ACADIA PHARMACEUTICALS INC
Form 10-Q
November 07, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2016

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
Commission File Number: 000-50768

ACADIA PHARMACEUTICALS INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	06-1376651
(State of Incorporation)	(I.R.S. Employer Identification No.)

3611 Valley Centre Drive, Suite 300

San Diego, California	92130
(Address of Principal Executive Offices)	(Zip Code)

(858) 558-2871

(Registrant’s Telephone Number, Including Area Code)

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 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer”, “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Securities Exchange Act of 1934.

Large accelerated filer Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

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 October 31, 2016:

Class	Number of Shares Outstanding
Common Stock, $0.0001 par value	121,113,846

ACADIA PHARMACEUTICALS INC.

FORM 10-Q

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS
ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share amounts)

	September 30, 2016 (unaudited)	December 31, 2015
Assets		
Cash and cash equivalents	$ 153,679	$ 102,138
Investment securities, available-for-sale	435,180	112,994
Accounts receivable, net	3,839	—
Interest and other receivables	1,385	1,638
Inventory	4,301	—
Prepaid expenses and other current assets	5,106	2,219
Total current assets	603,490	218,989
Property and equipment, net	3,159	2,203
Intangible assets, net	7,385	—
Restricted cash	2,375	375
Other assets	975	329
Total assets	$ 617,384	$ 221,896
Liabilities and stockholders' equity		
Accounts payable	$ 2,828	$ 1,672
Accrued liabilities	34,445	20,230
Deferred revenue	1,876	—
Total current liabilities	39,149	21,902
Long-term liabilities	177	232
Total liabilities	39,326	22,134
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized at September 30, 2016 and December 31, 2015; no shares issued and outstanding at September 30, 2016 and December 31, 2015	—	—
Common stock, $0.0001 par value; 225,000,000 shares authorized at September 30, 2016 and December 31, 2015; 121,107,222 shares and 101,938,702 shares issued and	12	10

outstanding at September 30, 2016 and December 31, 2015, respectively		
Additional paid-in capital	1,432,796	862,327
Accumulated deficit	(855,283)	(662,586)
Accumulated other comprehensive income	533	11
Total stockholders' equity	578,058	199,762
Total liabilities and stockholders' equity	$ 617,384	$ 221,896

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)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
Revenues				
Product sales, net	$5,268	$—	$5,365	$—
Collaborative revenue	—	39	4	44
Total revenues	5,268	39	5,369	44
Operating expenses				
Cost of product sales	845	—	1,371	—
License fees and royalties	475	—	723	—
Research and development	25,813	18,729	69,066	53,403
Selling, general and administrative	50,534	20,308	128,793	65,688
Total operating expenses	77,667	39,037	199,953	119,091
Loss from operations	(72,399)	(38,998)	(194,584)	(119,047)
Interest income, net	786	92	1,887	388
Net loss	$(71,613)	$(38,906)	$(192,697)	$(118,659)
Net loss per common share, basic and diluted	$(0.61)	$(0.39)	$(1.69)	$(1.18)
Weighted average common shares outstanding, basic and diluted	117,497	100,756	114,063	100,436

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)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
Net loss	$(71,613)	$(38,906)	$(192,697)	$(118,659)
Other comprehensive gain (loss):				
Unrealized gain on investment securities	328	34	524	51
Foreign currency translation adjustments	(1)	—	(2)	3
Comprehensive loss	$(71,286)	$(38,872)	$(192,175)	$(118,605)

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)

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities		
Net loss	$(192,697)	$(118,659)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	39,847	31,292
Amortization of premiums and accretion of discounts on investment securities, available for sale	145	(1,902)
Amortization of intangible assets	615	—
Depreciation	583	519
Loss on disposal of assets	5	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(3,839)	—
Interest and other receivables	253	758
Inventory	(3,503)	—
Prepaid expenses and other current assets	(2,887)	(782)
Restricted cash	(2,000)	—
Other assets	(646)	(118)
Accounts payable	994	144
Accrued liabilities	14,090	1,571
Deferred revenue	1,876	—
Long-term liabilities	(55)	104
Net cash used in operating activities	(147,219)	(87,073)
Cash flows from investing activities		
Purchases of investment securities	(592,868)	(215,926)
Maturities of investment securities	271,061	308,619
Intangible assets	(8,000)	—
Purchases of property and equipment	(1,257)	(1,848)
Net cash (used in) provided by investing activities	(331,064)	90,845
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	515,506	5,170
Proceeds from settlement agreement	14,320	—
Net cash provided by financing activities	529,826	5,170
Effect of exchange rate changes on cash	(2)	3
Net increase in cash and cash equivalents	51,541	8,945
Cash and cash equivalents		

Beginning of period	102,138	61,854
End of period	$153,679	$70,799
Supplemental disclosure of noncash information:		
Property and equipment purchases in accounts payable and accrued liabilities	$287	$186
Stock-based compensation capitalized in inventory	$798	$—

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.

On April 29, 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. NUPLAZID became available for prescription in the United States on May 31, 2016.

