ACADIA PHARMACEUTICALS INC
Form 10-Q
August 08, 2018

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, 2018

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 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 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 (§ 232.405 of this chapter) 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, smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer		Accelerated filer
Non-accelerated filer	(Do not check if a smaller reporting company)	Smaller reporting company
Emerging growth company		

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

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

Total shares of common stock outstanding as of the close of business on July 31, 2018:

Class	Number of Shares Outstanding
Common Stock, $0.0001 par value	125,006,723

ACADIA PHARMACEUTICALS INC.

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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, 2018 (unaudited)	December 31, 2017
Assets		
Cash and cash equivalents	$74,182	$69,418
Investment securities, available-for-sale	182,673	271,924
Accounts receivable, net	25,696	17,343
Interest and other receivables	986	1,087
Inventory	4,737	5,248
Prepaid expenses	12,822	8,457
Total current assets	301,096	373,477
Property and equipment, net	2,760	2,662
Intangible assets, net	4,800	5,538
Restricted cash	3,111	2,475
Other assets	3,193	354
Total assets	$314,960	$384,506
Liabilities and stockholders' equity		
Accounts payable	$3,333	$8,786
Accrued liabilities	45,881	40,244
Total current liabilities	49,214	49,030
Long-term liabilities	1,026	191
Total liabilities	50,240	49,221
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized at June 30, 2018 and December 31, 2017; no shares issued and outstanding at June 30, 2018 and December 31, 2017	—	—
Common stock, $0.0001 par value; 225,000,000 shares authorized at June 30, 2018 and December 31, 2017; 124,999,365 shares and 124,410,552 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	12	12
Additional paid-in capital	1,606,441	1,559,343
Accumulated deficit	(1,341,233)	(1,223,671)
Accumulated other comprehensive loss	(500)	(399)

Total stockholders' equity	264,720	335,285
Total liabilities and stockholders' equity	$314,960	$384,506

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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenues				
Product sales, net	$57,063	$30,475	$105,931	$45,761
Total revenues	57,063	30,475	105,931	45,761
Operating expenses				
Cost of product sales	3,562	2,224	5,715	4,487
License fees and royalties	1,516	982	2,848	1,657
Research and development	46,592	34,180	85,868	69,589
Selling, general and administrative	69,472	61,125	130,398	126,785
Total operating expenses	121,142	98,511	224,829	202,518
Loss from operations	(64,079)	(68,036)	(118,898)	(156,757)
Interest income, net	1,279	993	2,449	1,956
Other expense	(247)	—	(247)	—
Loss before income taxes	(63,047)	(67,043)	(116,696)	(154,801)
Income tax expense	219	398	866	483
Net loss	$(63,266)	$(67,441)	$(117,562)	$(155,284)
Net loss per common share, basic and diluted	$(0.51)	$(0.55)	$(0.94)	$(1.27)
Weighted average common shares outstanding, basic and diluted	124,910	122,122	124,819	121,888

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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net loss	$(63,266)	$(67,441)	$(117,562)	$(155,284)
Other comprehensive gain (loss):				
Unrealized gain (loss) on investment securities	195	(188)	(103)	(199)
Foreign currency translation adjustments	4	(3)	2	(4)
Comprehensive loss	$(63,067)	$(67,632)	$(117,663)	$(155,487)

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)

	Six Months Ended June 30,	
	2018	2017
Cash flows from operating activities		
Net loss	$(117,562)	$(155,284)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	40,994	33,815
(Amortization of premiums) and accretion of discounts on investment securities, net	(241)	(297)
Amortization of intangible assets	738	738
Loss on strategic investments	247	—
Depreciation	734	577
Loss on disposal of assets	32	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(8,353)	(5,691)
Interest and other receivables	101	453
Inventory	782	(1,927)
Prepaid expenses	(4,365)	(498)
Other assets	64	263
Accounts payable	(5,523)	(324)
Accrued liabilities	5,406	1,253
Deferred revenue	—	(2,644)
Long-term liabilities	835	105
Net cash used in operating activities	(86,111)	(129,461)
Cash flows from investing activities		
Purchases of investment securities	(85,762)	(250,007)
Maturities of investment securities	175,151	341,990
Purchases of strategic investments	(3,150)	—
Purchases of property and equipment	(563)	(749)
Net cash provided by investing activities	85,676	91,234
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	5,833	18,500
Net cash provided by financing activities	5,833	18,500
Effect of exchange rate changes on cash	2	(4)
Net increase (decrease) in cash, cash equivalents and restricted cash	5,400	(19,731)
Cash, cash equivalents and restricted cash		
Beginning of period	71,893	165,995
End of period	$77,293	$146,264
Supplemental disclosure of noncash information:		
Property and equipment purchases in accounts payable and accrued liabilities	$301	$43

Stock-based compensation capitalized in inventory	$(271)	$99

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, 2017 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.

