increasing in their frequency, sophistication and intensity. Cyber-attacks could include the deployment of harmful malware, denial-of-service, social engineering and other means to affect service reliability and threaten data confidentiality, integrity and availability. Our business partners face similar risks and any security breach of their systems could adversely affect our security posture. A security breach or privacy violation that leads to disclosure or modification of or prevents access to patient information, including personally identifiable information or protected health information, could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to litigation or other liability under laws and regulations that protect personal data, any of which could disrupt our business and/or result in increased costs or loss of revenue. Moreover, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have invested, and continue to invest, in the protection of our data and information technology infrastructure, there can be no assurance that our efforts will prevent service interruptions, or identify breaches in our systems, that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm to us. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyber-attacks and other related breaches.

**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. 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 United States for the treatment of hallucinations and delusions associated with PD Psychosis;
- the status and cost of our post-marketing commitments for NUPLAZID;
- the status and cost of development and commercialization of pimavanserin for indications other than in PD Psychosis, including with respect to our planned sNDA submission for pimavanserin in dementia-related psychosis, and in jurisdictions other than the United States;
- 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;
- any other communications or guidance from the FDA or other regulatory authorities that pertain to NUPLAZID or our product candidates;
- 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;
- 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 United States and in foreign countries;
- changes in the structure of healthcare payment systems;
- the announcement of, or developments in, any litigation matters;
- disruptions caused by man-made or natural disasters or public health pandemics or epidemics or other business interruptions, including, for example, the COVID-19 pandemic; 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, in March 2015, following our announcement of the update to the timing of our planned NDA submission to the FDA for NUPLAZID for the treatment of PD Psychosis and the subsequent decline of the price of our common stock, two putative securities class action complaints were filed against us and certain of our current and former officers, which complaints were subsequently consolidated into one complaint. The complaint generally alleged that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by making materially false and misleading statements regarding the timing of our planned NDA submission to the FDA for NUPLAZID, thereby artificially inflating the price of our common stock. The parties agreed to a settlement in that case, which was approved by the court in January 2018. Additionally, between July 19 and August 3, 2018, following negative publicity about NUPLAZID, three putative securities class action complaints were filed against us and certain of our current executive officers. On February 26, 2019, the Court appointed a lead plaintiff and lead counsel. Lead plaintiff filed a consolidated complaint on April 15, 2019. The consolidated complaint generally alleges that defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by making materially false and misleading statements regarding our business, operations, and prospects by failing to disclose that adverse events and safety concerns regarding NUPLAZID threatened initial and continuing FDA approval, and by failing to disclose that we engaged in business practices likely to attract regulatory scrutiny. The consolidated complaint seeks unspecified monetary damages and other relief. Defendants filed a motion to dismiss the consolidated complaint on June 7, 2019. On June 1, 2020, the Court granted the motion in part and gave lead plaintiff leave to file an amended complaint. On July 16, 2020, lead plaintiff filed the amended complaint.

In addition, on February 7, 2020, a purported company stockholder filed a derivative complaint (captioned *Barney v. Davis et al.*, Case No. 20-cv-0238) in the U.S. District Court for the Southern District of California against the Company's directors and certain of its current and former executive officers. The complaint asserts claims for breach of fiduciary duty, waste of corporate assets, and unjust enrichment arising from allegations similar to those in the federal securities class action described above. On February 19, 2020, the Court granted the parties' stipulation to stay the derivative action pending a ruling on the motion to dismiss in the federal securities class action. On July 16, 2020, the parties filed a joint motion to continue to stay the derivative action until the defendants answer, or the case is dismissed with prejudice and all appeals are exhausted, or any party gives 15 days' written notice that it no longer consents to the voluntary stay. The court stayed the action on July 22, 2020. On June 23, 2020, a purported company stockholder filed a derivative complaint (captioned *Lazarus v. Davis et al.*, Case No. 20-cv-0843) in the U.S. District Court for the District of Delaware against the Company's directors and certain of its current and former executive officers. The complaint asserts claims for contribution, breach of fiduciary duty, waste of corporate assets, and unjust enrichment arising from allegations similar to those in the federal securities class action described above. 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 could result in substantial costs and divert our management's attention and resources, 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 3, 2019, we filed a registration statement covering the sale of up to 40,203,111 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 April 29, 2019, and which represented approximately 28 percent of our outstanding shares at the time. Our registration obligations under this registration rights agreement 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 an indeterminate number of shares on our own behalf pursuant to a registration statement or in a private placement, from time to time. 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 five percent or more of our outstanding common stock and their affiliates beneficially own a substantial portion of our outstanding common stock. As a result, these stockholders, acting together, have the ability to significantly influence all matters requiring approval by our stockholders, including the election of all of our board members, amendments to our certificate of incorporation, going-private transactions, and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of our other stockholders.

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

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

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

***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 the COVID-19 pandemic) 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.

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

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

**ITEM 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>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>
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 Elena Ridloff, 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 Elena Ridloff, 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 June 30, 2020, filed on August 5, 2020, 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, and (v) Notes to Condensed Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

## 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: August 5, 2020

By: /s/ Elena Ridloff  
Elena Ridloff  
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 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: August 5, 2020

/s/ STEPHEN DAVIS  

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

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

I, Elena Ridloff, 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: August 5, 2020

/s/ ELENA RIDLOFF  

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**Elena Ridloff**  
**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 June 30, 2020, 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: August 5, 2020

/s/ STEPHEN DAVIS

**Stephen 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.

**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 June 30, 2020, as filed with the Securities and Exchange Commission on or about the date hereof (the “Report”), I, Elena Ridloff, 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: August 5, 2020

/s/ ELENA RIDLOFF

**Elena Ridloff**

**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.