2. Basis of Presentation and Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of ACADIA Pharmaceuticals Inc. should be read in conjunction with the audited financial statements and notes thereto as of and for the year ended December 31, 2015 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 and cash flows 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.

Accounts Receivable

Accounts receivable are recorded net of customer allowances for prompt payment discounts, distribution fees, chargebacks, and doubtful accounts. The Company estimates the allowance for doubtful accounts based on existing contractual payment terms, actual payment patterns of its customers and individual customer circumstances. To date, the Company has determined that an allowance for doubtful accounts is not required.

Inventory

Inventory, consisting of raw material and finished goods, is stated at the lower of cost or estimated net realizable value. The Company uses a combination of standard and actual costing methodologies to determine the cost basis for its inventories which approximates actual costs. Inventory is valued on a first-in, first-out basis and includes third-party manufacturing costs, freight, and indirect overhead costs. The Company capitalizes inventory costs associated with its products upon regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed. Prior to FDA approval of NUPLAZID, all costs related to the manufacturing of NUPLAZID were charged to research and development expense in the period incurred. At September 30, 2016 the Company had an immaterial amount of zero cost raw material that was available for use in the manufacturing of commercial product. The Company provides reserves for potentially excess, dated or obsolete inventory based on an analysis of forecasted demand compared to quantities on hand and any firm purchase orders, as well as product shelf life. To date, the Company has determined that a reserve for potentially excess, dated or obsolete inventory is not required.

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 has 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 $369,000 and $615,000 for the three and nine months ended September 30, 2016, respectively. As of September 30, 2016, estimated future amortization expense related to the Company's intangible asset was $369,000 for the remainder of 2016, $1.5 million for each of 2017, 2018, 2019, and 2020, and $1.1 million thereafter.

Royalty expense incurred in connection with the Company's license agreement with the Ipsen Group, as disclosed in Note 9, Commitments and Contingencies, is recorded to license fees and royalties as revenue from product sales is recognized.

Revenue Recognition

Product Sales, Net

The Company's net product sales consist of U.S. sales of NUPLAZID and are recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title to the product and associated risk of loss has passed to the customer, (iii) the price is fixed or determinable, and (iv) collectability is reasonably assured.

NUPLAZID was approved by the FDA on April 29, 2016 and the Company commenced shipments of NUPLAZID to specialty pharmacies ("SPs") and specialty distributors ("SDs") in late May 2016. Through September 30, 2016, the Company has determined it does not have the necessary volume of activity to reasonably estimate certain sales allowances at the time title and risk of loss transfers to the SP or SD. Accordingly, the price is not considered fixed or determinable at that time. Therefore, the Company recognizes revenue once the SP has filled a patient's prescription for NUPLAZID or the SD sells NUPLAZID. This approach is frequently referred to as the "sell-through" revenue recognition model. Under the sell-through approach, revenue is recognized when the SP dispenses product to a patient based on the fulfillment of a prescription or the SD sells product to a government facility, long-term care pharmacy or in-patient hospital pharmacy. As of September 30, 2016, the Company had a deferred revenue balance of $1.9 million, net of distribution fees, related to NUPLAZID product sales.

The Company recognizes revenue from product sales net of allowances for distribution fees, rebates, chargebacks, and co-payment assistance.

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 rights, 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 antidilutive. The Company incurred net losses for all periods presented and there were no reconciling items for potentially dilutive securities. More specifically, at September 30, 2016 and 2015, stock options, employee stock purchase rights, and warrants totaling approximately 14,463,000 shares and 12,309,000 shares, respectively, were excluded from the calculation of diluted net loss per share as their effect would have been anti-dilutive.

4. Stock-Based Compensation

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
Cost of product sales	$308	$—	$497	$—
Research and development	4,319	3,938	13,495	9,139
Selling, general and administrative	9,382	5,327	25,855	22,153
	$14,009	$9,265	$39,847	$31,292

As of September 30, 2016, total unrecognized compensation cost related to stock options and purchase plan rights was approximately $134.9 million, which is expected to be recognized over a weighted-average period of 3.0 years.

During the three months ended March 31, 2016, the Company granted options to purchase an aggregate of 3,059,835 shares of its common stock in connection with annual option grants to eligible employees. These stock options vest over a four-year period from the date of grant and have a weighted average exercise price of $23.88 per share. Stock-based compensation expense for the nine months ended September 30, 2015 included a one-time $9.0 million charge related to the transition agreement with the Company's former Chief Executive Officer in connection with his retirement from the Company in March 2015.