Reclassifications

The Company has reclassified certain prior period amounts to conform to current period presentation. Specifically, it has reclassified income tax expense previously included within selling, general and administrative expense and presented it separately in the Condensed Consolidated Statement of Operations. This reclassification reduced the Company's previously stated selling, general and administrative expense and total operating expense for the three and six months ended June 30, 2017 by $0.4 million and $0.5 million, respectively. The reclassification had no impact on the Company's net loss or stockholders' equity as previously reported.

In addition, pursuant to the adoption of ASU 2016-18, Statement of Cash Flows: Restricted Cash, the Company is presenting restricted cash with cash and cash equivalents in the beginning-of-period and end-of-period total amounts on its Condensed Consolidated Statements of Cash Flows. This reclassification reduced the Company's previously stated net cash used in operations and net decrease in cash and cash equivalents for the six months ended June 30, 2017 by $0.1 million. The reclassification had no impact on the Company's balance sheets as previously reported. The following table provides a reconciliation of cash, cash equivalents and restricted cash reported in the consolidated balance sheets that sum to the total of the same such amounts shown in the Consolidated Statements of Cash Flows (in thousands).

	Six Months Ended June 30, 2018		Six Months Ended June 30, 2017	
	Beginning of period	End of period	Beginning of period	End of period
Cash and cash equivalents	$69,418	$74,182	$163,620	$143,789
Restricted cash	2,475	3,111	2,375	2,475
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$71,893	$77,293	$165,995	$146,264

Accounts Receivable

Accounts receivable are recorded net of customer allowances for distribution fees, prompt payment discounts, chargebacks, and doubtful accounts. Allowances for distribution fees, prompt payment discounts and chargebacks are based on contractual terms. The Company estimates the allowance for doubtful accounts based on existing contractual payment terms, actual payment patterns of its

customers and individual customer circumstances. At June 30, 2018, the Company determined that an allowance for doubtful accounts was not required. No accounts were written off during the periods presented.

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, 2018 and 2017, respectively. As of June 30, 2018, estimated future amortization expense related to the Company's intangible asset was $0.7 million for the remainder of 2018, $1.5 million for each of 2019 and 2020, and $1.0 million for 2021.

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

Strategic Investments

In May 2018, the Company signed an Exclusivity Deed (the "Deed") with Neuren Pharmaceuticals Limited ("Neuren") that provides for exclusive negotiations for a period of three months from the date of the Deed. Under the terms of the Deed, the Company invested $3.1 million to subscribe for 1,330,000 shares of the company and paid $0.9 million for the exclusivity right, which was recorded in selling, general and administrative expenses in the Condensed Consolidated Statement of Operations for the three and six months ended June 30, 2018. At June 30, 2018, 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 net gains on strategic investments on the statement of operations. Net loss on strategic investments recognized in the Condensed Consolidated Statements of Operations in each of the three and six months ended June 30, 2018 was $0.2 million. As of June 30, 2018, the aggregate carrying amount of the Company's strategic equity investment was $2.9 million included in other assets on the Condensed Consolidated Balance Sheet.

Revenue Recognition

Product Sales, Net

The Company's net product sales consist of U.S. sales of NUPLAZID. Effective January 1, 2018, the Company adopted ASU 2014-09, Revenue from Contracts with Customers (Topic 606), and all the related amendments to all of the contracts using the modified-retrospective method. While results for reporting periods beginning after January 1, 2018 are presented under the new guidance, prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for the prior period. The accounting policy for revenue recognition for periods prior

to January 1, 2018 is described in Note 2 of the Notes to the Consolidated Financial Statements included in the Company's Annual Report. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract, determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Payment terms differ by customer, but typically range from 31 to 35 days from the date of shipment. Revenue for the Company's product sales has not been adjusted for the effects of a financing component as the Company expects, at contract inception, that the period between when the Company's transfers control of the product and when the Company receives payment will be one year or

less. No cumulative effect adjustment to the opening balance of retained earnings was necessary upon adoption, and there is no reconciliation of the Company's condensed consolidated statement of operations, as no revenue recognition differences were identified when comparing the revenue recognition criteria under Topic 606 to previous requirements.