5. Balance Sheet Details

Inventory consisted of the following (in thousands):

	September 30, 2016	December 31, 2015
Finished goods	$ 2,157	$ —
Raw material	2,144	—
	$ 4,301	$ —

Accrued liabilities consisted of the following (in thousands):

	September 30, 2016	December 31, 2015
Accrued research and development services	$ 9,866	$ 8,805
Accrued compensation and benefits	11,921	5,722
Accrued consulting and professional fees	9,488	4,508
Other	3,170	1,195
	$ 34,445	$ 20,230

6. Investment Securities

Investment securities, all classified as available-for-sale, consisted of the following (in thousands):

	September 30, 2016

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury notes	$53,947	$ 32	$ —	$53,979
Government sponsored enterprise securities	128,245	37	—	128,282
Corporate debt securities	68,664	—	(40)	68,624
Commercial paper	183,802	493	—	184,295
	$434,658	$ 562	$ (40)	$435,180

	December 31, 2015			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury notes	$9,000	$ —	$ (1)	$8,999
Government sponsored enterprise securities	103,996	12	(13)	103,995
	$112,996	$ 12	$ (14)	$112,994

At each reporting date, the Company performs an evaluation of impairment to determine if any unrealized losses are other-than-temporary. Factors considered in determining whether a loss is other-than-temporary include the length of time and extent to which fair value has been less than the cost basis, the financial condition of the issuer, and the Company's intent and ability to hold the investment until recovery of its amortized cost basis. The Company intends, and has the ability, to hold its investments in unrealized loss positions until their amortized cost basis has been recovered. Based on its evaluation, the Company determined that its unrealized losses were not other-than-temporary at September 30, 2016 and December 31, 2015. As of September 30, 2016 and December 31, 2015, all of the Company's available-for-sale investment securities had contractual maturity dates of less than one year.

7. Fair Value Measurements

As of September 30, 2016, the Company held $586.4 million of cash equivalents and available-for-sale investment securities consisting of a money market fund, U.S. Treasury notes, and high quality, marketable debt instruments of corporations and government sponsored enterprises in accordance with the Company's investment policy. The Company's investment policy defines allowable investments 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 and available-for-sale investment securities are classified within the fair value hierarchy as defined by authoritative guidance. The Company's investment securities classified as Level 1 are valued using quoted market prices. The Company obtains the fair value of its Level 2 financial instruments from third party pricing services. The pricing services utilize industry standard valuation models whereby all significant inputs, including benchmark yields, reported trades, broker/dealer quotes, issuer spreads, bids, offers, or other market-related data, are observable. The Company validates the prices provided by the third-party pricing services by reviewing their pricing methods and matrices, and obtaining market values from other pricing sources. After completing the validation procedures, the Company did not adjust or override any fair value measurements provided by these pricing services as of September 30, 2016 and December 31, 2015.

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 levels.

The fair value measurements of the Company's cash equivalents and available-for-sale investment securities are identified in the following tables (in thousands):

		Fair Value Measurements at Reporting Date Using		
	September 30, 2016	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market fund	$ 93,769	$93,769	$ —	$ —

U.S. Treasury notes	53,979	53,979	—	—
Government sponsored enterprise securities	151,764	—	151,764	—
Corporate debt securities	71,631	—	71,631	—
Commercial paper	215,264	—	215,264	—
	$ 586,407	$147,748	$438,659	$ —

		Fair Value Measurements at Reporting Date Using		
	December 31, 2015	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market fund	$46,437	$46,437	$ —	$ —
U.S. Treasury notes	8,999	8,999	—	—
Government sponsored enterprise securities	157,623	—	157,623	—
	$213,059	$55,436	$157,623	$ —

8. Stockholders’ Equity

Public Offerings

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, par value $0.0001 per share, 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 and $43.0 million of shares that the Baker Entities purchased at the public offering price in the January 2016 and August 2016 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 April 1, 2016, pursuant to the Registration Rights Agreement, the Company filed a registration statement covering all shares owned by the Baker Entities as of March 31, 2016.

Settlement Agreement Proceeds

In April 2016, the Company received a payment of $14.3 million pursuant to a settlement agreement with prior 10% stockholders who sold shares of the Company's stock in 2013 that may have resulted in short-swing profits by the stockholders pursuant to Section 16(b) of the Securities Exchange Act of 1934, as amended. The Company recognized these proceeds as a capital contribution from stockholders and reflected a corresponding increase to additional paid-in capital.

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.

Corporate Credit Card Program

In connection with the Company's credit card program, the Company established a letter of credit in April 2016 for $2.0 million, which has automatic annual extensions and is fully secured by restricted cash.

Legal Proceedings

In March 2015, following the Company's announcement of the update to the timing of its planned NDA submission to the FDA for NUPLAZID and the subsequent decline of the price of its common stock, two putative securities class action complaints (captioned Rihn v. ACADIA Pharmaceuticals Inc., Case No. 15-cv-0575-BTM-DHB, and Wright v. ACADIA Pharmaceuticals Inc., Case No. 15-cv-0593- BTM-DHB) were filed in the U.S. District Court for the Southern District of California (the "Court") against the Company and certain of its current and former officers. The

complaints 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 the Company's planned NDA submission to the FDA for NUPLAZID, thereby artificially inflating the price of its common stock. The complaints sought unspecified monetary damages and other relief. On April 10 and June 1, 2015, the Court entered orders deferring the defendants' response to the Rihn and Wright complaints until after the Court appointed a lead plaintiff and assigned lead counsel. On May 12, 2015, several putative stockholders filed separate motions to consolidate the two actions and be appointed lead plaintiff. On September 8, 2015, the Court issued an order consolidating the two actions, appointing lead plaintiff, and assigning lead counsel. On November 16, 2015, lead plaintiff filed a consolidated complaint with the Court which, like the prior complaints, accused the defendants of making materially false and misleading statements regarding the anticipated timing of the Company's planned NDA submission to the FDA for NUPLAZID. On January 15, 2016, the defendants filed a motion to dismiss the consolidated complaint. On September 19, 2016, the Court issued an order denying the motion to dismiss the consolidated complaint. On October 18, 2016, the Company filed a motion for reconsideration of the Court's order denying the motion to dismiss. On October 21, 2016, the Company filed its answer to the consolidated complaint. The hearing on the Company's motion for reconsideration is scheduled for December 16, 2016. The Company has assessed such legal proceedings, and given the unpredictability inherent in litigation, the Company cannot predict the outcome of these matters. At this time, the Company is unable to estimate possible losses or ranges of losses that may result from such legal proceedings, and it has not accrued any amounts in connection with such legal proceedings other than ongoing attorneys' fees.

10. Recent Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued authoritative guidance related to accounting for credit losses on financial instruments that 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. The Company is currently evaluating the impact of the adoption of this guidance on the Company's consolidated financial statements.

In March, April, and May 2016, the FASB issued updates to its authoritative guidance for revenue from contracts with customers. The updates clarify certain aspects of the revenue guidance, including but not limited to, the implementation guidance on principal versus agent considerations, the licensing implementation guidance, identification of performance obligations, assessment of the collectability criterion, presentation of sales taxes and other similar taxes, and measurement of noncash consideration. The authoritative guidance for revenue from contracts with customers to which these updates apply is effective for annual reporting periods beginning after December 15, 2017, with early adoption permitted only as of annual reporting periods beginning after December 15, 2016. Companies may use either a full retrospective or a modified retrospective approach to adopt this guidance. The Company is continuing to evaluate which transition approach to use and its impact, if any, on its consolidated financial statements.

In March 2016, the FASB issued authoritative guidance related to accounting for employee share-based compensation which is intended to simplify several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, classification on the statement of cash flows, and accounting for forfeitures. This guidance is effective for annual reporting periods beginning after December 15, 2016, including interim periods within those years. The Company is currently evaluating the impact of the adoption of this guidance on the Company's consolidated financial statements.

In February 2016, the FASB issued authoritative guidance related to accounting for leases. This accounting guidance will require a lessee to recognize a lease liability and a right-of-use asset for all leases with lease terms of more than 12 months. This guidance is effective for annual reporting periods beginning after December 15, 2018, including interim periods within those years, and early adoption is permitted. The Company is currently evaluating the impact of the adoption of this guidance on the Company's consolidated financial statements.

In August 2014, the FASB issued authoritative accounting guidance related to an entity's ability to continue as a going concern. This guidance explicitly requires management to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. The new standard is effective for annual reporting periods ending after December 15, 2016, and for annual periods and interim periods thereafter, with early adoption permitted. The Company early adopted this guidance in the first quarter of 2016 with no impact to its consolidated financial statements or related disclosures.

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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, 2015 included with our Annual Report on Form 10-K 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 our strategies, objectives, expectations, discoveries, collaborations, clinical trials, regulatory submissions, commercial activities, product candidates, proprietary and external programs, financial condition and resources, and other statements that are not historical facts, including statements which may be preceded by the words "believes," "expects," "hopes," "may," "will," "plan "intends," "estimates," "could," "should," "would," "continue," "seeks," "aims," "projects," "predicts," "pro forma," "anticipat similar words. For such 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 were made. We undertake no obligation to update publicly or revise 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 identified in our filings with the SEC, including this Quarterly Report.

Overview

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, or FDA, on April 29, 2016 for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis, or PDP, and is the only drug approved in the United States for this condition. NUPLAZID is a selective serotonin inverse agonist, or SSIA, preferentially targeting 5-HT_{2A} receptors. Through this novel mechanism, NUPLAZID demonstrated significant efficacy in reducing the hallucinations and delusions associated with PDP in our Phase III pivotal trial and has the potential to avoid many of the debilitating side effects of existing antipsychotics, none of which are approved by the FDA in the treatment of PDP. We hold worldwide commercialization rights to pimavanserin. In connection with FDA approval of NUPLAZID, we hired a U.S. specialty sales force of approximately 135 sales specialists who are focused on promoting NUPLAZID to physicians who treat PDP patients, including neurologists, psychiatrists and long-term care physicians. NUPLAZID became available for prescription in the United States on May 31, 2016.

In connection with the FDA approval of NUPLAZID, we have committed to conduct post-marketing studies, including a randomized, placebo-controlled withdrawal study in PDP patients treated with NUPLAZID and randomized, placebo-controlled eight-week 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 believe that pimavanserin has the potential to address important unmet medical needs in neurological and psychiatric disorders in addition to PDP and we plan to continue to study the use of pimavanserin in multiple disease states.