NUPLAZID was approved by the FDA in April 2016 and the Company commenced shipments of NUPLAZID to specialty pharmacies ("SPs") and specialty distributors ("SDs") in late May 2016. Prior to the second quarter of 2017, the Company deferred sales of NUPLAZID and recognized revenue when an SP dispensed product to a patient based on the fulfillment of a prescription and when an SD sold product to a government facility, long-term care pharmacy, or in-patient hospital pharmacy. In the second quarter of 2017 the Company determined that it had sufficient volume of activity to reasonably estimate its allowances for rebates and chargebacks and began recognizing NUPLAZID revenue, net of estimated allowances for rebates, price adjustments, returns, chargebacks, and prompt payment discounts, at the point of sale to the SPs and SDs which is commonly referred to as the "sell-in" revenue recognition model.

The effect on income from operations and on net income is that the Company is able to recognize revenue earlier using this sell-in method, net of a provision for estimated allowances, since the Company can record revenue once sold to the SP or SD rather than waiting until the product is sold to the end user on a sell-through basis, which it had done for periods prior to the second quarter of 2017.

Product shipping and handling costs are included in cost of product sales.

The Company recognizes revenue from product sales at the net sales price (the "transaction price") which includes estimates of variable consideration for which reserves are established and reflects each of these as either a reduction to the related account receivable or as an accrued liability, depending on how the allowance is settled. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which the Company is entitled based on the terms of the contract. The amount of variable consideration that is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from estimates, the Company may need to adjust its estimates, which would affect net revenue in the period of adjustment.

Distribution Fees: Distribution fees include distribution service fees paid to the SPs and SDs based on a contractually fixed percentage of the wholesale acquisition cost ("WAC"), fees for data, and prompt payment discounts. Distribution fees are recorded as an offset to revenue based on contractual terms at the time revenue from the sale is recognized.

Rebates: Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program and the Medicare Part D prescription drug benefit. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements with, or statutory requirements pertaining to, Medicaid and Medicare benefit providers. The allowance for rebates is based on statutory discount rates and expected utilization. The Company's estimates for expected utilization of rebates is based on historical data received from the SPs and SDs since product launch. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for prior quarters' unpaid rebates.

Chargebacks: Chargebacks are discounts and fees that relate to contracts with government and other entities purchasing from the SDs at a discounted price. The SDs charge back to the Company the difference between the price initially paid by the SDs and the discounted price paid to the SDs by these entities. The Company also incurs group purchasing organization fees for transactions through certain purchasing organizations. The Company estimates sales

with these entities and accrues for anticipated chargebacks and organization fees, based on the applicable contractual terms.

Co-Payment Assistance: The Company offers co-payment assistance to commercially insured patients meeting certain eligibility requirements. Co-payment assistance is accrued for based on actual program participation and estimates of program redemption using data provided by third-party administrators.

Product Returns: Consistent with industry practice, the Company offers the SPs and SDs limited product return rights for damages, shipment errors, and expiring product; provided that the return is within a specified period around the product expiration date as set forth in the applicable individual distribution agreement. The Company does not allow product returns for product that has been dispensed to a patient. As the Company receives inventory reports from the SPs and SDs and has the ability to control the amount of product that is sold to the SPs and SDs, it is able to make a reasonable estimate of future potential product returns based on this on-hand channel inventory data and sell-through data obtained from the SPs and SDs. In arriving at its estimate for product returns, the Company also considers historical product returns, the underlying product demand, and industry data specific to the specialty pharmaceutical distribution industry.

3. Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common shares and common stock equivalents outstanding for the period determined using the treasury stock method. For purposes of this calculation, stock options, employee stock purchase plan rights, and 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, 2018 and 2017, stock options, employee stock purchase plan rights, and warrants totaling approximately 19,834,000 shares and 16,563,000 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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Cost of product sales	$1,137	$881	$2,187	$1,761
Research and development	7,894	6,420	15,551	11,721
Selling, general and administrative	11,521	10,943	23,256	20,333
	$20,552	$18,244	$40,994	$33,815

5. Balance Sheet Details

Inventory consisted of the following (in thousands):

	June 30,	December 31,

	2018	2017
Raw material	$ 3,334	$ 4,084
Work in process	744	—
Finished goods	659	1,164
	$ 4,737	$ 5,248

Accrued liabilities consisted of the following (in thousands):

	June 30, 2018	December 31, 2017
Accrued consulting and professional fees	$ 16,086	$ 9,395
Accrued compensation and benefits	11,805	15,260
Accrued research and development services	8,900	9,487
Accrued sales allowances	5,853	3,591
Other	3,237	2,511
	$ 45,881	$ 40,244

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, 2018			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury notes	$—	$ —	$ —	$—
Government sponsored enterprise securities	—	—	—	—
Corporate debt securities	139,304	—	(502)	138,802
Commercial paper	43,879	6	(14)	43,871
Equity securities	3,149	—		