For example, we believe Alzheimer's disease represents one of our most important opportunities for further exploration. We recently completed enrollment of a Phase II study exploring the utility of pimavanserin for the treatment of Alzheimer's disease psychosis, or ADP, a disorder for which no drug is currently approved by the FDA. We expect to have top-line results from the study by the end of 2016. Additionally, in October 2016, we announced that we initiated SERENE, a Phase II study with pimavanserin in Alzheimer's disease agitation, a debilitating condition for which there is no drug approved by the FDA.

We also believe schizophrenia represents a disease with multiple unmet or ill-served needs and we are currently exploring the utility of pimavanserin in this area. Despite a large number of FDA-approved therapies for schizophrenia, current drugs do not adequately address some very important symptoms of schizophrenia, such as the inadequate response to current antipsychotic treatment of psychotic symptoms. In November 2016, we announced that we initiated ENHANCE-1, a Phase III study for adjunctive treatment of schizophrenia in patients with an inadequate response to current antipsychotic therapy. There is no FDA-approved treatment for this condition.

In addition to the studies we have previously announced, we plan to initiate two clinical studies for additional indications in the fourth quarter of 2016.

We have incurred substantial operating losses since our inception due in large part to expenditures for our research and development activities. As of September 30, 2016, we had an accumulated deficit of $855.3 million. We expect to continue to incur operating losses for at least the next few years as we advance our programs and incur significant development and commercialization costs. In particular, we will be incurring new, additional costs over the next several quarters related to our studies in schizophrenia and Alzheimer's disease indications, our post-marketing study commitments, and the commercialization of NUPLAZID.

We maintain a website at 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.

Financial Operations Overview

Product and Collaborative Revenues

Net product sales consist of sales of NUPLAZID, which was approved by the FDA on April 29, 2016 and became available for prescription in the United States on May 31, 2016.

Prior to the generation of revenue from NUPLAZID, our revenues had been generated substantially from payments under our current and past collaboration agreements. Our prior collaboration agreement with Allergan focused on muscarinic product candidates for the treatment of glaucoma terminated in 2015 and we will not be receiving any further payments under that agreement. Our continuing collaboration agreement with Allergan involves the development of product candidates in the area of chronic pain. Under this continuing agreement, we are eligible to receive payments upon achievement of development and regulatory milestones, as well as royalties on future product sales, if any. We no longer receive research funding from this agreement and additional payments are dependent upon the advancement of an applicable product candidate. Our continuing collaboration agreement with Allergan in chronic pain is subject to termination upon notice by Allergan.

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, 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 Parkinson's disease psychosis on April 29, 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 in PDP. Additionally, we will be responsible for all costs incurred for post-marketing studies that we committed to conduct in connection with FDA approval of NUPLAZID.

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. 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 by project for the three and nine months ended September 30, 2016 and 2015 (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
Costs of external service providers:				
NUPLAZID (pimavanserin)	$14,229	$9,328	$34,947	$29,454
Other programs	120	236	461	607
Subtotal	14,349	9,564	35,408	30,061
Internal costs	7,145	5,227	20,163	14,203
Stock-based compensation	4,319	3,938	13,495	9,139
Total research and development	$25,813	$18,729	$69,066	$53,403

Although NUPLAZID was approved by the FDA for the treatment of hallucinations and delusions associated with PDP, 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 Alzheimer's disease and schizophrenia. 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 in PDP, 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 in PDP, including studies within Alzheimer's disease and schizophrenia indications. 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 recently hired 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 professional fees associated with legal and accounting services, costs associated with patents and patent applications for our intellectual property, and fees paid to external service providers to support our commercial activities associated with NUPLAZID. 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 in PDP.

Critical Accounting Policies and Estimates

Other than the additional critical accounting policy related to revenue discussed below, there have been no significant changes to our critical accounting policies and estimates since December 31, 2015. For a description of our other critical accounting policies that affect our significant judgments and estimates used in the preparation of our consolidated financial statements, refer to our Annual Report on Form 10-K for the year ended December 31, 2015.

Revenue Recognition

Product Sales, Net

Our net product sales consist of U.S. sales of NUPLAZID and are recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title to the product and associated risk of loss has passed to the customer, (iii) the price is fixed or determinable, and (iv) collectability is reasonably assured. NUPLAZID was approved by the FDA on April 29, 2016 and we commenced shipments of NUPLAZID to specialty pharmacies, or SPs, and specialty distributors, or SDs, in late May 2016. Through

September 30, 2016, we have determined we do not have the necessary volume of activity to reasonably estimate certain sales allowances at the time title and risk of loss transfers to the SP or SD. Accordingly, the price is not considered fixed or determinable at that time. Therefore, we recognize revenue once the SP has filled a patient's prescription for NUPLAZID or the SD sells NUPLAZID. This approach is frequently referred to as the "sell-through" revenue recognition model. Under the sell-through approach, revenue is recognized when the SP dispenses product to a patient based on the fulfillment of a prescription or the SD sells product to a government facility, long-term care pharmacy or in-patient hospital pharmacy. As of September 30, 2016, we had a deferred revenue balance of $1.9 million, net of distribution fees, related to NUPLAZID product sales.

We recognize revenue from product sales net of allowances for distribution fees, rebates, chargebacks, and co-payment assistance.

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 in PDP, the progress and timing of expenditures related to studies pursuant to our post-marketing commitments, and the timing and amount of payments received pursuant to our current collaboration and any potential future collaborations. Due to these fluctuations, we believe that the period-to-period comparisons of our operating results are not a good indication of our future performance.

Comparison of the Three Months Ended September 30, 2016 and 2015

Product Sales, Net

Net product sales were $5.3 million for the three months ended September 30, 2016 and were comprised of sales of NUPLAZID which was approved by the FDA on April 29, 2016 and became available for prescription on May 31, 2016. No similar net product sales were recognized during the three months ended September 30, 2015.

During the initial launch period, we defer the recognition of revenue from sales of NUPLAZID until product is dispensed to patients by the SPs or sold to government facilities and long-term care and in-patient hospital pharmacies by the SDs. At September 30, 2016, deferred product revenue of $1.9 million was recorded as a liability on our consolidated balance sheet, net of distribution fees.

Cost of Product Sales

Cost of product sales was $845,000 for the three months ended September 30, 2016, or approximately 16% of net product sales. Product sold during the three months ended September 30, 2016 was manufactured with raw material that was previously charged to research and development expense prior to FDA approval of NUPLAZID. This zero cost raw material did not materially impact our cost of product sales and related product gross margins for the three months ended September 30, 2016. No similar cost of product sales was recognized during the three months ended September 30, 2015.

License Fees and Royalties

License fees and royalties were $475,000 for the three months ended September 30, 2016 and include the amortization of the $8.0 million milestone paid to the Ipsen Group upon the FDA approval of NUPLAZID. The $8.0 million milestone was recorded as an intangible asset and is being amortized over the estimated useful life of the asset through the second half of 2021. In addition, license fees and royalties include royalties due to the Ipsen Group of two percent of net sales of NUPLAZID. No similar license fees and royalties expense was recorded for the comparable period of 2015.

Research and Development Expenses

Research and development expenses increased to $25.8 million for the three months ended September 30, 2016, including $4.3 million in stock-based compensation expense, from $18.7 million for the three months ended September 30, 2015, including $3.9 million in stock-based compensation expense. The increase in research and development expenses was primarily due to an increase of $4.8 million in external service costs driven largely by increased clinical costs related to the development of pimavanserin in indications other than in PDP. Also contributing to the increase in research and development expenses was an increase of $2.3 million in personnel and related costs and stock compensation expense associated with our expanded research and development organization.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased to $50.5 million for the three months ended September 30, 2016, including $9.4 million in stock-based compensation expense, from $20.3 million for the three months ended September 30, 2015, including $5.3 million in stock-based compensation expense. The increase in selling, general and administrative expenses was due to an increase of $15.8 million in personnel and related costs and stock compensation expense and an increase of $14.4 million in external service costs. The increase in personnel and related costs was largely due to costs associated with the hiring of our specialty sales force in April 2016. The increase in external service costs was primarily due to costs incurred to support our commercial activities for NUPLAZID, as well as additional medical education programs.

Comparison of the Nine Months Ended September 30, 2016 and 2015

Product Sales, Net

Net product sales were $5.4 million for the nine months ended September 30, 2016 and were comprised of sales of NUPLAZID which was approved by the FDA on April 29, 2016 and became available for prescription on May 31, 2016. No similar net product sales were recognized during the nine months ended September 30, 2015.

During the initial launch period, we defer the recognition of revenue from sales of NUPLAZID until product is dispensed to patients by the SPs or sold to government facilities and long-term care and in-patient hospital pharmacies by the SDs. At September 30, 2016, deferred product revenue of $1.9 million was recorded as a liability on our consolidated balance sheet, net of distribution fees.

Cost of Product Sales

Cost of product sales was $1.4 million for the nine months ended September 30, 2016 , or approximately 26% of net product sales. Product sold during the nine months ended September 30, 2016 was manufactured with raw material that was previously charged to research and development expense prior to FDA approval of NUPLAZID. This zero cost raw material did not materially impact our cost of product sales and related product gross margins for the nine months ended September 30, 2016. No similar cost of product sales was recognized during the nine months ended September 30, 2015.

License Fees and Royalties

License fees and royalties were $723,000 for the nine months ended September 30, 2016 and include the amortization of the $8.0 million milestone paid to the Ipsen Group upon the FDA approval of NUPLAZID. The $8.0 million milestone was recorded as an intangible asset and is being amortized over the estimated useful life of the asset through the second half of 2021. In addition, license fees and royalties include royalties due to the Ipsen Group of two percent

of net sales of NUPLAZID. No similar license fees and royalties expense was recorded for the comparable period of 2015.

Research and Development Expenses

Research and development expenses increased to $69.1 million for the nine months ended September 30, 2016, including $13.5 million in stock-based compensation expense, from $53.4 million for the nine months ended September 30, 2015, including $9.1 million in stock-based compensation expense. The increase in research and development expenses was due to an increase of $10.3 million in personnel and related costs and stock compensation expense associated with our expanded research and development organization and an increase of $5.4 million in external service costs. The increase in external service costs was due to increased clinical costs related to the development of pimavanserin in indications other than in PDP as well as costs associated with the FDA's Psychopharmacologic Drugs Advisory Committee meeting that occurred in March 2016. These increases were partially offset by a decrease in manufacturing development costs.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased to $128.8 million for the nine months ended September 30, 2016, including $25.9 million in stock-based compensation expense, from $65.7 million for the nine months ended September 30, 2015, including $22.2 million in stock-based compensation expense. The increase in selling, general and administrative expenses was due to an increase of $35.8 million in external service costs and an increase of $27.3 million in personnel and related costs and stock compensation expense. The increase in external service costs was primarily due to preparations for, and support of, the launch of NUPLAZID and related commercial activities, as well as additional medical education programs. The increase in personnel and related costs was primarily driven by costs associated with the hiring of our specialty sales force in April 2016. These increases were partially offset by a one-time expense of $9.6 million incurred in the first quarter of 2015 in connection with the transition agreement with our former Chief Executive Officer upon his retirement in March 2015. Included in this compensation expense of $9.6 million was $9.0 million in stock-based compensation expense.

Liquidity and Capital Resources

Since inception, we have funded our operations primarily through sales of our equity securities, payments received under our collaboration agreements, debt financings, and interest income. 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 in PDP, and studies to be conducted pursuant to our post-marketing commitments. 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, and other research and development programs;
- 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 potentially in additional indications other than in PDP and for other product candidates, as well as the costs required to support review of such applications;
- the costs of manufacturing and distributing NUPLAZID 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 PDP, or from 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, and to maintain existing, 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 or other product candidates; and
- the costs associated with litigation, including the costs incurred in defending against any product liability claims that may be brought against us related to NUPLAZID and against claims made in connection with our announcement of the update to the timing of our planned NDA submission to the FDA for NUPLAZID and the subsequent decline of the price of our common stock in March 2015.

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. These events, coupled with other factors, may limit our access to additional financing in the future. This could have a material adverse effect on our ability to access sufficient funding. We cannot be certain that additional funding will be available to us on acceptable terms, or at all. If funds are not available, we will be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts. We also may be required to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Additional funding, if obtained, may significantly dilute existing stockholders and could negatively impact the price of our stock.

We have invested a substantial portion of our available cash in a money market fund, 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 September 30, 2016, we had $588.9 million in cash, cash equivalents, and investment securities, compared to $215.1 million at December 31, 2015. This $373.8 million increase was primarily due to our January and August 2016 follow-on public offerings which raised total net proceeds of approximately $497.5 million, partially offset by cash used in operations. Net cash used in operating activities increased to $147.2 million for the nine months ended September 30, 2016 compared to $87.1 million for the nine months ended September 30, 2015. This increase of $60.1 million was primarily due to the increase in our net loss offset by an increase of $8.6 million in non-cash stock-based compensation expense.

Net cash used in investing activities totaled $331.1 million for the nine months ended September 30, 2016 compared to net cash provided by investing activities of $90.8 million for the nine months ended September 30, 2015. The net cash used in investing activities for the nine months ended September 30, 2016 compared to the net cash provided by investing activities for the comparable period of 2015 was primarily due to an increase in purchases of investment securities attributable to the January and August 2016 follow-on public offerings that contributed approximately $497.5 million in total net proceeds available for investment. Also contributing to the net cash used in investing activities for the nine months ended September 30, 2016 was the payment of an $8.0 million regulatory milestone pursuant to our license agreement with the Ipsen Group in connection with the FDA approval of NUPLAZID.

Net cash provided by financing activities increased to $529.8 million for the nine months ended September 30, 2016 compared to $5.2 million for the nine months ended September 30, 2015. This increase in net cash provided by financing activities for the nine months ended September 30, 2016 was primarily attributable to the January and August 2016 follow-on public offerings that contributed approximately $497.5 million in total net proceeds. Also contributing to the increase in net cash provided by financing activities for the nine months ended September 30, 2016 were proceeds of $17.7 million from stock option exercises and purchases under our employee stock purchase plan and $14.3 million received pursuant to a settlement agreement with prior 10% stockholders who sold shares of our stock in 2013, as described in Item 1 of Part I, "Notes to Condensed Consolidated Financial Statements — Note 8 — Stockholders' Equity".

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 a money market fund, 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 September 30, 2016, 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 principal executive officer and principal financial officer, 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.

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, as of September 30, 2016. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2016.

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 change 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.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

In March 2015, following our announcement of the update to the timing of our planned NDA submission to the FDA for NUPLAZID and the subsequent decline of the price of our common stock, two putative securities class action complaints (captioned Rihn v. ACADIA Pharmaceuticals Inc., Case No. 15-cv-0575-BTM-DHB, and Wright v. ACADIA Pharmaceuticals Inc., Case No. 15-cv-0593- BTM-DHB) were filed in the U.S. District Court for the Southern District of California, or the Court, against us and certain of our current and former officers. The complaints 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 complaints sought unspecified monetary damages and other relief. On April 10 and June 1, 2015, the Court entered orders deferring the defendants' response to the Rihn and Wright complaints until after the Court appointed a lead plaintiff and assigned lead counsel. On May 12, 2015, several putative stockholders filed separate motions to consolidate the two actions and be appointed lead plaintiff. On September 8, 2015, the Court issued an order consolidating the two actions, appointing lead plaintiff, and assigning lead counsel. On November 16, 2015, lead plaintiff filed a consolidated complaint with the Court which, like the prior complaints, accused the defendants of making materially false and misleading statements regarding the anticipated timing of our planned NDA submission to the FDA for NUPLAZID. On January 15, 2016, we filed a motion to dismiss the consolidated complaint. On September 19, 2016, the Court issued an order denying the motion to dismiss the consolidated complaint. On October 18, 2016, we filed a motion for reconsideration of the Court's order denying the motion to dismiss. On October 21, 2016, we filed our answer to the consolidated complaint. The hearing on our motion for reconsideration is scheduled for December 16, 2016. We plan to continue to vigorously defend against the claims advanced.

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 to 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, which received approval in April 2016 from the U.S. Food and Drug Administration, or FDA, as a treatment for hallucinations and delusions associated with Parkinson's disease psychosis, and became available for prescription in the United States in May 2016. 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 PDP, in the United States. We are focusing a significant portion of our activities and resources on NUPLAZID, and we believe our prospects are highly dependent on, and a significant portion 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. Prior to NUPLAZID, we had never, as an organization, launched or commercialized any product, and there is no guarantee that we will be able to successfully launch or commercialize NUPLAZID for its approved indication. There are numerous examples of unsuccessful

product launches and 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 maintain and further develop the team in order to successfully coordinate the launch and commercialization of NUPLAZID. Even if we are successful in maintaining and continuing to develop our commercial team, there are many factors that could cause the launch and 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 PDP, it is especially difficult to estimate NUPLAZID's market potential. The commercial success of NUPLAZID depends on the extent to which patients and physicians recognize and diagnose PDP and accept and adopt NUPLAZID as a treatment for hallucinations and delusions associated with PDP, and we do not know whether our or others' estimates in this regard will be accurate. For example, if the patient population suffering from hallucinations and delusions associated with PDP is smaller than we estimate or if physicians are unwilling to prescribe or patients are unwilling to take NUPLAZID due to its "boxed" warning or other reasons, the commercial potential of NUPLAZID will be limited. We have limited information about how physicians, patients and payors will respond to the pricing of NUPLAZID, including because as part of

our initial launch strategy we have provided free product as samples and through a 30-day free trial period of NUPLAZID, and do not know whether patients that initially use NUPLAZID will continue to do so after the sample or 30-day free trial period ends. 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 development for NUPLAZID in our post-marketing commitments, in clinical development in additional indications other than in PDP, 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.

If the launch or commercialization of NUPLAZID is unsuccessful 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 NUPLAZID for other indications in the United States, or for any indications in foreign jurisdictions, we will not be able to market NUPLAZID for other indications or in other jurisdictions, which will limit our commercial revenues.*

While NUPLAZID (pimavanserin) has been approved by the FDA for the treatment of hallucinations and delusions associated with PDP, it has not been approved by the FDA for any other indications, and it has not been approved in any other jurisdiction for this indication or for any other indication. In order to market NUPLAZID for other indications or in other jurisdictions, we must obtain regulatory approval for each of those indications and in each of the applicable jurisdictions, and we may never be able to obtain such approval. Approval of NUPLAZID by the FDA for the treatment of hallucinations and delusions associated with PDP does not ensure that the foreign jurisdictions will also approve NUPLAZID for that indication, nor does it ensure that NUPLAZID will be approved by the FDA for any other indications. 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. This will require additional time, expertise and expense, including the potential need to conduct additional studies or development work for other jurisdictions beyond the work that we have conducted to support our NDA submission in PDP. In particular, in May 2016 we received comments from the European Medicines Agency, or EMA, on our proposed pediatric investigation plan, or PIP, related to our planned submission of a marketing authorization application, or MAA, for NUPLAZID in Europe. Since receiving these comments we worked with the Pediatric Commission of the EMA to develop an appropriate PIP for NUPLAZID in Europe. While discussions with the EMA are ongoing, we submitted our new PIP in the third quarter and are waiting for a response from the Pediatric Commission of the EMA. As we will need to have agreement on the PIP before we can submit our MAA, this has pushed back the proposed timing of our 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 other than the FDA, we will never be able to commercialize NUPLAZID for any other indication in the United States or for any indication in any other jurisdiction. 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 PDP, 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 PDP. 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 wit